Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Commerce, Division of Cannabis Control

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

Rule Package 7 – Testing Requirements for Cannabis

Rule Number(s): OAC 1301:18-1-01 (NEW), OAC 1301:18-3-17 (NEW), OAC 1301:18-4-11 (NEW), OAC 1301:18-4-13 (NEW), OAC 1301:18-4-14 (NEW), OAC 1301:18-6-06 (NEW), OAC 1301:18-6-07 (NEW), OAC 1301:18-6-08 (NEW), OAC 1301:18-7-02 (NEW), OAC 1301:18-7-03 (NEW), OAC 1301:18-7-07 (NEW), OAC 1301:18-7-08 (NEW), OAC 1301:18-7-09 (NEW), OAC 1301:18-7-10 (NEW), OAC 1301:18-7-11 (NEW), OAC 1301:18-8-13 (NEW), OAC 1301:18-9-02 (NEW), OAC 1301:18-9-03 (NEW)

OAC 1301:18-2-09 (Amend), OAC 1301:18-4-22 (Amend)

OAC 1301:18-1-01 (Rescind), OAC 3796:2-2-02 (Rescind), OAC 3796:3-2-02 (Rescind), OAC 3796:4-2-02 (Rescind), OAC 3796:4-2-03 (Rescind), OAC 3796:4-2-04 (Rescind), OAC 3796:4-2-05 (Rescind), OAC 3796:4-2-06 (Rescind), OAC 3796:4-2-08 (Rescind), OAC 3796:4-2-09 (Rescind), OAC 3796:4-2-10 (Rescind), OAC 3796:4-3-01 (Rescind), OAC 3796:5-4-01 (Rescind), OAC 3796:5-6-04 (Rescind), OAC 3796:5-8-01 (Rescind), OAC 3796:6-2-03 (Rescind), OAC 3796:6-2-04 (Rescind), OAC 3796:6-2-08 (Rescind), OAC 3796:6-2-09 (Rescind), OAC 3796:6-2-10 (Rescind), OAC 3796:6-2-13 (Rescind), OAC 3796:6-2-14 (Rescind), OAC 3796:6-3-01 (Rescind), OAC 3796:6-3-04 (Rescind), OAC 3796:6-3-07 (Rescind), OAC 3796:6-3-08 (Rescind), OAC 3796:6-3-09 (Rescind), OAC 3796:6-3-10 (Rescind), OAC 3796:6-3-11 (Rescind), OAC 3796:6-3-12 (Rescind), OAC 3796:6-3-13 (Rescind), OAC 3796:6-3-15 (Rescind), OAC 3796:6-3-17 (Rescind), OAC 3796:6-3-20 (Rescind), OAC 3796:6-3-23 (Rescind), OAC 3796:7-1-01 (Rescind), OAC 3796:7-2-02 (Rescind), OAC 3796:7-2-06 (Rescind), OAC 3796:7-2-09 (Rescind),

OAC 3796:7-2-12 (Rescind), OAC 3796:8-1-01 (Rescind), OAC 3796:8-2-01 (Rescind), OAC 3796:8-2-02 (Rescind), OAC 3796:8-2-04 (Rescind), OAC 3796:8-2-05 (Rescind), OAC 3796:8-2-06 (Rescind), OAC 3796:8-3-01 (Rescind)

Date of Submission for CSI Review February 12, 2026

Public Comment Period End Date: March 12, 2026

Rule Type/Number of Rules:

New/ 18 rules **No Change/ ____ rules (FYR? ___)**

Amended/ 2 rules (FYR? No) Rescinded/ 47 rules (FYR?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.

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.

OAC 1301:18-3-17 Business to Business Transfers – cannabis intended for further production, manufacture, or extraction (New)

- Establishes record keeping and inventory and control requirements for cultivators, processors, and dispensaries to adhere to when transferring cannabis between licensed entities.
- Establishes limitations on the quantity of bulk cannabis that may be transferred between licensed entities.
- Licensed cultivators, processors, and dispensaries must report all bulk cannabis transferred between licensed entities in the state inventory tracking system.

