IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
CENTRAL DIVISION

CLIMBING KITES LLC, *et al.*, *Plaintiffs*, v. STATE OF IOWA, *et al.*, *Defendants.*	Case No. 4:24-cv-202-SMR-SBJ

DEFENDANTS' SUPPLEMENTAL BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

Plaintiffs sued Defendants seeking to enjoin enforcement of THC-related laws and regulations in Iowa. While Plaintiffs sued, amended their suit, and pursued multiple preliminary injunctions, the Department of Health and Human Services continued its work to ensure a smooth transition to the new protections enacted related to selling THC. The Department held public hearings to hear comments and concerns over the then-draft Rules. And it issued draft then final Rules. Now, the Rules have taken effect, as of July 17, 2024, under the Department's emergency authority. At the same time, Department employees completed the difficult task of rolling out a new online tool to assist the Department in enforcing Iowa's revised hemp laws. As of today, the Department has processed all consumable hemp products submitted between July 1 and July 17, 2024, for the Department's review. Each Plaintiff, and every Registrant, that submitted new products for approval between July 1 and July 17, has, by now, received notice that their product was either approved or denied.

Meanwhile, Plaintiffs' argument in their supplemental brief boils down to this: "Plaintiffs need some indication from the Department of how to conduct their business lawfully without the risk of violating the Department's interpretation of the law." Dkt. 40, at 2.

The Rules are now final and effective. And the Department has now processed all products Plaintiffs submitted for approval. Plaintiffs now have more than an "indication" of how to conduct their business lawfully. They have clear answers. The Court should deny Plaintiffs' renewed motion for preliminary injunction.

BACKGROUND

A. The Consumable Hemp Registrant Portal.

When Iowa's consumable hemp industry began a few years ago, the Department understood it needed infrastructure to enforce the program, which required each consumable hemp

manufacturer, establishment, or distributor in Iowa, as defined by Iowa Admin. Code r. 641—156.1, to obtain (1) a consumable hemp registration from the Department and (2) approval of their product as compliant by the Department. Parker Decl. ¶¶ 4, 11. The Department reviewed more than 46,000 products submitted by 1,200 Registrants. Given that influx, the Department needed a useful tool to help it approve products for retail sale. *Id.* ¶¶ 5, 7, 8, 18.

So the Department, and its Bureau of Cannabis Regulation, with the help of a third-party developer, built and maintained a "Consumable Hemp Registrant Portal" to support registration and product approvals. *Id.* ¶¶ 5, 7. When registering with the Department on the Portal, each Registrant signs an attestation stating its understanding of the Iowa Hemp Act and agreeing to comply with State and federal law when selling their consumable hemp products. *Id.* ¶ 9. Approval of a product for sale does not alleviate each Registrant's responsibility to ensure their product continues to comply with state and federal law. *Id.* ¶ 10.

Registrants looking to have their products approved for sale in Iowa use the Portal and its included resources. Before July 1, 2024, the Department's primary criteria for approval was complying with the 2018 Farm Bill's less-than 0.3% THC threshold. *Id.* ¶ 25. Rules required Registrants to disclose the "cannabinoids per serving" and "cannabinoids per container" somewhere on their product. *Id.* ¶¶ 14–15. So the Department gave Registrants an Excel template that laid out that required information. *Id.* No Registrant ever complained that they did not know what this "per serving" disclosure requirement meant; they knew that "cannabinoids per serving" meant cannabinoids per serving of the product you put the cannabinoid in. *Id.* ¶ 16. Registrants were also required to submit a Certificate of Analysis, which would include the information necessary to allow the Department to calculate whether the product complied with the federal <0.3% THC threshold. *Id.* ¶¶ 25–28.

Once new or revised products are submitted for the Department's review, the Department has 30 days to review and act on the submission. *Id.* ¶ 6; Iowa Admin. Code r. 641—156.2(1)(*c*) and 2(2)(*c*). While the product is pending approval, Registrants cannot begin selling it; they may only sell consumable hemp products in Iowa that are approved by the Department. *Id.* ¶ 11. If registrants sell noncompliant or unapproved products, the Department can enforce in a few different ways, including civil penalties. *Id.* ¶ 13. But such penalties are usually issued after repeated violations. *Id.*

After receiving Registrants' submissions, the Department provides emails receipt of the submission, confirming that the product is under review and, per the Department's obligation, will be acted on within 30 days. *Id.* ¶ 19. Though instantaneous review is not possible, because of how thorough the Department's process is, the Department was still able to maintain an average decision time of four days between July 1, 2023, and June 30, 2024. *Id.* ¶ 20.

