

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/HB 179 Florida Kratom Consumer Protection Act  
**SPONSOR(S):** Regulatory Reform & Economic Development Subcommittee, Andrade  
**TIED BILLS:** **IDEN./SIM. BILLS:** CS/SB 136

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Regulatory Reform & Economic Development Subcommittee	11 Y, 0 N, As CS	Wright	Anstead
2) Commerce Committee	19 Y, 0 N	Wright	Hamon

### SUMMARY ANALYSIS

Kratom, *Mitragyna speciosa*, is a tropical tree native to Southeast Asia that contains psychoactive ingredients in its leaves, which may be crushed and then smoked, brewed with tea, or placed into gel capsules. Consumption of kratom leaves can produce stimulant and sedative effects, and addiction may lead to psychotic symptoms. Currently, kratom is not listed as a controlled substance under federal law or Florida law, and is generally regulated as a food. There are no specific state laws related to the regulation of kratom.

The bill places the regulation of kratom products within ch. 500, F.S., which is under the Department of Agriculture and Consumer Services (DACS).

The bill defines "kratom product" to mean a food product, food ingredient, dietary ingredient, dietary supplement, or beverage intended for human consumption which contains any part of the leaf of the plant *Mitragyna speciosa* or an extract, synthetic alkaloid, or synthetically derived compound of such plant and is manufactured as a powder, capsule, pill, beverage, or other edible form.

As a food product, kratom products are subject to regulation and inspection by DACS.

The bill provides that it is unlawful to sell, deliver, barter, furnish, or give, directly or indirectly, any kratom product to any person who is under 21 years of age.

If any retail food store, food establishment, or cottage food operation sells kratom products to someone under 21, they are subject to an administrative fine of not more than \$100 for the first offense, not more than \$500 for the second offense, and not more than \$1,000 for the third or subsequent offense.

The bill does not appear to have a fiscal impact on local governments and may have a negative fiscal impact on state government. See Fiscal Analysis and Economic Impact Statement.

The bill provides an effective date of July 1, 2023.

# FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED CHANGES:

#### Kratom

Kratom, or *Mitragyna speciosa*, is a tropical tree native to Southeast Asia that contains the alkaloids mitragynine and 7-hydroxymitragynine in its leaves, which are two major psychoactive ingredients.<sup>1</sup> The leaves are crushed and then smoked, brewed with tea, or placed into gel capsules.<sup>2</sup>

Some people consumer kratom to treat muscle ache, fatigue, and other conditions.<sup>3</sup> Low doses of kratom are said to produce a stimulant effect, while higher doses may produce an opioid-like effect.<sup>4</sup> Research finds that kratom can be used as a substitute for opiate users to combat withdrawal symptoms,<sup>5</sup> though kratom addiction may lead to psychotic symptoms.<sup>6</sup>

The U.S. Food and Drug Administration (FDA) has found that:<sup>7</sup>

Kratom is abused for its ability to produce opioid-like effects... Evidence suggests that kratom is abused individually and with other psychoactive substances. Kratom does not have an approved medical use in the United States and has not been studied as a treatment agent in the United States. Kratom has a history of being used as an opium substitute in Southeast Asia. In the United States, kratom is misused to self-treat chronic pain and opioid withdrawal symptoms. Consumption of kratom can lead to a number of health impacts, including, among others, respiratory depression, vomiting, nervousness, weight loss, and constipation. Kratom has been reported to have both narcotic and stimulant-like effects, and withdrawal symptoms may include hostility, aggression, excessive tearing, aching of muscles and bones, and jerky limb movements.

