

Consumable Hemp: HF 2605 FAQ – What it Means, Rules Effective July 17

On May 17, 2024, Governor Reynolds signed [HF2605](#) into law. This FAQ is provided to current Consumable Hemp Registrants to help them understand regulatory changes to the program that will be in effect on July 1, 2024, and pursuant to rules promulgated by HHS.

On May 24, 2024, HHS released an FAQ and proposed draft rules to registrants, and requested comment from the industry. On June 7 HHS released an updated FAQ with amendments to proposed draft rules, held a virtual townhall on June 10, and virtual public hearings on July 2 and July 8.

Amendments and Clarifications to June 7 FAQ and June 12 NOIA Based on Public Comment

- **HHS has amended the proposed rules for the warning label and required information below:**
 - j. A warning label containing the following or substantially similar language, in addition to any other warning language necessitated by the specific product. This warning label may be divided into multiple sections on a label, provided that all information is included on the container in a prominent and conspicuous manner as compared to other words, statements, or designs on the container label:
 - (1) A statement that the product has not been evaluated or approved by the United States Food and Drug Administration (unless such approval has been secured);
 - (2) The potential for the product to cause the consumer to fail a drug test for THC;
 - (3) A statement that products containing THC may cause impairment and impact a consumer's ability to operate a vehicle;
 - (4) A statement that the product is not recommended for use by pregnant or breastfeeding women;
 - (5) A statement that product use may result in health risks and medication interactions; and
 - (5) A statement in capital letters to KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.

IMPORTANT NOTICE on Warning Label Enforcement - Registrants are expected to take reasonable steps to comply with the warning label regulations pursuant to the administrative rules in effect on July 17, 2024. Department enforcement of the labeling requirements will occur through inspection and investigation of complaints as they are received. Repeated violations of labeling regulations will be addressed through the imposition of civil penalties.

- **How do the serving and container limits for Total THC relate to topical products?**
 - HHS' confirmation of table 2 of 21 CFR 101.12 for the definition of “*servings*” relates only to products intended to be ingested (“eaten”) or contain food. As topically applied products (lotions, creams, salves, etc.) are not contained in table 2 of 21 CFR 101.12, they will not be held to a standard for serving, but any individual topical product cannot contain >10 mg Total THC per container.
- **The Definition of “*Accredited laboratory*” has been amended as follows:**
 - “*Accredited laboratory*” means a laboratory accredited in accordance with the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) Standard 17025:2017 (July 17, 2024), by an International Laboratory Accreditation Cooperation (ILAC) recognized accreditation body for the analyses performed on consumable hemp products.
- **Will there be changes to the Registrant Portal and how I submit my product list?**
 - There will be minimal changes to the Registrant Portal and the product list process. The Product List Upload Template will have minor changes to reflect “mg Total THC per serving” and “mg total THC per container” reporting for each product.
 - Due to the changes to the Registrant Portal, registrants renewing a registration or updating a product list after July 1, 2024, will be asked to restart and submit a complete product list.

Expectations of HHS and the Rulemaking Process

- **When will the proposed rules become effective?**
 - A Notice of Intended Action (NOIA) of proposed administrative rules was published on June 12. These draft rules, and additional implementation resources, remain hosted on the consumable hemp website and within the Registrant Portal.
 - Registrants had the opportunity to provide written public comment, as well as provide comment during virtual public hearings hosted on July 2 from 3:00 pm to 4:00 pm, and July 8 from 10:00 am to 11:00 am.
 - An Administrative Rules Review Committee (ARRC) meeting was held on July 16. These rules are effective today, July 17 and it is expected the adopted rules will be published in the Administrative Bulletin on August 7. The adopted rules are available on the HHS website.
 - Consumable Hemp Registrants will be held accountable to these rules on July 17, and HHS will be processing registrations and product list updates accordingly.