No products are approved or denied without the Department providing notice to the Registrant. *Id.* ¶ 21. If a product is approved, the Registrant receives a receipt of the approval instantaneously and may view the product in its "approved product list" on the Portal. *Id.* ¶ 22. When a Registrant submits a product list update during the registration's effective period, only newly submitted products are reviewed, while previously approved products on the list are maintained. *Id.* ¶ 23. But if the product is denied, the Registrant receives an email communication explaining which specific products were denied and why. *Id.* ¶ 24. The Department does not issue denials without also issuing express notice and explanation to the Registrant. *Id.*

HF2605's Potency Provision required the Department to build and implement substantive, and technical, updates to the Portal ahead of the law's July 1 effective date. *Id.* ¶ 30. That required extensive work by the Department and third-party web developers. *Id.* ¶¶ 7, 29, 30. To ensure a

timely rollout, the Department began the work in April 2024, even before the Governor signed the law in May. *Id.* The Department timely completed the necessary updates and rolled out the updated Portal at midnight on July 1, 2024. *Id.* ¶ 30.

The key update to the Portal was that Registrants must now disclose "Total THC per Serving" and "Total THC per Container," instead of total *cannabinoids*, for any products submitted after July 1, 2024. *Id.* ¶ 31. The Department made related necessary changes to the Excel template. *Id.* ¶ 33. And it revised the "Consumable Hemp Product List Upload Guide" to outline the changes for Registrants' per-serving and per-container THC declarations and explaining why products may be denied by the Department. *Id.* ¶¶ 33–34.

But the Department did not begin reviewing products' compliance with HF2605 until after the law took effect. It had no authority to approve or deny products submitted for review under HF2605's new standards before the law's July 1, 2024, effective date. *Id.* ¶ 29. Meanwhile, until July 1, 2024, the Department still had the responsibility to continue approving products meeting the pre-HF2605 standards. *Id.* Processing products based on HF2605 before July 1 would have risked sending the signal to the public that the Department was enforcing the law before it was even in effect. *Id.* ¶ 42. And from a practical standpoint, as a matter of resources and staffing, the Department could not double its Portal-derived workload—having to review the same product under both the pre- and post- July 1 standards—all while working hard to ensure a clean rollout of the amended hemp program at midnight on July 1, 2024. *Id.* ¶ 43.

Instead, the Department made an operational decision to require any Registrant entering the Portal on or after July 1, 2024, whether seeking to renew a registration or make a product list update, to submit a new product list in accordance with the portal updates and newly effective law. *Id.* ¶ 35. At that time, the Department had more than 46,000 products on file; instead of *sua sponte*

re-approving or de-approving all those products, the Department pursued administrative efficiency and it expected Registrants—consistent with Registrants' continuing obligation under their Portal attestations to comply with state and federal law—to sift out any products that did not comply with the new law *Id.*

On July 1, 2024, Registrants with up-to-date registrations could still sell their products in Iowa, so long as (1) the Department had approved the product and (2) it complied with the new requirements set forth in HF2605 *Id.* ¶ 39. Otherwise, Registrants were expected to submit their product for the Department's review. *Id.* ¶ 35.

B. The Department Updates the Portal Then Processes All Registrants' Post-July 1 Product Submissions.

Once the Department rolled out the updated Portal on July 1, thus allowing it to enforce HF2605's updated THC potency standards, it immediately began accepting new or updated products submissions. Registrants entering the Portal after the July 1 rollout would have seen a banner atop the homepage flagging the substantial changes under HF2605, highlighting that the changes "will be in effect on July 1, 2024," and providing various resources for Registrants. *Id.* ¶ 32. Included in those resources was the revised Upload Guide outlining the changes for Registrants' per-serving and per-container THC declarations and explaining why products may be denied by the Department. *Id.* ¶¶ 33–34. Another of those resources was the new template Excel spreadsheet Registrants were expected to use when submitting new and revised product lists for approval. *Id.* Because THC potency was newly regulated post-July 1, the template now requires Registrants to declare the "Total THC per serving" and "Total THC per container" for their product. *Id.* ¶¶ 15, 33.

Registrants could then submit their new product list updates for the Department's review if they declared the amount of THC per serving and THC per container for their products complied

with HF2605. ¶¶ 36, 40. Once Registrants submitted new or updated products list post-July 1, their list of products approved pre-July 1 were archived from Registrants view, though the Department maintained access to those still-approved products. *Id.* ¶¶ 36–38. Those earlier approved products were not "denied"—no communications were sent to any Registrant *sua sponte* "de-approving" any products. *Id.* ¶ 38 After all, the Department does not issue denials without giving Registrants notice. *Id.* ¶¶ 24, 38. Instead, the Department would have 30 days from the date of the product's submission to act on the submission.