A Centers for Disease Control and Prevention study of approximately 27,000 overdoses that occurred between 2016 and 2017 found that kratom was implicated in less than one percent of deaths.<sup>8</sup> The exact incidence of kratom dependency is not known and there is no U.S. reporting system.<sup>9</sup> It is estimated that there are between 10-16 million kratom users in the U.S.<sup>10</sup> Users indicate self-treatment of anxiety, depression, pain, fatigue, and substance use disorder symptoms.<sup>11</sup>

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<sup>1</sup> Drug Enforcement Administration, *Kratom* (April 2020), available at [https://www.dea.gov/sites/default/files/2020-06/Kratom-2020\\_0.pdf](https://www.dea.gov/sites/default/files/2020-06/Kratom-2020_0.pdf) (last visited Feb. 15, 2023).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> See Dimy Fluyau and Neelambika Revedigar, *Biochemical Benefits, Diagnosis, and Clinical Risks Evaluation of Kratom*, *Frontiers in Psychiatry Journal* Volume 8 (April 24, 2017).

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> 86 FR 39038.

<sup>8</sup> Emily O'Malley Olsen, PhD; Julie O'Donnell, PhD; Christine L. Mattson, PhD; Joshua G. Schier, MD; Nana Wilson, PhD; *Notes from the Field: Unintentional Drug Overdose Deaths with Kratom Detected — 27 States, July 2016–December 2017*; CDC Morbidity and Mortality Weekly Report, Apr. 12, 2019; [Notes from the Field: Unintentional Drug Overdose Deaths with Kratom Detected — 27 States, July 2016–December 2017 | MMWR \(cdc.gov\)](https://www.cdc.gov/mmwr/preview/mmwrhtml/ww04a1.htm) (last visited Feb. 15, 2023); Maia Szalavitz, *The FDA Shouldn't Support a Ban on Kratom*, *Scientific American*, Aug. 12, 2021, [The FDA Shouldn't Support a Ban on Kratom - Scientific American](https://www.scientificamerican.com/article/the-fda-shouldnt-support-a-ban-on-kratom/) (last visited Jan. 30, 2022).

<sup>9</sup> Charles Veltri and Oliver Grundmann, *Current Perspectives on the Impact of Kratom Use*. *Substance Abuse and Rehabilitation Journal* Volume 10 23-31 (July 1, 2019).

<sup>10</sup> Maia Szalavitz, *supra* note 8.

<sup>11</sup> Jeffrey Rogers, Kirsten Smith, Justin Strickland, and David Epstein, *Kratom Use in the US: Both a Regional Phenomenon and a White Middle-Class Phenomenon? Evidence From NSDUH 2019 and an Online Convenience Sample*, *Frontiers on Pharmacology*, <https://www.frontiersin.org/articles/10.3389/fphar.2021.789075/full> (last visited Feb. 19, 2023).

Kratom is a \$1.3 billion industry in the U.S. with sales generally occurring online and in smoke shops.<sup>12</sup> Hundreds of businesses around Florida sell the product.<sup>13</sup>

Public opinions in the U.S. range on the topic of kratom bans, either citing concerns of addiction or praising perceived health benefits. Some point to kratom's uses for opioid addicts to cease use and aid in withdrawal symptoms.<sup>14</sup> Other reports indicate that the use of kratom may lead to addiction.<sup>15</sup>

## State and Federal Prohibitions

Currently, kratom is not listed as a controlled substance under federal law or Florida law. In 2016, the U.S. Drug Enforcement Administration (DEA) submitted a notice of intent to place kratom into Schedule I of the Controlled Substances Act (CSA) based on abuse potential and risk to public health.<sup>16</sup> However, the DEA withdrew the notice a few months later based on public comments.<sup>17</sup> In a letter obtained by an industry group, U.S. Health and Human Services appeared to rescind their recommendation to the DEA to place kratom on Schedule I of the CSA in 2018, stating that such action should wait until it is supported by further research on kratom uses, abuse, and risks.<sup>18</sup> The DEA continues to label kratom as a drug of concern.<sup>19</sup>

The FDA has stated that there is substantial concern regarding the safety of kratom and the risk it may pose to public health, and indicated that there are currently no FDA-approved uses for kratom.<sup>20</sup> The FDA is actively evaluating all available scientific information on the safety and effects of kratom and continues to warn consumers not to use any kratom products, but has made no official findings.<sup>21</sup>