Packaging and Labeling: Serving and Container Definitions, Total THC

- **How will HHS define a “*Serving*?”**

- “*Serving*” means the size or portion customarily consumed per eating occasion, expressed in a common household measure as established in [table 2 of 21 CFR 101.12](#) (as amended through May 27, 2016). If a solid consumable hemp product is packaged in a manner that includes more than a single serving, each serving must be clearly identified and severable from the other servings in the container. If a liquid consumable hemp product is packaged in a manner that includes more than a single serving, the number of servings must be conspicuously labeled. Liquid consumable hemp products shall be packaged in a container that holds a minimum of 12 fluid ounces.
- Serving sizes for various consumable hemp products cannot surpass the amounts indicated in Federal guidelines for packaging and labeling, and cannot contain >4 mg total THC. Please review table 2 in the provided link for any serving sizes not described below:
 - Edibles – See “Sugar and Sweets” in table 2
 - Gummy (fruit snack) = 30 g
 - Chocolate, confectionaries = 10-30 g
 - Carbonated and non-carbonated beverages = 12 fl oz (360 mL)
 - Syrups = 30 mL (2 tbsp)
 - Ingestible Fats and Oils – See “Fats and Oils” in table 2
 - Drink mixes = Amount to make 360 mL drink
- **How will HHS define a “*Container*?”**
 - “*Container*” means the object which holds one or more servings of a consumable hemp product.
 - Examples:
 - Edibles
 - Compliant – A 5-pack of gummies at 2 mg THC per gummy
 - Compliant – A 10-pack of gummies at 1 mg THC per gummy
 - Compliant – A 10 mg chocolate bar scored into 5, 2 mg THC squares
 - Compliant – An individually packaged gummy containing 4 mg THC
 - Not Compliant – An individually packaged gummy containing >4 mg THC
 - Beverages
 - Compliant - An individual 12 fl oz can at 4 mg THC
 - Compliant – An individual 24 fl oz can at 8 mg THC
 - Compliant – An individual 30 fl oz can at 10 mg THC
 - Not Compliant – A 12 fl oz can containing >4 mg THC
 - Not Compliant – A liquid consumable hemp product in a container with <12 fluid ounces, regardless of mg of THC it contains.
- **How will total THC be calculated and reviewed by HHS?**
 - The formula used by HHS to calculate THC per serving and per container shall be the following:

- 4 mg per serving \geq Delta-9 THC + $(0.877 \times \text{THCa})$
- 10 mg per container \geq Delta-9 THC + $(0.877 \times \text{THCa})$
 - *NOTE: Products containing “synthetic cannabinoids,” including but not limited to Delta-8, Delta-10, THC-P, HHC, THC-O etc., may no longer be sold in Iowa on July 1.*
- Examples:
 - A gummy product contains 3 mg per serving of Delta-9 THC and 1 mg THCa per serving. There are 2 gummies per package, and the serving size is designated as 1 gummy per serving. The total THC per serving would be 3.877 mg. The total THC per container would be 7.754 mg. This product would be permissible.
 - A tablet contains 1 mg of Delta-9 THC, and the serving size is designated as 1 tablet per serving. There are 10 tablets per bottle. The total THC per serving would be 1 mg, and the total THC per container would be 10 mg. This product would be permissible.
 - A chocolate bar contains 4 mg of Delta-9 THC per square, and there are 12 squares per chocolate bar. The serving size designated is 1 square per serving. The total THC per serving would be 4 mg. The total THC per container would be 48 mg. This chocolate bar would NOT be permissible.

Prohibited Products on July 1, 2024

- **What products are prohibited for sale in Iowa on July 1?**
 - Consumable hemp products containing more than 4 mg total tetrahydrocannabinol (THC) per serving and more than 10 mg total THC per container will be prohibited from sale in Iowa on July 1. As of July 1, products in excess of these THC limits are considered a controlled substance under Iowa law and not legal for sale in the state.
 - Synthetic consumable hemp products in any form.
 - “Flower” or “raw bud” consumable hemp product.
- **How will HHS define a “synthetic consumable hemp product?” Can I still sell them?**
 - “Synthetic consumable hemp products” are products containing synthetic or semi-synthetic cannabinoids. Synthetic and semi-synthetic cannabinoids refer to a class of cannabinoids created through a chemical process, and are structurally similar to naturally occurring cannabinoids, or cannabinoids that may occur in very small amounts naturally. Examples of synthetic consumable hemp products include, but may not be limited to:
 - Delta-8 THC
 - Delta-10 THC
 - Hexahydrocannabinol (HHC)
 - Tetrahydrocannabiphorol (THC-P)
 - Tetrahydrocannabinol-O-acetate (THC-O)
 - On July 1, synthetic consumable hemp products will be prohibited and may no longer be sold in Iowa. Any product containing these cannabinoids will not be

approved for sale, and Registrants must remove such products from their product lists and from sale at their establishments.

- **Can I sell any form of “flower” or “raw bud” product?**
 - Raw or dried flower marketed or distributed for the purposes of inhalation is prohibited in Iowa’s consumable hemp program.
 - Any raw or dried flower form marketed or distributed in Iowa shall contain a notice stating “this is a raw or dried agricultural commodity is not suitable or intended for human consumption in conjunction with Iowa code section 204.14A, subsection 1, paragraph “b” or “c”.”
 - HHS will evaluate proposed and marketed flower products to determine whether, despite having the required notice affixed, such product is being sold with the intent that it be used for human consumption or for inhalation