So, starting July 1, many Registrants began submitting their products for approval. And between July 1 and July 17, 2024, Registrants have submitted via the Portal 186 product list updates, 8 new applications for registrations, and 14 renewal applications for the Department's review under the new standards. *Id.* ¶ 46. And as of today, the Department has processed all such submissions—written notices of approval or denial have issued. *Id.* In the case of a denial, the Department explained to registrants why it determined their product did not comply with HF2605 and administrative rules, per the Department's standard practice as detailed above. *Id.*

Before and after July 1, the Department followed its standard operating procedures, reviewing each Registrant and product submission in accordance with its standard procedures. *Id.* ¶ 51. And it did so while maintaining compliance with the 30-day period it is given, by regulation, to review new or updated products. *Id.* ¶¶ 41–42.

This includes all products Plaintiffs have submitted since July 1, including, for example, products submitted by Climbing Kites and Field Day Brewing—plaintiffs in the companion case, Case No. 4:24-cv-202. *Id.* ¶¶ 47–51.

Some products Plaintiffs submitted have already been approved. Climbing Kites submitted a new product list on July 9, 2024, and received instantaneous confirmation that the Department

had received its submission, which was then under review. *Id.* ¶¶ 22, 48. A copy of that email receipt is attached to the Parker Declaration as Exhibit 7. That email receipt was opened by Climbing Kites on July 11. *Id.* ¶ 48. On July 18, Climbing Kites received notice that the Department approved several of its products as compliant with HF2605. *Id.* ¶ 49. That approval notice is attached to the Parker Declaration as Exhibit 8. For example, one approved product was the Climbing Kites "4MG - Pineapple Passion Fruit," which is a 12-oz carbonated beverage that includes 4 mg of THC per serving and 4 mg of THC per container. *Id.* The Department approved the 12-oz can because it contains 4 mg or less of THC in the one, 12-oz serving of carbonated beverage, and it therefore complies with HF2605. *Id.*

Other products Plaintiffs submitted have already been denied. Plaintiff Field Day Brewing received notice and explanation of several product denials on July 18 and 19, 2024. *Id.* ¶ 50. That notice and Excel explanation are attached to the Parker Declaration as Exhibits 9 and 10, respectively. The first product denial detailed in the Excel sheet—the Day Dreamer Classic Raspberry Hibiscus, a 12-oz can of carbonated beverage—was denied because it contained more than 4 mg of THC in the 12-oz can, which violates the definition of serving. *See* Exhibit 6 to the Parker Declaration (Final FAQ Guidance), at 3 ("Not Compliant – A 12 fl oz can containing >4 mg THC"). It did not matter that Field Day reported to the Department that the product contained 4 mg of THC per serving, because the 12-oz container held 8 mg of THC. Parker Decl. ¶ 50. But a 12-oz can of carbonated beverage is one serving of carbonated beverage, so it cannot contain more than 4 mg of THC. *Id.* Yet this product contained 8 mg of THC, so it was denied. *Id.* Another Field Day Brewing product—the Day Dreamer Low Key Raspberry Hibiscus—was denied because, although it was reported on the Excel template that the 12-oz carbonated beverage product contained 4 mg of THC per serving, and 4 mg of THC per container, the testing did not match that

reporting. *Id.* The Certificate of Analysis revealed that the product contained 4.62 mg of THC per serving, thus exceeding the per-serving limit. So the Department denied the product. *Id.*

Because the Department is following its standard review process, and treating all Registrants similarly, the above examples are also how all Plaintiffs'—indeed, all Registrants'—products submissions have been processed since July 1. *Id.* ¶¶ 38–41, 46–52.

C. The Department's Final Rules Became Effective On July 17, 2024.

Since Defendants last briefed this case and appeared in court for the hearing, the Department invoked its emergency authority to finalize the Rules and make them effective as of July 17, 2024. *See* Iowa Code §§ 17A.4(3)(a); 17A.5(2)(b). The Rules are materially like the draft Rules noticed on June 12. The Final Rules are attached as Exhibit 5 to the Parker Declaration. *See also* Iowa Admin. Code. r. 641-156.1–156.11 (2024), available at https://perma.cc/8UKU-BTXT. The Department has also issued Final FAQ guidance document (attached as Exhibit 6 to the Parker Declaration), which explains the final Rules and addresses concerns raised by community members during the public comment period. *See* Iowa Dep't of Health and Human Servs., Consumable Help: HF 2605 FAQ – What it Means, Rules Effective July 17 (July 17, 2024) ("Final FAQ Guidance"), https://perma.cc/CE8J-C9ME.

ARGUMENT

Plaintiffs' claims have now winnowed down to one: whether the Potency Provision's "per serving" limit is unconstitutionally vague as applied to Plaintiffs. It is not. The statute's plain meaning gives Plaintiffs clarity so that they may act lawfully. The Rules confirm that plain meaning. And the Department's processing of Plaintiffs' product submissions establish that the statute means what it says.