OAC 1301:18-4-11 Voluntary In-Process Testing, Remediation, Re-testing (New)

- Establishes limitations on the scope of permissible in-process testing, remediation, and re-testing on bulk cannabis and cannabis intended for direct customer sale, prior to final compliance testing.
- Establishes limited voluntary in-process testing for all licensees in accordance with the applicable regulations for business-to-business transfer.
- Establishes safeguards to ensure that all cannabis that is sold at licensed dispensaries is safe for all potential consumers and patients.
- Under limited circumstances, licensees are permitted to remediate cannabis and re-test it for all required analytes for final compliance testing.
- There are certain analytes that due to public health concerns and the lack of viable remediation methods to address potential harm, are not permitted to remediate and re-test and must destroy the coordinating batch or lot of cannabis.
- Requires licensees to notify the division if cannabis tests for certain unapproved analytes.
- Unless the rule specifically allows for a type of remediation and re-testing, licensees must request written approval from the division to re-test for any other analytes or cannabis product category.

OAC 1301:18-4-13 Minimum State-Required Testing for Cannabis and Hemp Derived Ingredients Intended for Further Production, Manufacture, or Extraction (New)

- Establishes the minimum testing requirements for marijuana and hemp-derived ingredients that will be subject to further production prior to sale at a licensed dispensary.
- Establishes the minimum testing requirements for marijuana and hemp-derived ingredients in accordance with the applicable regulations for business-to-business transfer.

- Outlines specific analytes that must be tested to ensure public health and safety (e.g., salmonella and E.coli for all cannabis) and as applicable based upon the form of cannabis and method of intended administration by the patient, caregiver, or consumer.

OAC 1301:18-4-14 Minimum State-Required Final Compliance Testing for Cannabis Intended for Direct Customer Sale (New)

- Establishes the minimum testing requirements for all cannabis that will be sold to a patient, caregiver, or consumer at a licensed dispensary.
- Outlines specific analytes that must be tested to ensure public health and safety, and as applicable based upon the form of cannabis and method of intended administration by the patient or consumer.

OAC 1301:18-6-06 Manufacturing Cannabis Products (New)

- Establishes limitations on the types of extraction processes and cannabis products that licensed processors may manufacture in accordance with their licensure.
- Ensures that all extraction processes are maintained in a safe manner both for the safety of processor employees and the patients and consumers that administer the end cannabis product.
- All cannabis products must contain the universal THC symbol, and each portion of a cannabis product must be clearly marked with the universal THC symbol, as applicable.

OAC 1301:18:6-07 Non-Marijuana Ingredients (New)

- Establishes standards for non-marijuana ingredients used in adult-use and medical marijuana products, which take into account industry best-practices and criteria set by the federal food and drug administration for food ingredients, vitamins, and supplements.
- Precludes processors from including certain ingredients such as alcohol, tobacco, and un-regulated dietary supplements and ingredients from use in a final cannabis product.
- Precludes the use of any ingredients that may, or are marketed to, increase the potency, toxicity, or addictive nature of a cannabis product.
- Requires all processors to properly label all non-marijuana ingredients for proper inventory and control purposes.
- Provides specific parameters for hemp-derived ingredients to ensure that all such ingredients are recorded within the state inventory tracking system for proper inventory and control.
- Processors must seek written approval from the division prior to utilizing any non-marijuana ingredient. This rule will also work in conjunction with the Division's current rule on product registration, OAC 1301:18-4-09, to ensure that all new products are reviewed, registered, and safe for public consumption prior to sale to a patient, caregiver, or consumer.

OAC 1301:18:6-08 Packaged Cannabis for Direct Customer Sale (New)

- Allows licensed processors to remove plant material packaged for sale at dispensary to be removed from the packaging and extracted into bulk distillate, bulk extract, or final

form cannabis products so long as the plant material is not adulterated and tested prior to use.

OAC 1301:18-7-02 Testing Laboratory Operating Procedures and Quality Assurance (New)

- Testing laboratories are required to establish, maintain, and comply with written policies and procedures for the daily operation and testing of cannabis. This rule prescribes certain requirements for a testing laboratory's licensed premises, areas within the facility, and sets requirements for licensees to make a major modification to the facility.
- Additionally, the rule outlines certain parameters for the testing methodologies used by licensed testing laboratories when performing state-required testing.