In 2015, the FDA issued an import alert<sup>22</sup> that labels kratom as an adulterating ingredient.<sup>23</sup> As a result, the FDA seized imports of kratom-containing dietary supplements and bulk dietary ingredients. In May of 2021, the FDA announced the seizure of around 37,500 tons of adulterated kratom in Fort Myers, Florida, worth an estimated \$1.3 million.<sup>24</sup> On October 26, 2021, a consent decree of condemnation and destruction against the seized articles by the FDA was entered, which required the claimants to pay a penal bond and destroy all seized articles.<sup>25</sup>

Generally, the official federal legal and regulatory status of kratom or kratom included in food products is still being decided.

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<sup>12</sup> Brody Ford, *Opiate Alternative Kratom Spurs Investor Interest*, Bloomberg News, Dec. 20, 2021, <https://www.bloomberg.com/news/newsletters/2021-12-20/kratom-attracts-investor-attention-after-regulatory-win> (last visited Jan. 30, 2022).

<sup>13</sup> Kirby Wilson, *Florida Kratom for customers under 21 to be banned if this bill passes*, Tampa Bay Times, Jan. 18, 2022, [Florida Kratom for customers under 21 to be banned if this bill passes \(tampabay.com\)](https://www.tampabay.com/news/health/addiction/news/20190211/regulations-are-on-hold-as-kratom-debate-rages) (last visited Jan. 30, 2022).

<sup>14</sup> Jennifer Clopton, *Regulations Are On Hold as Kratom Debate Rages*, WebMD, Feb. 11, 2019, <https://www.webmd.com/mental-health/addiction/news/20190211/regulations-are-on-hold-as-kratom-debate-rages> (last visited Feb. 15, 2023).

<sup>15</sup> Mayo Clinic, *Kratom for opioid withdrawal: Does it work?*, <https://www.mayoclinic.org/diseases-conditions/prescription-drug-abuse/in-depth/kratom-opioid-withdrawal/art-20402170> (last visited Feb. 15, 2023).

<sup>16</sup> 81 FR 59929.

<sup>17</sup> 81 FR 70652

<sup>18</sup> Josh Long, *HHS in 2018 rescinded recommendation to schedule kratom as a drug*, Jan. 28, 2021, <https://www.naturalproductsinsider.com/regulatory/hhs-2018-rescinded-recommendation-schedule-kratom-drug> (last visited Feb. 15, 2023).

<sup>19</sup> U.S. Drug Enforcement Administration, *Kratom*, <https://www.dea.gov/factsheets/kratom> (last visited Feb. 15, 2023).

<sup>20</sup> U.S. Food and Drug Administration, *FDA and Kratom*, <https://www.fda.gov/news-events/public-health-focus/fda-and-kratom> (last visited Feb. 15, 2023).

<sup>21</sup> *Id.*

<sup>22</sup> U.S. Food and Drug Administration, *Import Alert 54-15*, [Import Alert 54-15 \(fda.gov\)](https://www.fda.gov/oc/2015/05/15) (last visited Feb. 15, 2023).

<sup>23</sup> *Id.* The FDA labeled kratom as adulterating based on the absence of a history of use or other evidence of safety establishing that kratom will reasonably be expected to be safe as a dietary ingredient, kratom and kratom-containing dietary supplements and bulk dietary ingredients are adulterated because they contain a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.

<sup>24</sup> U.S. Food and Drug Administration, *FDA Announces Seizure of Adulterated Dietary Supplements Containing Kratom*, May 21, 2021, <https://www.fda.gov/news-events/press-announcements/fda-announces-seizure-adulterated-dietary-supplements-containing-kratom> (last visited Feb. 15, 2023).

