

PHILLIP D. MURPHY Governor

TAHESHA L. WAY *Lt. Governor* DIANNA HOUENOU, Chair SAMUEL DELGADO, Vice Chair KRISTA NASH, Commissioner MARIA DEL CID-KOSSO, Commissioner CHARLES BARKER, Commissioner JEFF BROWN, Executive Director

RESOLUTION 2023-<u>144</u> WAIVER OF N.J.A.C. 17:30-11.5(c)(2) AND N.J.A.C. 17:30-11.6(b) TO ALLOW CLASS 2 CANNABIS MANUFACTURERS TO MANUFACTURE ADDITIONAL INGESTIBLE FORMS OF CANNABIS PRODUCTS

WHEREAS, pursuant to N.J.A.C. 17:30-3.7(a), the Commission, in accordance with the general purposes and intent of the Cannabis Regulatory, Enforcement Assistance, and Marketplace Modernization Act, P.L.2021, c. 16, N.J.S.A. 24:6I-31 et seq., (the "Act") or the implementing Personal-Use Cannabis Rules (the "Personal-Use Regulations"), may waive a regulatory requirement regarding the operations of a cannabis business, to the extent such waiver does not conflict with any other State law, if in the Commission's determination, such a waiver: is necessary to achieve the purpose of the Act; is necessary to provide access to cannabis items to consumers; and does not create a danger to the public health, safety, or welfare; and

WHEREAS, pursuant to N.J.A.C. 17:30-11.5(c)(2), a cannabis manufacturer is authorized to manufacture the ingestible forms of cannabis products, which shall only include syrups, pills, tablets, capsules, oral suspensions, and chewable forms; and

WHEREAS, pursuant to N.J.A.C. 17:30-11.6(b), all ingredients used to manufacture cannabis products shall be United States Pharmacopeia National Formulary (USP-NF), analytical reagent (AR), certified American Chemical Society (ACS), or Food Chemicals Codex (FCC) grade substances. If a USP-NF, AR, ACS, or FCC grade substance ingredient is not available, the cannabis manufacturer shall establish the purity and safety of the ingredient by reasonable means, which may include lot analysis, manufacturer reputation, or reliability of source study; and

WHEREAS, the Commission has received, reviewed, and considered multiple requests to allow the manufacturing and dispensing of additional edible and ingestible forms of cannabis; and

WHEREAS, the Commission has determined that this waiver is necessary to achieve the purpose of the Act, is necessary to provide access to additional forms of cannabis items to consumers, and does not create a danger to the public health, safety, or welfare;

NOW, THEREFORE, BE IT RESOLVED, by the New Jersey Cannabis Regulatory Commission, that N.J.A.C. 17:30-11.5(c)(2) and -11.6(b) are hereby waived to allow the production and dispensing of edible forms of medical cannabis products that do not require time

and/or temperature control for safety to limit pathogenic microorganism growth or toxin formation (known as "non-TCS" foods), subject to the terms and conditions listed below. This waiver applies only to personal, adult-use cannabis products. It does not apply to the production of medicinal cannabis products.

- 1. This waiver applies only to holders of a Class 2 Cannabis Manufacturer license. Nothing herein shall be construed to authorize any person or entity that does not hold a Class 2 Cannabis Manufacturer license to engage in any manufacturing activities authorized by this waiver.
- 2. A license holder with a Class 2 Cannabis Manufacturer license may manufacture the following ingestible forms:
 - a. Syrups or single-serve beverages;
 - b. Pills, capsules, or tablets;
 - c. Oral suspensions; and
 - d. Non-TCS food items, such as chocolates, gummies, baked goods, butters, jams, and jellies, such that the product does not require time or temperature control to limit pathogenic microorganism growth or toxin formation.
- 3. Ingestible products shall not:
 - a. Be an alcoholic beverage, as defined in N.J.S.A. 33:1-1;
 - b. Contain tobacco or nicotine;
 - c. Require cooking or baking by the consumer;
 - d. Require storage in sterile conditions by the consumer; or
 - e. Contain any controlled dangerous substance, as defined in N.J.S.A. 24:2I-2.
- 4. Class 2 Cannabis Manufacturers shall manufacture ingestible forms in accordance with all applicable regulations and guidance, including limitations on the amount of THC permitted in ingestible food items, uniform symbol requirements, and the requirements provided in N.J.A.C. 17:30-11.1 through -11.13.
- 5. For the purposes of this waiver, the use of ingredients that are Generally Recognized as Safe (GRAS) under sections 201(s) and 409 of the Federal Food, Drug and Cosmetic Act shall be permissible for non-TCS food items.
- 6. Beverages must be packaged and labeled in single-serve containers. Beverage containers shall not include more than one serving per container. Single-serve beverages shall contain no more than 5 milligrams of total tetrahydrocannabinols.
- 7. To protect the health and welfare of adult consumers, in addition to labeling requirements at N.J.A.C. 17:30, non-TCS food and beverage items shall be labeled with a list of ingredients in descending order of predominance by weight or volume as applicable, a nutritional label, and indication if the item requires refrigeration after product opening or consumption within a specified number of days after opening. For products manufactured such that the product's effects are intended to be felt in less than 20 minutes, the item shall contain the following consumer warning in no less than tenpoint font: "The intoxicating effects of this product usually occur in less than 20 minutes but may be delayed by two or more hours."
- 8. To protect public health, employees involved in the manufacturing of ingestible products newly authorized by this waiver shall, prior to engaging in the manufacturing process, undergo food safety training that includes: the causes and prevention of foodborne illnesses; prevention of common foodborne illnesses according to the