OAC 1301:18-7-03 Testing Laboratory Employee Training (New)

- In addition to general employee training requirements outlined in the Division's current rule, OAC 1301:18-3-10, due to the nature of the job duties performed, this rule provides additional technical requirements for testing laboratory employees.
- Similar to those found in other regulated industries, the rule requires that testing laboratory employees evidence proficiency in certain test sampling procedures to ensure safe, compliant, and impartial testing in accordance with the division's rules.

OAC 1301:18-7-07 State-Required Testing Analysis Generally (New)

- Requires that each testing laboratory establishes, maintains, and complies with written policies and procedures to ensure that all testing analysis performed within the scope of their licensure is safe, compliant, and impartial and in accordance with all division rules.
- Establishes that testing laboratories must record all cannabis tested at the facility within the state inventory tracking system.
- Establishes certain guardrails to ensure all testing laboratories test for all required analytes, as prescribed by the rules, to preclude non-compliant or other unsafe practices that ensure all cannabis products are safe for patients and non-medical consumers alike.

OAC 1301:18-7-08 Test Sample Collection Generally (New)

- Requires that each testing laboratory establish, maintain, and comply with written policies and procedures to ensure consistent, safe, and impartial testing sample collection is employed by all licensed testing laboratories.
- Each testing laboratory is required to record all test sample received and collected within the state inventory tracking system.
- Each testing laboratory must adhere to certain cleanliness and hygiene standards to ensure no test sample is contaminated during the collection process.

OAC 1301:18-7-09 Test Sample Collection Procedure (New)

- Requires each testing laboratory's written policies and procedures related to test sample collection to include the outlined procedures.

- Each test sample collector must ensure prior to collecting any test sample that the cannabis presented for collection matches the cannabis recorded within the request contained within the state inventory tracking system.
- Ensures that each test sample is collected in a representative and impartial manner throughout the batch or lot of cannabis subject to state-required testing.
- Requires that each test sample is of adequate weight to ensure the testing laboratory has enough material to complete all state-required testing in accordance with each laboratory's methodologies.

OAC 1301:18-7-10 Testing Laboratory Limitations on In-Process Testing, Remediation, and Re-Testing (New)

- Establishes and harmonizes the limitations for voluntary in-process testing, remediation, and re-testing outlined in the Division's proposed rule OAC 1301:18-4-11 as applicable to licensed cultivators and processors.
- Ensures that testing laboratories are conducting analysis in an impartial manner to ensure all cannabis is safe for patients and non-medical consumers alike.

OAC 1301:18-7-11 Testing Laboratory Prohibited Activities (New)

- In addition to all the general prohibited activities outlined in the Division's proposed rule OAC 1301:18-9-05, this rule establishes certain preclusions for testing laboratories within the scope of their license.
- Precludes testing laboratories from maintaining a financial interest or other incentives with a licensed cultivator, processor, or testing laboratory to ensure scientific integrity and impartiality for all cannabis.
- Precludes testing laboratories from maintaining a financial interest or other incentive with a physician who is certified to recommend medical cannabis to registered patients and caregivers to prevent misuse or overconsumption of a medicine.

OAC 1301:18-8-13 Dispensary Prohibited Activities (New)

- In addition to all of the general prohibited activities outlined in the Division's proposed rule 1301:18-9-05, this rule establishes certain preclusions for dispensaries within the scope of their license.
- Precludes a physician who is certified to recommend medical cannabis from performing any patient examination or issuing any recommendations for medical cannabis at the dispensary's licensed premises.
- Incorporates updates from Senate Bill 56, specifying that a dispensary cannot also maintain a liquor permit, as provided in Chapter 4303 of the Revised Code.
- Prevents dispensaries from dispensing potentially hazardous foods, or compounding drugs, as provided in section 4729.01 of the Revised Code.

OAC 1301:18-9-02 General Requirements (New)

- Requires each licensee to establish, maintain, and comply with written policies and procedures to ensure compliance with certain general requirements for licensure.

- Each licensee must submit a request to change their operations prior to implementation of any change.
- Requires each licensee to promptly notify the Division and local law enforcement for any unauthorized entry at the licensed premises, any incident of theft, loss, or diversion, and any transfer, sale, or distribution of any cannabis to anyone not authorized under Chapter 3796 of the Revised Code.
- Requires each licensee to report any ongoing civil or criminal investigations related to the licensed entity or any owner, officer, board member, employee, or controller of the licensee related to the licensed entity.