<sup>25</sup> *Id.*

In 2014, Sarasota County banned kratom, labeling it as a designer drug.<sup>26</sup> With the exception of Sarasota County, in Florida, all parts of the plant and its extracts are legal to cultivate, buy, possess, and distribute without a license or prescription. Kratom is illegal in Alabama,<sup>27</sup> Arkansas,<sup>28</sup> Indiana,<sup>29</sup> Vermont,<sup>30</sup> and Wisconsin.<sup>31</sup> Other states such as Arizona,<sup>32</sup> Georgia,<sup>33</sup> and Utah<sup>34</sup> regulate kratom under their state's version of the Kratom Consumer Protection Act.

## Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act (FDCA) is a federal law which establishes the legal framework within which the FDA operates.<sup>35</sup> The FDA develops regulations under the FDCA for the safety of foods, drugs, and cosmetics based on the laws set forth in the FDCA, including when a food is adulterated.<sup>36</sup> Instances where a food must be determined to be adulterated include when it:<sup>37</sup>

- Bears or contains any poisonous or deleterious substance which may render it injurious to health; such as consisting in whole or in part of any filthy, putrid, or decomposed substance;
- Is a dietary supplement or contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under use pursuant to the label;
- Is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.

When a food is determined to be adulterated, the FDA may take the following compliance measures:<sup>38</sup>

- Warning and untitled letters,
- Import alerts,
- Recalls,
- Debarment,
- Civil money penalties,
- Seizure of products,
- Injunctions, and
- Criminal prosecution.

## Florida Department of Agriculture and Consumer Services, Division of Food Safety

The Department of Agriculture and Consumer Services (DACS) is the department in charge of regulating agriculture in Florida.<sup>39</sup> As such, DACS promotes Florida agriculture, protects the environment, safeguards consumers, and ensures the safety and wholesomeness of food.<sup>40</sup>

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<sup>26</sup> See Sarasota, FL., Code of Ordinances, Sec. 62-351 (2014).

<sup>27</sup> See Alabama Public Health, *Controlled Substance List* (Jan. 20, 2021), available at <https://www.alabamapublichealth.gov/blog/assets/controlledsubstanceslist.pdf> (last visited Jan. 22, 2022).

<sup>28</sup> See Arkansas Department of Health, *List of Controlled Substances*, available at [http://securervercdn.net/166.62.109.105/e17.085.myftpupload.com/wp-content/uploads/2016/02/arkansas-controlled\\_substances\\_list.pdf](http://securervercdn.net/166.62.109.105/e17.085.myftpupload.com/wp-content/uploads/2016/02/arkansas-controlled_substances_list.pdf) (last visited Jan. 22, 2022).

<sup>29</sup> See IC 35-31.5-2-321.

<sup>30</sup> See Vt. Admin. Code 12-5-23:4.0.

<sup>31</sup> See W.S.A. 961.14.

<sup>32</sup> See [AZ Rev Stat § 36-795.02](#).

<sup>33</sup> See GA Code § 16-13-121.

<sup>34</sup> See [UT Code § 4-45-101](#).

<sup>35</sup> 21 U.S.C. 301.

<sup>36</sup> See 21 C.F.R. §§ 1-1299.

<sup>37</sup> 21 U.S.C. 342.

<sup>38</sup> CRS Report R43609, *Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues*, February 9, 2018, <https://www.everycrsreport.com/reports/R43609.html#fn96> (last visited Feb. 15, 2023).

<sup>39</sup> S. 20.14, F.S. DACS also regulates certain professions, unfair and deceptive business practices and provides consumer information.

<sup>40</sup> Florida Department of Agriculture and Consumer Services, *About Us*, [h <https://www.fdacs.gov/About-Us>](https://www.fdacs.gov/About-Us) (last visited Feb. 15, 2023).

The Division of Food Safety (division), under DACS, is responsible for assuring a safe, wholesome, and properly represented food supply in Florida. This is accomplished through the permitting and inspection of food establishments, inspection of food products, and through specialized laboratory analyses on a variety of food products sold or produced in the state. The division monitors food from the farm gate through processing and distribution to the retail point of purchase.<sup>41</sup>

The division is charged with administration and enforcement of food, poultry, and egg laws, and also provides support in the enforcement of other food safety laws. In addition to regulatory surveillance and enforcement, the division evaluates consumer complaints related to food.<sup>42</sup>

“Food” includes:<sup>43</sup>

- Articles used for food or drink for human consumption;
- Chewing gum;
- Articles used for components of any such article;
- Articles for which health claims are made, which claims are approved by the Secretary of the United States Department of Health and Human Services and which claims are made in accordance with s. 343(r) of the federal act, and which are not considered drugs solely because their labels or labeling contain health claims; and
- Certain dietary supplements.