Centers for Disease Control and Prevention; and safe food handling practices, including handling of major food allergens as defined in N.J.A.C. 8:24-1.5.

- 9. Pursuant to N.J.A.C. 17:30-11.8(c)(2), the maximum expiration date for non-TCS food and single-serve beverage items is six months, beginning from the manufacture date.
- 10. Failure to adhere to the terms and conditions of this waiver shall be considered a regulatory violation and is subject to adverse action by the Commission consistent with N.J.A.C. 17:30-20.1 through -20.10.

Submitted by:

Dianna Houenou, Chair

CERTIFICATION

I hereby certify that the foregoing is a true copy of the Resolution adopted by the Cannabis Regulatory Commission at its meeting held on the 8th day of September 2023.

Christopher Riggs, Chief Counsel

Vote on the Approval of This Resolution	Motion	Second	Yes	No	Abstain	Absent
Commissioner Barker			Х			
Commissioner Del Cid-Kosso						Х
Commissioner Delgado		Х	Х			
Chairwoman Houenou			Х			
Commissioner Nash	Х		Х			



State of New Jersey Cannabis Regulatory Commission P.O. BOX 216 Trenton, N.J. 08625-0216

PHILLIP D. MURPHY Governor

SHEILA Y. OLIVER Lt. Governor DIANNA HOUENOU, Chair SAMUEL DELGADO, Vice Chair KRISTA NASH, Commissioner MARIA DEL CID-KOSSO, Commissioner CHARLES BARKER, Commissioner JEFF BROWN, Executive Director

CERTIFICATE OF WAIVER OF REGULATION

Authority: Date Issued:	N.J.S.A. 24:6I-7(a)(6) and N.J.A.C. 17:30-3.7 September 8, 2023
Regulation(s) Affected:	N.J.A.C. 17:30-11.5 Prohibited manufacturing; authorized forms; authorized amounts
	N.J.A.C. 17:30-11.6 Ingredients in cannabis products
Effective Date:	September 8, 2023
Expiration Date:	Upon modification or revocation by the Board of Commissioners

The New Jersey Cannabis Regulatory Commission (Commission) grants relief in the form of this temporary regulatory waiver to allow for the temporary expansion of permissible ingestible cannabis products, subject to the criteria and conditions set forth herein. N.J.A.C. 17:30-3.7 provides that the Commission may waive a regulatory requirement regarding the operations of a cannabis business if such waiver is necessary to achieve the purpose of the Cannabis Regulatory, Enforcement Assistance, and Marketplace Modernization Act, N.J.S.A. 24:6I-31, et seq. (P.L.2021, c.16); is necessary to provide access to cannabis items to consumers; and does not create a danger to public health, safety, or welfare.

Pursuant to N.J.A.C. 17:30-11.5(c)(3), the Commission may authorize a Class 2 Cannabis Manufacturer license holder to manufacture a product in a form not already authorized by N.J.A.C. 17:30-11.5(c) in accordance with the Commission's power to waive regulatory requirements, provided at N.J.A.C. 17:30-3.7. The Commission has determined to issue this regulatory waiver to immediately allow licensed cannabis manufacturers to produce food and beverage products that do not need to be temperature controlled in order to limit pathogenic microorganism growth or toxin formation (i.e., is a "non-TCS" or "shelf stable" food or beverage).

N.J.A.C. 17:30-11.6(b), prescribes the ingredients permissible for manufacturing cannabis products. The Commission has determined to issue this regulatory waiver to immediately allow licensed cannabis manufacturers to use ingredients that are Generally Recognized as Safe (GRAS) under sections 201(s) and 409 of the Federal Food, Drug and Cosmetic Act for non-TCS food

items.