OAC 1301:18-9-03 General Prohibited Activities (New)

- Establishes certain prohibited activities that apply to each licensed entity and any owner, officer, board member, employee, agent, or controller of a licensee.
- Precludes any anti-competitive business behavior or other financial misconduct.
- Precludes receipt of anything of value, monetary or otherwise, from another licensee or other third party, in exchange for business or referrals.
- Precludes any conduct that constitutes a crime, as outlined under Chapter 29 of the Revised Code.
- Precludes violating any requirement outlined under Chapter 3796 of the Revised Code.
- Precludes violating any rule outlined under division 1301:18 of the Administrative Code.

OAC 1301:18-1-01 Definitions (Rescind/New)

- The proposed rule is being amended due to recent legislative updates as outlined in Senate Bill 56.
- Adds new definitions codified by Senate Bill 56 to ensure continuity between the Division of Cannabis Control, the Ohio Department of Agriculture, and Chapter 29 of the Ohio Revised Code.
- Adds new definitions related to state-required testing and testing laboratories, as reflected in the above-referenced new rules in this package.

OAC 1301:18-2-09 Fee Schedule (Amended)

- The proposed rule is being amended due to recent legislative updates as outlined in Senate Bill 56. Specifically, SB 56 requires that all advertising must be submitted by each licensee for review and written approval by the Division prior to use. Therefore, the Division is amending the rule to adopt the $100 advertising submission fee that currently exists under the medical program rules.
- Furthermore, the Division is amending the rule to update the dispensary licensing and renewal fee from $35,000 annually to $50,000 annually, while licenses are to be renewed every two years.

OAC 1301:18-4-22 Advertising (Amended)

- The proposed rule is being amended due to recent legislative updates as outlined in Senate Bill 56.
- Specifies that all advertising must be submitted by each licensee for review and written approval by the division prior to use.
- Provides necessary updates to the rule for clarification purposes regarding the universal THC symbol and requisite placement on certain advertisements, containers, packaging, and labeling.

The Division is also proposing to rescind several of the current medical marijuana rules under Chapter 3796 which the Division's new rules under Chapter 1301 replace.

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.**

Authorized By: R.C. 3796.03 Amplifies: R.C. 3796.09, 3796.14, 3796.18, 3796.19, 3796.21, 3796.32

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

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.**

N/A

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)?**

The rules in this package are all aimed at ensuring customer safety, product transparency, and prevent the diversion, theft, or loss of cannabis.

The Division is adopting business-to-business transfer rules as a result of statutory updates permitting licensees to make certain transfers of cannabis between licensed entities, where previously the statute and therefore rules restricted movement that unnecessarily hindered supply chain realities and responsiveness. The proposed rules ensure that these transfers are done in a manner that protects public health and safety during transportation as well as by requiring limited testing when necessary.

The proposed testing rules establish reasonable standards for when testing is required, what the cannabis is tested for, and what action limits are permissible for each test analyte. The Division's thoughtful approach in crafting these rules helps ensure that first and foremost, cannabis sold to customers at a dispensary meets potency limitations and is free of harmful contaminants, and second that the traceability of all cannabis and testing is maintained within the state inventory tracking system, while balancing what testing is necessary to achieve those objectives and eliminating testing that does not add value. While in-process testing is a new permission, the rules also limit remediation and re-testing in ways that meaningfully ensure the pillars of the testing requirements and product safety.

Testing laboratory operations rules proposed in this package serve to ensure that testing laboratory employees are properly certified and trained to conduct the testing they are responsible for, testing facilities maintain sanitary operating procedures, and that test sample collection is conducted in a uniform manner to ensure representative sampling and prevent cross-contamination.

The proposed rules in this package also establish manufacturing process and ingredient standards for processors. The Division is required by Senate Bill 56 to adopt rules establishing standards for non-marijuana ingredients, taking into account industry best-practices and criteria set by the FDA, and the Division may prohibit ingredients not meeting such standards. The objective is to ensure that all non-marijuana ingredients used in the manufacture of cannabis products are sourced from a licensed and regulated entity and are safe for human consumption both individually and in combination with other ingredients or product types.