“Food establishment” means a factory, food outlet, or other facility manufacturing, processing, packing, holding, or preparing food or selling food at wholesale or retail. A food permit is required of any person who operates a food establishment.<sup>44</sup>

“Retail food store” means any establishment or section of an establishment where food and food products are offered to the consumer and intended for off-premises consumption.<sup>45</sup>

A food permit from the department is required of any person who operates a food establishment or retail food store, except:<sup>46</sup>

- Persons operating minor food outlets that sell food that is commercially prepackaged, not potentially hazardous, and not time or temperature controlled for safety, if the shelf space for those items does not exceed 12 total linear feet and no other food is sold by the minor food outlet.
- Persons subject to continuous, onsite federal or state inspection.
- Persons selling only legumes in the shell, either parched, roasted, or boiled.
- Persons selling sugar cane or sorghum syrup that has been boiled and bottled on a premise located within the state.

The division or its duly authorized agent has free access at all reasonable hours to any food establishment to ensure food safety laws are followed. The inspectors:<sup>47</sup>

- secure a sample or a specimen of any food after paying or offering to pay for such sample,
- see that all sanitary rules are complied with,
- facilitate tracing of food products in the event of a food-borne illness outbreak or identification of an adulterated or misbranded food item, and
- enforce the special-occupancy provisions of the Florida Building Code which apply to food establishments.

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<sup>41</sup> Florida Department of Agriculture and Consumer Services, *Division of Food Safety*, <http://www.freshfromflorida.com/Divisions-Offices/Food-Safety> (last visited Feb. 15, 2023).

<sup>42</sup> *Id.*

<sup>43</sup> S. 500.003(1)(n), F.S.

<sup>44</sup> S. 500.03(1)(r), F.S.

<sup>45</sup> S. 500.03(1)(bb), F.S.

<sup>46</sup> S. 500.12(1)(a), F.S.

<sup>47</sup> S. 500.147, F.S.

If a food establishment or retail store violates the FFSA, the division may impose an administrative fine not more than \$5,000. The division may also revoke or suspend the permit of any such retail food store or food establishment if the retail food store or food establishment has:<sup>48</sup>

- Violated the FFSA.
- Violated or aided or abetted in the violation of any law of this state governing or applicable to retail food stores or food establishments or any lawful rules of DACS.
- Knowingly committed, or been a party to, any material fraud, misrepresentation, conspiracy, collusion, trick, scheme, or device whereby another person, lawfully relying upon the word, representation, or conduct of a retail food store or food establishment, acts to her or his injury or damage.
- Committed fraud or dishonest dealing.

DACS may determine that a food establishment requires immediate closure when the food establishment fails to comply with the FFSA and presents an imminent threat to the public health, safety, and welfare. DACS may accept inspection results from other state and local building officials and other regulatory agencies as justification for such action.<sup>49</sup>

Many FDA regulations have been adopted as rules of the division.<sup>50</sup>

### **Florida Food Safety Act**

The division is responsible for the administration and enforcement of the Florida Food Safety Act (FFSA).<sup>51</sup> The division regulates food products under the FFSA, which include articles used for food or drink for human consumption, as well as dietary supplements.<sup>52</sup>

The FFSA is designed to:

- Promote public welfare by protecting the consuming public from injury by product use and the purchasing public from injury by merchandizing deceit, flowing from intrastate commerce in food;
- Provide uniform legislation so far as practical with federal regulations; and
- Promote uniform administration and enforcement of federal and state food safety laws.<sup>53</sup>