The specific rule(s) being waived is(are) as follows:

N.J.A.C. 17:30-11.5 Prohibited manufacturing; authorized forms; authorized amounts

(c) A cannabis manufacturer is authorized to manufacture the following forms:

. . .

. . . .

2. A cannabis-infused product, either in solid form or liquid form, containing either usable cannabis or cannabis concentrate along with an additional ingredient that includes, but is not limited to:

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iv. Ingestible forms, which shall only include syrups, pills, tablets, capsules, oral suspensions, and chewable forms[.]

N.J.A.C. 17:30-11.6 Ingredients in cannabis products

(b) All ingredients used to manufacture cannabis products shall be United States Pharmacopeia National Formulary (USP-NF), analytical reagent (AR), certified American Chemical Society (ACS), or Food Chemicals Codex (FCC) grade substances. If a USP-NF, AR, ACS, or FCC grade substance ingredient is not available, the cannabis manufacturer shall establish the purity and safety of the ingredient by reasonable means, which may include lot analysis, manufacturer reputation, or reliability of source study.

This waiver applies only to personal, adult-use cannabis products. It does not apply to the production of medicinal cannabis products. Additionally, this waiver is subject to the following terms and conditions:

- 1. This waiver applies only to holders of a Class 2 Cannabis Manufacturer license. Nothing herein shall be construed to authorize any person or entity that does not hold a Class 2 Cannabis Manufacturer license to engage in any manufacturing activities authorized by this waiver.
- 2. A license holder with a Class 2 Cannabis Manufacturer license may manufacture the following ingestible forms:
 - a. Syrups or single-serve beverages;
 - b. Pills, capsules, or tablets;
 - c. Oral suspensions; and
 - d. Non-TCS food items, such as chocolates, gummies, baked goods, butters, jams, and jellies, such that the product does not require time or temperature control to limit pathogenic microorganism growth or toxin formation.
- 3. Ingestible products shall not:
 - a. Be an alcoholic beverage, as defined in N.J.S.A. 33:1-1;
 - b. Contain tobacco or nicotine;
 - c. Require cooking or baking by the consumer;
 - d. Require storage in sterile conditions by the consumer; or

- e. Contain any controlled dangerous substance, as defined in N.J.S.A. 24:2I-2.
- 4. Class 2 Cannabis Manufacturers shall manufacture ingestible forms in accordance with all applicable regulations and guidance, including limitations on the amount of THC permitted in ingestible food items, uniform symbol requirements, and the requirements provided in N.J.A.C. 17:30-11.1 through -11.13.
- 5. For the purposes of this waiver, the use of ingredients that are Generally Recognized as Safe (GRAS) under sections 201(s) and 409 of the Federal Food, Drug and Cosmetic Act shall be permissible for non-TCS food items.
- 6. Beverages must be packaged and labeled in single-serve containers. Beverage containers shall not include more than one serving per container. Single-serve beverages shall contain no more than 5 milligrams of total tetrahydrocannabinols.
- 7. To protect the health and welfare of adult consumers, in addition to labeling requirements at N.J.A.C. 17:30, non-TCS food and beverage items shall be labeled with a list of ingredients in descending order of predominance by weight or volume as applicable, a nutritional label, and indication if the item requires refrigeration after product opening or consumption within a specified number of days after opening. For products manufactured such that the product's effects are intended to be felt in less than 20 minutes, the item shall contain the following consumer warning in no less than tenpoint font: "The intoxicating effects of this product usually occur in less than 20 minutes but may be delayed by two or more hours."
- 8. To protect public health, employees involved in the manufacturing of ingestible products newly authorized by this waiver shall, prior to engaging in the manufacturing process, undergo food safety training that includes: the causes and prevention of foodborne illnesses; prevention of common foodborne illnesses according to the Centers for Disease Control and Prevention; and safe food handling practices, including handling of major food allergens as defined in N.J.A.C. 8:24-1.5.
- 9. Pursuant to N.J.A.C. 17:30-11.8(c)(2), the maximum expiration date for non-TCS food and single-serve beverage items is six months, beginning from the manufacture date.
- 10. Failure to adhere to the terms and conditions herein shall be considered a regulatory violation and is subject to adverse action by the Commission consistent with N.J.A.C. 17:30-20.1 through -20.10.

This relief granted by the Commission is based upon assessments of New Jersey's personal-use cannabis industry and the history of conduct by regulated entities, including any entity's history of regulatory violations committed. The relief granted is subject to review, modification, or revocation as the Commission deems appropriate.

BY: Dianna Houenou, Chairperson New Jersey Cannabis Regulatory Commission