Defendants do not intend to re-brief the legal issues in this case. For the reasons detailed in Defendants' earlier briefing, *see* Dkts. 19, 35, this Court should deny Plaintiffs' request for preliminary injunctive relief.

I. The Court Should Not Consider Plaintiffs' Facial Vagueness Challenges.

As this Court emphasized at the hearing, Hr'g Tr. 5:17–24, facial challenges to criminal statutes for vagueness are unavailable on non-First Amendment grounds. *See also* Dkt. 35 at 5, 10; *United States v. Ghane*, 673 F.3d 771, 777 (8th Cir. 2012). When a vagueness challenge to a statute does not involve First Amendment freedoms, courts evaluate the challenge on an "as-applied basis." *Sanimax USA, LLC v. City of S. St. Paul*, 95 F.4th 551, 569 (8th Cir. 2024); *see Gallagher v. City of Clayton*, 699 F.3d 1013, 1021 (8th Cir. 2012) ("It is well established that vagueness challenges to statutes which do not involve First Amendment freedoms must be examined in the light of the facts of the case at hand." (quotation marks omitted)).

Plaintiffs' facial challenge to the Potency Provision does not concern the First Amendment. So their facial vagueness challenge fails. *Sanimax*, 95 F.4th at 569–573.

II. The Potency Provision is Not Unconstitutionally Vague.

The Potency Provision's "per serving" limit is not unconstitutionally vague as applied to Plaintiffs. The State maintains that the term "serving" carries its plain meaning, as confirmed by its common usage in the food industry. *See* Dkt 35 at 10–17. The statute's plain meaning thus notifies a person of ordinary intelligence of what is prohibited and sets standards for law enforcement to prevent arbitrary and discriminatory enforcement. Dkt. 35 at 5–10.

Yet even if there is any potential ambiguity, the Department's Rules are now final and took effect on July 17, under the Department's emergency rulemaking authority. *See* Exhibit 5 to the Parker Declaration (Final Rules); Iowa Code §§ 17A.4(3)(a); 17A.5(2)(b). So to the extent there was any ambiguity in the statute's text (there is not), the now-final Rules provide Plaintiffs with

their desired answers. *See Guedes v. ATF*, 920 F.3d 1, 28 (D.C. Cir. 2019) (promulgation of rules through notice-and-comment procedures can afford fair notice of prohibited conduct to avoid unconstitutional vagueness); *Vill. of Hoffman Estates v. Flipside, Hoffman Ests., Inc.*, 455 U.S. 489, 503–04 (1982) (Courts do not "assume that the [government] will take no further steps to minimize the dangers of arbitrary enforcement. The [government] may adopt administrative regulations that will sufficiently narrow potentially vague or arbitrary interpretations of the ordinance.").

The Final Rules say a "serving" is:

> 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 to July 17, 2024). 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.

Iowa Admin. Code r. 641–156.1. The Rule confirms the term's plain meaning. Dkt. 35 at 10–17. And it puts Plaintiffs on notice about what is a serving for eaten consumable hemp products. Plaintiffs are directed to federal regulations covering serving sizes for food and drinks—and Plaintiffs' only products are THC-infused carbonated beverages, which are drinks.

More, Plaintiffs submitted several products for the Department's review under the post-July 1 standards. Parker Decl. ¶¶ 46–52. And the Department has since approved every compliant product and denied—with written explanation for the denial—every noncompliant product. *Id.*

There is no further notice or indication of compliant products that the Department could provide Plaintiffs. Plaintiffs' as-applied vagueness challenge fails.

III. The "Per Serving" Limit Has Not Resulted in Arbitrary Enforcement.

The Department followed its standard operating procedures, reviewing each Registrant and product submission. Parker Decl. ¶ 51. Contrary to Plaintiffs' assertions, the Department did not remove any of Plaintiffs'—or any other Registrants'—products from the approved list. *Id.* ¶¶ 35–40. Instead, it reviews each newly submitted product list for compliance, applying the plain meaning of "per serving" to products—"per serving" having the meaning confirmed by its common usage in the food industry and the Final Rules. And it did so while complying with Iowa law's 30-day review period to review new or updated products. *See id.* ¶¶ 41–42; Iowa Admin. Code r. 641—156.2(1)(*c*) and 2(2)(*c*). There has been no arbitrary enforcement of the Potency Provision.

CONCLUSION

For these reasons, and those in Defendants' prior briefing, Dkts. 19, 35, the Court should deny Plaintiffs' motion.

Respectfully submitted,

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PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served on counsel for all parties of record by delivery in the following manner on July 19, 2024:

☐ U.S. Mail	☐ FAX
☐ Hand Delivery	☐ Overnight Courier
☐ Federal Express	☐ Other
☒ CM/ECF	

Signature: */s/Patrick C. Valencia*