The proposed rules in this package also include moving the advertising submission review fee from current medical cannabis rules to updated rules in Chapter 1301 and updating the dispensary license issuance and renewal fee to $50,000 annually (with renewal every two years). These fees help to cover the cost of Division licensing and compliance staff who review applications and inspect/investigate licensees to ensure compliance with cannabis laws and rules.

Lastly, rules in this package establish reporting requirements for licensees and general prohibited activities. These requirements and prohibitions are aimed at ensuring licensees do not violate ORC Chapter 3796 or any of the Division's rules, and if they do, they notify the Division as prescribed.

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

The success of the regulations will be measured by compliance, consumer safety, and the prevention of theft, loss, and diversion.

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 Division posted the proposed rules for early stakeholder feedback on its website and sent a direct email to cannabis license holders soliciting feedback originally from September 20, 2024 to October 9, 2024. Following that initial feedback, the Division made updates based on stakeholder comments and solicited additional comments from May 9, 2025 to May 30, 2025. The Division has also received feedback during many roundtables and meetings with both individual licensees and associations representing those license holders.

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

The Division has worked diligently to develop a testing rule framework that requires testing when and for what is necessary and eliminates testing that does not serve to increase product safety or traceability and accountability. To that end, these rules generally require the final form of the cannabis product to be tested prior to being sent to a dispensary for customer purchase, with some variation – including suggestions from stakeholders – for specific product types (i.e., edibles and beverages) in which it is more appropriate to test the intermediate cannabis oils. Furthermore, the tests that are required on plant material prior to the material being subjected to a technology solution or sent to a processor are only those that are necessary to meet these objectives. These rules represent a thoughtful, measured approach, to ensuring that testing is done when it makes sense and for what it makes sense scientifically to protect public health and ensure accountability.

In response to early stakeholder feedback, the Division made modifications to the testing rule framework, as well as some batch/lot size and sample size requirements. For example, the Division has proposed to increase the batch size for shake/trim material that is being sent to a processor for extraction. Additionally, the Division has provided an updated and more operable sample size procedure and increments required to be collected for testing.

The Division also clarified definitions for terms used throughout the rules based on stakeholder feedback, such as raw single serving units and shake/trim, which are not required to be strain-specific, and defining technology solutions. Business-to-business transfer requirements were refined and clarified as well, including the movement of both bulk cannabis and cannabis packaged for final retail sale.

Based on comments from cultivators and processors, the Division eliminated a proposed rule addition that would have created duplicate work unnecessarily for them to request a test from a licensed laboratory.

Finally, while the testing rules outline categories of required tests, the Division's guidance provides technical requirements for specific test analytes required. The Division feels it is necessary to discuss required testing analytes and their failure thresholds to adequately provide the full scope of cannabis testing rules; therefore, that list is attached to this submission. The Division has modified proposed testing analytes and failure thresholds based on many conversations with licensees – primarily testing laboratories – as well as careful review of required analytes and action thresholds in other states, including what has worked and what hasn't. A few additional pesticides, solvents, and heavy metals will be tested to ensure compliance with allowable pesticides and solvents and to ensure metals that are harmful if present in certain amounts do not contaminant cannabis products. The Division has also raised action limits where necessary for adequate scientific quantification or where possible without compromising health and safety standards.

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?

The Division carefully reviewed many scientific journal articles, research, testing standards and methodologies, and other state cannabis markets and regulations to help develop these rules, and worked diligently to ensure these rules not only include best practices from other states, but that they are scientifically sound and based on research and understanding within the scientific community.

For example:

- Current research supports the Division's requirement for salmonella and Shiga toxin-producing *Escherichia coli* to be tested prior to remediating or processing of cannabis. Those two pathogens may be eliminated by some remediation and processing techniques, and therefore not detected in testing, but they leave behind a toxic material that is extremely dangerous if present and is not detected in testing. The current research indicates that the only method of remediating the toxic remnants is subjecting the cannabis to acid which would render the cannabis unsafe for public consumption and unusable. Therefore, the Division requires testing of these analytes prior to any remediation or processing efforts that may remove any traceability.
- The Division relied upon statistical realities, testing laboratory analysis, and other state data when considering the appropriate batch/lot sizes and testing sample sizes.
- Regarding pesticides, the Division reviewed the pesticide list from Oregon that conducted an extensive research study on harmful pesticides within the cannabis industry. Additionally, the Division reviewed states within the same geographic region and climate to better target those pests and insects most prevalent to the Ohio area. The Division ensured that all updates to the pesticide list had pre-existing reliable analytical standard mixes, which will allow for decreased costs associated with compliance with these updates. Last, the Division reviewed scientific research to ensure that all the pesticides and test limits could be properly tested in accordance with all licensed testing laboratories' current instrumentation to ensure that no additional costs would be incurred. Furthermore, all such limits are appropriate.
- Regarding total yeast and mold action limits, the Division has reviewed research from the NIH and other peer-reviewed journal articles, as well as thresholds set in other states and countries, to determine the appropriate increased limit. These adjusted limits balance the need to ensure patients have access to safe cannabis as well as allowing more flexibility for licensees to utilize products that would be deemed unsuitable under current limits but are not unsafe pursuant to current research.
- Regarding testing methods that laboratories are required to use, the Division reviewed the available cannabis testing methodologies from reputable standards and methods organizations to ensure those methods are utilized when available and to ensure that appropriate, scientifically accurate method validation and verification procedures are utilized.

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 Division strives to establish standard-based, performance-based regulations. The goal is to allow businesses the flexibility in how they meet the Division's standards set in the rules, unless more prescriptive requirements are necessary to help ensure the public health and safety.

These proposed rules meet those objectives; while the Division does specify when certain testing must occur to ensure public health and safety and licensee accountability, the rules also permit licensees to seek additional testing throughout the cultivation and manufacturing process so they may better understand the cannabis plant material or extracts they intend to use in products. The rules also permit licensees to remediate batches or lots that do not meet standards for certain tests; for example, plant material that fails moisture tests can be dried further and re-tested. Similarly, the proposed rules do require testing laboratories to utilize known standard testing methodologies when available but provides flexibility otherwise with guardrails necessary to ensure appropriate validation and/or verification processes.

13. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Ohio Revised Code places sole regulatory authority over the cannabis industry with the Division of Cannabis Control. Therefore, no other entity has administrative authority over the licensing and regulation of the cannabis entities subject to these rules. However, the Division does recognize that as manufacturing, testing, and retail businesses, cannabis licensees are subject to other regulations. For example, the Division does not regulate fire safety, building code, environmental protection, certain equipment registration requirements (such as radiation technology), or laboratory accreditation; instead deferring to the entities and their rules responsible for those regulations. The Division, may, however, take enforcement action against licensees that do not comply with other regulatory bodies' laws and rules.

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.

All licensees must comply with the Division's rules. The Division regularly issues industry guidance documents to communicate rule requirements and how to maintain compliance, emails those updates out to licensees, and posts them on the Division's website.

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

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.

The business community impacted by these rules includes licensed cannabis cultivators, processors, testing laboratories, and dispensaries.

In 2025, 40% of cultivator compliance testing was plant material that was destined for processing. The proposed rule package expands the definition of "batch" for plant material and permits batches of plant material to be harvested over a 72-hour period of time, as opposed to the current 48-hour timeframe. The proposed rule package increases the batch limit from 25 lbs. to 50 lbs. for dried plant material and 25 lbs. to 125 lbs. for fresh frozen plant material. Additionally, the rule package will now allow for cultivators to create 50 lb. multi-strain batches of cannabis plant material to be transferred to a processor. A processor will then be permitted to extract the plant material for use in final form cannabis products. This update will ultimately cut down on unnecessary waste at a cultivator. The required testing for plant material that is destined for processing will be reduced; the current required testing includes cannabinoids, pesticides, mycotoxins, and foreign matter; Rule Package 7 required testing is limited to pesticides, salmonella, and Shiga toxin-producing *Escherichia coli* (STEC). The Division expects that cultivators will be able to immediately recognize reduced costs for plant material that is destined for processing.

In 2025, 60% of cultivator compliance testing was flower and shake/trim that was destined for sale to dispensaries. The proposed rule maintains batch size at the current 15 lb. limit for flower/buds but increases the batch size for shake/trim to 25 lbs. and the same overall types of required testing (cannabinoids, pesticides, mycotoxins, heavy metals, foreign matter, moisture content, water activity, and microbial contamination). Under Rule Package 7, the Division will add chromium testing to the list of lead, mercury, arsenic, and cadmium heavy metals that are currently tested. Pesticide testing will increase from 20 pesticides to 58 pesticides in order to ensure a more comprehensive review of pesticides that are prohibited for use under Division rules. Please refer to answers above regarding the reasonings for the addition of these analytes.