#### *Adulterated and Misbranded Foods in Florida*

Under the FFSA, individuals may not sell food that is adulterated, adulterate food, or receive food in commerce that is adulterated or misbranded.<sup>54</sup> These prohibitions are similar to federal law.<sup>55</sup>

The following are examples when food is deemed adulterated:<sup>56</sup>

- Food that bears or contains any poisonous or deleterious substance which may render it injurious to health;
- Food that bears or contains any added poisonous or added deleterious substance; a food additive; or a color additive, which is unsafe;
- Food that is or bears or contains any food additive which is unsafe;
- Food whose container is composed, in whole or in part, of any poisonous or deleterious substance;
- Food where any substance has been substituted wholly or in part therefor;
- Food where damage or inferiority has been concealed in any manner; and

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<sup>48</sup> S. 500.121(1), F.S.

<sup>49</sup> S. 500.121(7), F.S.

<sup>50</sup> R. 5K-4.002, F.A.C.

<sup>51</sup> See ch. 500, F.S.

<sup>52</sup> See ch. 500, F.S.

<sup>53</sup> S. 500.02, F.S.

<sup>54</sup> S. 500.04, F.S.

<sup>55</sup> 21 U.S.C. 331.

<sup>56</sup> S. 500.10, F.S.

- A dietary supplement or its ingredients that present a significant risk of illness or injury due to certain labeling and ingredient requirements.

Misbranded food includes food offered for sale and its label or labeling does not comply with the requirements of 21 U.S.C. s. 343(r) pertaining to nutritional content claims and health claims. Labels for supplements may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.<sup>57</sup>

DACS may inspect food that may be adulterated or misbranded;<sup>58</sup> seize food that is adulterated or misbranded;<sup>59</sup> suspend permits of those who sell food that is adulterated or misbranded, adulterate or misbrand food, or receive food in commerce that is adulterated or misbranded;<sup>60</sup> and impose a fine for adulterated or misbranded food, not to exceed \$5,000<sup>61</sup> per violation.<sup>62</sup>

**Food that contains kratom currently falls within in the definition of “food”<sup>63</sup> in the FFSA, and is subject to all applicable permitting, labeling, sanitation, and other food safety requirements. There are no existing age limits related to the sale of these products.**

### Regulation of Similar Products

Hemp<sup>64</sup> is an agricultural commodity grown and used worldwide to produce a variety of industrial and commercial products, including human food and nutritional supplements.<sup>65</sup> After hemp was removed from Schedule I of the federal CSA, the state hemp program (program) within DACS to regulate the cultivation of hemp in Florida was created in 2019.<sup>66</sup>

Any person seeking to cultivate hemp must apply for a hemp cultivation license with DACS<sup>67</sup> and any establishment that manufactures, processes, packs, holds, prepares or sells hemp extract intended for human consumption is considered a hemp food establishment and must have a permit from the division to operate in Florida.<sup>68</sup>

Violations of the hemp laws and rules<sup>69</sup> may result in the imposition of stop-sale/stop-use orders, an administrative fine of up to \$5,000 per violation, permit suspension, permit revocation, or any combination thereof.<sup>70</sup> Hemp extract intended for human consumption distributed or sold in violation of hemp laws and rules are considered adulterated or misbranded.

Hemp extract products must be distributed or sold in a container that has certain batch and identifying information<sup>71</sup>

Hemp extract products that are intended for inhalation may not be sold to a person who is under 21 years of age.<sup>72</sup> There is no liability shield for retailers based on misrepresentations by a manufacturer.

<sup>57</sup> S. 500.11(1)(n), F.S.; 21 U.S.C. s. 343 (r)(6)(C).

<sup>58</sup> S. 500.147(1), F.S.

<sup>59</sup> S. 500.173, F.S.

<sup>60</sup> S. 500.12(4), F.S.

<sup>61</sup> S. 570.971(1)(b), F.S.

<sup>62</sup> S. 500.121, F.S.

<sup>63</sup> S. 500.03(1)(n), F.S.

