## Consumable Hemp: HF 2605 FAQ - What it Means, Draft Rules, Townhall Info

On May 17, 2024, Governor Reynolds signed <u>HF2605</u> 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. This FAQ contains specific updates to the May 24 communication, and also contains updates to the draft rules.

## Packaging and Labeling: Serving and Container Definitions, Warning Label

- 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



Adam Gregg, Lt. Governor

Kelly Garcia, Director

- 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.</li>

## What is the language in the required warning label?

- o HHS intends to propose the warning label information below:
- "This product has not been analyzed or approved by the United States Food and Drug Administration. There is limited information on the side effects of using this product, and there may be associated health risks and medication interactions. This product may cause the consumer to fail a drug test for THC. Products containing THC may cause impairment and a consumer's ability to operate a vehicle. This product is not recommended for use by pregnant or breastfeeding women. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN"

# 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 ≥ Delta-9 THC + (0.877 × THCa)
  - 10 mg per container ≥ Delta-9 THC + (0.877 × 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 lowa on July 1.

#### o Examples:

- A <u>gummy</u> 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 <u>tablet</u> 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 <u>chocolate bar</u> 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.

Adam Gregg, Lt. Governor

Kelly Garcia, Director

# **Prohibited Products on July 1, 2024**

# What products are prohibited for sale in lowa 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 lowa'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



Adam Gregg, Lt. Governor

Kelly Garcia, Director

- 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 lowa 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.

#### 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.

# • As a Retail establishment, how should I be communicating with my product vendors?

 Retail Registrants should inform their product vendors of lowa'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 lowa 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 lowa retailers prior to July 1, and should communicate with their retail partners about these changes.



Adam Gregg, Lt. Governor

Kelly Garcia, Director

#### • 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?

- O 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**

- Will I have the opportunity to provide comment on the draft rules?
  - HHS will be conducting a one-hour, Virtual Town Hall on June 10 to outline draft rules and host a public comment period. Entry into the meeting will be limited to 1,000 participants.
  - The meeting information is below:
    - Date and Time: Monday, June 10 12:00 pm 1:00 pm CST
    - Zoom Link HF2605 Implementation Townhall



Adam Gregg, Lt. Governor

Kelly Garcia, Director

• Click the link to join at the scheduled time

• **Passcode**: 073735

Webinar ID: 160-034-3671

• **Dial-in:** 669-254-5252, 1600343671#

- Participation in the public comment period will on a fist come, first served basis, and participants will be given two minutes to provide comment.
- If you desire to participate in the public comment period, please you're your name and contact information to <u>consumable.hemp@idph.iowa.gov</u>. Your screenname must be clearly identified in the participants list in order to be promoted to speak.

# • Will there be additional administrative rules and clarifications about these changes?

- Yes, administrative rules have been drafted to implement this legislation, and have been updated following comments on the initial release from May 24. To support registrant understanding and preparation for the implementation of HF2605, these draft rules have been posted to the Consumable Hemp website.
- Standard administrative rule adoption procedures will apply and Registrants will be able to provide comments on proposed and noticed rules throughout the process and before the rules become effective.

## 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.