Any increase in costs for testing these additional analytes will be tempered by an increase to the allowable limit for total yeast and molds, which the Division has proposed to better align with industry standards while maintaining a threshold appropriate for ensuring public health and safety. Upon review of the applicable market data, the Division determined that, in 2025, this would have allowed more than 2,000 batches of plant material to proceed to non-solvent-based extraction or customer sale. Furthermore, the Division chose to remove required testing for total aerobic bacteria in plant material and the majority of other final form cannabis products as the recent research indicates that such testing is overinclusive and led to unnecessary testing failures due to the presence of "good" bacteria that otherwise is not unsafe for consumption. Additionally, the Division previously required licensees to submit to both total coliform and total bile-tolerant microbial testing. However, in accordance with recent research and other updates in other states with medical and non-medical cannabis industries, the Division chose to streamline this testing into one test for ease of compliance into total enterobactereacie.

The list price for testing flower that is destined for sale at dispensaries ranges from $365 to $480. Most of the labs offer discount programs, however, so the actual price for testing will vary between labs and between clients at each lab. However, based upon review of testing laboratory data, the Division determined that overall if there will be any increase in costs for cultivators or processors on the test panels/analytes under the new rules, it would be de minimus.

The proposed rules represent an amendment to sample sizes in accordance with recent updates and recommendations within the scientific community, which continues to develop as the overall cannabis industry matures nationwide. When contemplating updates to sample sizes for processed products, the Division implemented a measured, thoughtful approach and researched and relied upon all resources available to balance public safety and minimize any adverse impact to businesses to comply with these updates. Furthermore, the Division's proposed sample sizes vary depending on the type of product and the stage at which it is tested. The majority of the final form products will require a sample size that is representative of the overall lot of cannabis tested and is generally 0.5% of the net weight of the final form products. Certain cannabis products, such as cannabis infused-edibles and cannabis-infused beverages, which make up 27% of the current market share for processed products, provides licensees with sample increments based upon the final packages size.

The Division is not requiring licensees to test final form cannabis products within their final package or container. In conjunction with this allowance, and in accordance with current scientific research, the Division is allowing licensees to remediate certain categories of cannabis within a limited scope should the product not meet the standards established by the Division for final compliance testing. It should also be noted that the Division is not requiring final form compliance testing of vaporization products, which account for 68% of the current market share for processed products, to be tested within any applicable vaporization device. This will save any associated cost incurred by a licensee in the event the vaporization solution within the device does not meet the standards for state-required testing. Upon review of the cost data provided by licensed testing laboratories, the Division determined that the increase cost associated with the proposed testing rule updates would be approximately $0.16 per vaporization product. This represents 0.5% cost increase related to the total cost of testing for that product.

Some products will be required to be tested in process for a very limited number of analytes, which, if present, represent potential harmful contaminants that cannot be further remediated within current manufacturing practices. Furthermore, both required compliance testing and optional in process testing will ultimately assist the Division and licensees in limiting the scope of any ongoing operational deficiencies, environmental impacts, or quality assurance concerns.

In 2025, 10% of processor compliance testing was marijuana-derived ingredients; most of this testing was conducted on ingredients that were produced using a solvent such as butane, propane, or ethanol. The proposed rule limits the scope of testing by requiring only microbial and pesticides be tested on lots of cannabis extract or distillate intended to be used as an ingredient in a product. For edibles and beverages specifically, in addition to microbials and pesticides, the lot must be tested for mycotoxins, heavy metals, and residual solvents if applicable. For edibles and beverages, those bulk distillate and extract test results carry through to the final compliance testing requirements, meaning most of those analytes are not required to be tested again. By contrast, current testing on bulk extracts and distillates includes cannabinoids, pesticides, mycotoxins, heavy metals, foreign matter, and residual solvents if applicable. Under Rule Package 7, the Division will add chromium testing to the list of lead, mercury, arsenic, and cadmium heavy metals that are currently tested; pesticide testing will increase from 20 pesticides to 58 pesticides; and residual solvent testing will increase from 10 solvents to 22 solvents.