<sup>64</sup> Hemp is defined as the plant *Cannabis sativa* L. and any part of that plant with a delta-9 tetrahydrocannabinol (THC) concentration that does not exceed 0.3 percent on a dry weight basis. 7 U.S.C. s. 5940 (2014); 7 U.S.C. s. 1639o (2018); *see also* s. 581.217, F.S.

<sup>65</sup> Congressional Research Service (CRS), *Hemp as an Agricultural Commodity*, CRS Report 7-5700 (June 22, 2018), available at <https://fas.org/sgp/crs/misc/RL32725.pdf> (last visited Feb. 15, 2023).

<sup>66</sup> Ch. 2019-132, L.O.F.; codified as s. 581.217, F.S.

<sup>67</sup> S. 581.217(5), F.S.

<sup>68</sup> Department of Agriculture and Consumer Services, *Hemp Food Establishment Permit Checklist*, <https://www.fdacs.gov/content/download/93802/file/hemp-food-establishment-permit-checklist.pdf> (last visited Feb. 15, 2023).

<sup>69</sup> *Id.*; R. 5K-4.034, F.A.C.

<sup>70</sup> R. 5K-4.034(9)(d)-(e), F.A.C.

<sup>71</sup> S. 581.217(7)(a)2., F.S.

<sup>72</sup> S. 581.217(7)(c), F.S.

## **Effect of the Bill**

The bill may be cited as the "Florida Kratom Consumer Protection Act."

The bill defines "kratom product" to mean a food product, food ingredient, dietary ingredient, dietary supplement, or beverage intended for human consumption which contains any part of the leaf of the plant *Mitragyna speciosa* or an extract, synthetic alkaloid, or synthetically derived compound of such plant and is manufactured as a powder, capsule, pill, beverage, or other edible form.

The bill provides that it is unlawful to sell, deliver, barter, furnish, or give, directly or indirectly, to any person who is under 21 years of age, any kratom product.

If any retail food store, food establishment, or cottage food operation sells kratom products to someone under 21, they are subject to an administrative fine of not more than \$100 for the first offense, not more than \$500 for the second offense, and not more than \$1,000 for the third or subsequent offense.

The bill provides DACS with rulemaking authority.

The bill provides an effective date of July 1, 2023.

### **B. SECTION DIRECTORY:**

**Section 1:** Creates s. 500.92, F.S.; providing age prohibitions for the sale of kratom products.

**Section 2:** Provides an effective date.

## **II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

### **A. FISCAL IMPACT ON STATE GOVERNMENT:**

#### **1. Revenues:**

There may be an increase in administrative fines collected by DACS, but the amount is indeterminate.

#### **2. Expenditures:**

Indeterminate. DACS will likely see an increase in regulatory actions and costs.

### **B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

#### **1. Revenues:**

None.

#### **2. Expenditures:**

Unknown. Law enforcement may receive complaints about local businesses selling kratom to underage buyers.

### **C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:**

Food establishments will need to cover any associated costs of complying with new age verification requirements, however such cost should be insignificant.

### **D. FISCAL COMMENTS:**



None.

### III. COMMENTS

#### A. CONSTITUTIONAL ISSUES:

##### 1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to require counties or municipalities to spend funds or take action requiring the expenditures of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

##### 2. Other:

None.

#### B. RULE-MAKING AUTHORITY:

The bill provides DACS with rulemaking authority to promulgate rules to enforce the bill.

#### C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

### IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On February 23, 2023, the Regulatory Reform and Economic Development Subcommittee adopted one amendment and reported the bill favorably as a committee substitute. The committee substitute:

- Prohibits sales of kratom products to individuals under 21 years of age.
- Clarifies enforcement authority to the Department of Agriculture and Consumer Services and applicability to certain food establishments.
- Removes the creation of specific new regulations from the bill in favor of uniformity such that kratom will be subject to existing regulations related to food products.

This analysis is drafted to the committee substitute as passed by the Regulatory Reform and Economic Development Subcommittee.