Registrant Preparation with HF2605

- **Will there be a “grace period” for on-hand products that do not meet the new serving and container limits?**
 - No, products that contain >4 mg total THC per serving or >10 mg THC per container must not be available for sale on July 1. Registrants should ensure that
 - they are not in possession of these products on July 1. HHS is not responsible for the facilitation or the destruction of non-compliant products.
 - Products not compliant with HF2605 are considered controlled substances pursuant to Iowa Code section 124.401. Penalties may range from a serious misdemeanor to a class B felony, depending on the amount of product in their possession.
- **As a Consumable Hemp Retailer, can I repackage or relabel on-hand products to conform with the new serving and container limits?**
 - No, pursuant to 641 IAC chapter 156.6(4), a retailer cannot manufacture, process, package, repackage, relabel, mix, blend, or otherwise manipulate a consumable hemp product.
- **What should I do with the non-conforming products that I have on-hand?**
 - Registrants should inquire with product vendors to determine if non-conforming products can be returned to the vendor. If this is not possible, Registrants may work with local law enforcement to destroy the product.
- **Can I store or warehouse non-conforming products in Iowa if I am not selling them directly to consumers?**
 - No, consumable hemp products not conforming with these regulations are prohibited in Iowa, whether they are distributed, exported, imported, or offered for sale pursuant to Iowa code section 204.2, subsection 2, paragraph c.

- **As a Retail establishment, how should I be communicating with my product vendors?**
 - Retail Registrants should inform their product vendors of Iowa's new law, particularly the ban on synthetic consumable hemp products and the per serving and per container total THC limits. Retail Registrants should inquire with their vendors about the opportunity to return non-conforming product prior to July 1.

- **As an in-state or out-of-state Manufacturing Registrant, how should I prepare and be communicating with Retailers?**
 - Out-of-state Manufacturing Registrants should prepare to no longer distribute non-conforming products to Iowa retailers prior to July 1, and should communicate with their retail partners about these changes.
 - In-state Manufacturing Registrants should prepare to no longer manufacture or distribute non-conforming products to Iowa retailers prior to July 1, and should communicate with their retail partners about these changes.

- **How should I verify that I am not selling products to persons under 21?**
 - Registrants should check photo IDs of every individual purchasing consumable hemp products to verify they are 21 years of age or older prior to making a sale.

- **How should I prepare for these changes?**
 - HHS encourages registrants to contact their product vendors regarding updated regulations, remove non-conforming products from sale, and update their product lists to prepare for these changes. Registrants may also want to understand vendor and manufacturer processes for updating packaging and labeling pursuant to the forthcoming administrative rules on labeling.
 - It is the Registrant's responsibility to ensure they are compliant with all changes pursuant to HF 2605.

Penalties and Enforcement

- **What are the penalties if I sell or distribute products to persons under 21?**
 - Individuals or business owners found selling, giving, or otherwise distributing consumable hemp products to a person under age 21 may be found guilty of a simple misdemeanor pursuant to Iowa code section 204.14D.

- **What are the penalties if I sell non-conforming or illegal products?**
 - Selling non-conforming or illegal products in Iowa may result in civil and criminal penalties. Products which contain tetrahydrocannabinols and do not conform with Iowa's Consumable Hemp law are "controlled substances" pursuant to Iowa Code sections 124.101(20), 124.202, and 124.204(4)(m). Those possessing, manufacturing, or distributing controlled substances in Iowa may be criminally prosecuted.
 - Additionally, HHS may order confiscation and disposal of any non-conforming hemp product or product sold by a person who is not registered with HHS.

Reasonable costs incurred for destroying non-conforming products may be assessed to the Registrant or unregistered individual.

- **What are the penalties for selling products without a registration?**
 - Penalties for selling consumable hemp products without a registration are severe. Businesses selling consumable hemp products without a registration may be subject to civil penalties of up to \$10,000 per day and/or criminal penalties pursuant to Iowa code sections 204.14B and C.

Expectations of HHS and the Rulemaking Process

- **Is HHS aware of key dates of the rulemaking process?**
 - Yes, a Notice of Intended Action (NOIA) of proposed administrative rules is expected to be published on June 12. Registrants will be notified, and the public comment process will be provided with the NOIA.
 - Virtual public hearings are planned to be hosted by HHS on July 2 from 3:00 pm to 4:00 pm, and July 8 from 10:00 am to 11:00 am.
 - Rules are intended to be adopted no earlier than July 17, with final rules published August 7.
- **What should Registrants expect from HHS regarding inspection and enforcement?**
 - Registrants should be aware that the penalties for non-compliance implemented by HF 2605 are severe and HHS intends to enforce these new regulations when they become effective on July 1. Registrants should expect enforcement activities on and on behalf of HHS.
 - If Registrants are unsure of the legality of the products they intend to sell or manufacture, they are strongly encouraged to contact HHS or seek private legal counsel.