In 2025, 33% of processor compliance testing was finished products that had not previously been tested by the processor. Under the Division's proposed rules, all products must be tested in final form and the required analytes vary by product type and manufacturing process. In addition to the pesticides, heavy metals, and residual solvents required for testing mentioned above, in line with scientific research, cannabis-infused beverages will require pH testing to ensure shelf stability; this will cause a trivial increase in beverage testing. The Division expects a potential modest increase in testing costs for finished products that have not previously been tested by the processor due to additional analytes within heavy metals, pesticides, and residual solvents testing groups; however, as noted above, any cost increase is expected to be tempered by other proposed changes to testing requirements.

On the testing laboratory side, there may be expenses to ensure compliance with these rules. Though difficult to quantify due to variations in additional work needed or equipment expenses per lab, the projected estimated cost for each licensed laboratory will be approximately $50,000 to $100,000. This cost may include labor, supplies and materials, and contract services for method development and validation. The cost breakdown includes development and validation of updated testing methods for pesticides, residual solvents, terpenes, STEC, and cannabinoids. STEC testing is the only method that will require labs to make a meaningful expenditure to purchase additional equipment; this cost is estimated to be $50,000. However, some labs already possess the instruments necessary for STEC testing. All labs currently have the instruments that are required to conduct all updates for state-required testing of pesticides, residual solvents, terpenes, and cannabinoids.

Furthermore, while each testing laboratory will incur some expenses to become compliant with the proposed rules, the ongoing labor cost associated with each test panel is not projected to increase significantly as the types of testing that are conducted will remain the same for the majority of testing conducted under the current regulations.

It should be noted that some of the costs associated with compliance are costs that would have been incurred by the licensed testing laboratory irrespective of the new proposed rules due to requirements by accrediting bodies and/or sound scientific practice. Specifically, it is a common requirement for any testing laboratory in any industry to continuously update their methodologies based upon new developments in science. Additionally, the testing laboratories would have been required to provide ongoing maintenance to their respective instrumentation, irrespective of the proposal.

Lastly, aside from the testing requirements, the cost to comply with advertising pre-approval is $100 for an application. The cost to initially obtain a dispensary Certificate of Operation and to renew it is $100,000 every two years.

16. Are there any proposed changes to the rules that will <u>reduce</u> 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).

The proposed rules have been adapted to reflect common sense and practical requirements based upon the stage at which the cannabis is being tested and contemplates the form and method of administration of the final product. For example, the proposed testing rules for cannabis-infused edibles and beverages do not require certain analytes to be tested in the final form. This is due to the fact that testing of mycotoxins, pesticides, and heavy metals is more accurately conducted on a cannabis extract or distillate than it would be on the final form of the product (e.g., a gummy). Furthermore, the Division chose to increase the limit for total yeast and mold for all plant material, which will result in less required destruction and therefore cost savings. Additionally, the Division removed certain analytes throughout the testing framework that were otherwise duplicative unless supported by scientific evidence regarding the necessity for public health and safety purposes. Finally, as discussed above, the Division has proposed increases to certain batch sizes.

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

The Division reviewed multiple scientific studies and testing rules from other states with medical and non-medical cannabis programs to ensure that they are in line with nation-wide standards and public health initiatives. Furthermore, the Division harmonized all testing requirements for both medical and non-medical cannabis, alike. Therefore, all testing proposals need to also ensure the health and safety for all Ohioans.

Regulatory Flexibility

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

These rules are largely focused on public health and safety, and the requirements that must be met to ensure that priority are intended to create a level playing field for all licensees.

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?

The DCC works diligently to ensure that all licensees understand all compliance requirements. The Division does not fine licensees for simple paperwork violations, but does work with licensees who encounter challenges to ensure they have the information necessary to comply with all laws and rules.

20. What resources are available to assist small businesses with compliance of the regulation?

The DCC regularly issues guidance to licensees and posts those documents and other helpful information on its website: www.com.ohio.gov/cannabiscontrol. Additionally, the DCC has a team of inspectors and licensing examiners who work closely with all licensees to ensure they are able to achieve and maintain compliance with program regulations.