

### Fiscal Estimate - 2021 Session

Original     
  Updated     
  Corrected     
  Supplemental

|                                    |   |
|------------------------------------|---|
| <b>LRB Number</b> <b>21-3796/1</b> | <b>Introduction Number</b> <b>AB-0599</b> |
|------------------------------------|---|

**Description**  
 regulating kratom products, granting rule-making authority, and providing a penalty

**Fiscal Effect**

**State:**

|   |   |  |
|---|---|--|
| <input type="checkbox"/> No State Fiscal Effect           | <input type="checkbox"/> Increase Existing Revenues | <input checked="" type="checkbox"/> Increase Costs - May be possible to absorb within agency's budget<br><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No |
| <input checked="" type="checkbox"/> Indeterminate         | <input type="checkbox"/> Decrease Existing Revenues |  |
| <input type="checkbox"/> Increase Existing Appropriations |   | <input type="checkbox"/> Decrease Costs  |
| <input type="checkbox"/> Decrease Existing Appropriations |   |  |
| <input type="checkbox"/> Create New Appropriations        |   |  |

**Local:**

|  |  |  |
|--|--|--|
| <input type="checkbox"/> No Local Government Costs                     | 5. Types of Local Government Units Affected<br><input type="checkbox"/> Towns <input type="checkbox"/> Village <input type="checkbox"/> Cities<br><input type="checkbox"/> Counties <input type="checkbox"/> Others<br><input type="checkbox"/> School Districts <input type="checkbox"/> WTCS Districts |  |
| <input type="checkbox"/> Indeterminate                                 |  |  |
| 1. <input type="checkbox"/> Increase Costs                             | 3. <input type="checkbox"/> Increase Revenue   |  |
| <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory | <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory   |  |
| 2. <input type="checkbox"/> Decrease Costs                             | 4. <input type="checkbox"/> Decrease Revenue   |  |
| <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory | <input type="checkbox"/> Permissive <input type="checkbox"/> Mandatory   |  |

|  |                                       |
|--|---------------------------------------|
| <b>Fund Sources Affected</b>   | <b>Affected Ch. 20 Appropriations</b> |
| <input checked="" type="checkbox"/> GPR <input type="checkbox"/> FED <input checked="" type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEGS | 20.115 (1)(a); 20.115 (1)(gb)         |

|                                     |                             |             |
|-------------------------------------|-----------------------------|-------------|
| <b>Agency/Prepared By</b>           | <b>Authorized Signature</b> | <b>Date</b> |
| DATCP/ Caitlin Jeidy (608) 224-4696 | Jason Gherke (608) 224-4748 | 12/7/2021   |

## Fiscal Estimate Narratives

DATCP 12/7/2021

|   |           |                     |         |               |          |
|---|-----------|---------------------|---------|---------------|----------|
| LRB Number  | 21-3796/1 | Introduction Number | AB-0599 | Estimate Type | Original |
| <b>Description</b><br>regulating kratom products, granting rule-making authority, and providing a penalty |           |                     |         |               |          |

### Assumptions Used in Arriving at Fiscal Estimate

The proposed legislation increases costs to DATCP by an indeterminate amount well beyond what could be absorbed within the agency's budget. The legislation would require "from scratch" development of a regulatory program, including licensing, outreach, training, inspection, sampling, laboratory analysis, compliance, and enforcement components, distinct from any existing DATCP program.

The legislation essentially creates a new category of food processing plants, by requiring kratom products processors to register, and DATCP to approve, each kratom product intended for sale in Wisconsin. Of the 2000+ food processing plants licensed in Wisconsin, it is unknown how many would diversify into processing of kratom products. The Department does not have pre-existing capability or capacity to maintain a registry of kratom (or any other) products that are allowed to be sold in this state. A registry would need to be designed, developed and integrated in DATCP's current licensing software. This would be a significant task and involve developers from DATCP's Bureau of Information Technology Services, as well as the Division of Food and Recreational Safety's licensing and program units, plus inspection staff.

Along with creating a licensing and kratom product registry, DATCP would bear the costs of developing effective outreach materials for consumers and kratom products processors. DATCP would also have to develop internal procedures for program operation, including the training of inspectors. These activities would require indeterminate but significant resources.

The legislation requires DATCP to develop standards for testing a kratom product for safety, as well as standards for accurate labeling. Aside from the intrinsic hazard of excessive 7-hydroxymitragynine, and the broad category of synthetic versions of mitragynine, 7-hydroxymitragynine, or other compounds found in the *Mitragyna speciosa* plant, the legislation does not state which of the myriad of possible contaminants should be included in safety and labeling standards. These contaminants could include microbes such as *Salmonella* bacteria or toxin-producing molds, chemicals such as pesticide residues or heavy metals, or physical debris. Each hazard chosen as a safety standard would necessitate the development and validation of a laboratory method to be used by DATCP in surveillance and enforcement. Each laboratory method must be validated in a specified matrix, e.g. dried tea preparation, baked goods, gummies, in order to be suitably rigorous for being contested in legal proceedings. Given the range of kratom products that might be processed, the costs to DATCP of laboratory method development, validation, and routine use would be indeterminate and significant.

The proposed legislation authorizes DATCP to seize and destroy unregistered kratom products and requires DATCP to develop and impose monetary penalties for failure to register kratom products or process kratom products in a licensed food processing plant. Limited analogous provisions related to seizure, destruction, and imposition of monetary penalties by the Department exist in current DATCP programs. The department would incur indeterminate but significant costs developing these processes and training staff to carry them out.

Each of the aforementioned components must be guided by administrative rules that DATCP would first need to write, within the statutorily required 30-month window between Scope Statement approval and submission to the Legislature. Timely rule revision would require indeterminate but significant allocation of DATCP resources.

It should be noted that the development of a kratom products program by DATCP would be complicated by several legal incongruities in the existing legislative language. By including "food supplements" in the definition of "kratom product" and requiring a kratom processor to hold a food processing plant license, the legislation would create a situation in which a product not regulated by DATCP (dietary supplements are regulated by FDA, not DATCP) must be made in a facility licensed and inspected by DATCP.

The legislation also may consider whether further statutory changes are needed to permit foods containing kratom in intrastate commerce. Wis. Stat. § 97.02 defines a food as adulterated if it is adulterated within the

meaning of 21 USC 342, with an exemption for hemp. As with hemp, it may be necessary to exempt kratom from the definition of adulterated. In interstate commerce, the FDA may continue to consider foods containing Kratom to be adulterated. FDA states, "There are no FDA-approved uses for kratom, and the agency has received concerning reports about the safety of kratom. FDA is actively evaluating all available scientific information on this issue and continues to warn consumers not to use any products labeled as containing the botanical substance kratom or its psychoactive compounds, mitragynine and 7-hydroxymitragynine." Available: <https://www.fda.gov/news-events/public-health-focus/fda-and-kratom> (last accessed 12/02/2021).

The bill language does not account for the likelihood that retail food establishments such as coffee shops, candy stores or grocery stores would be at least as likely as food processing plants to "prepare, process, sell, or offer for sale" kratom products. The food safety regulatory system currently in place in Wisconsin allows for local retail food establishment inspection and licensing when food product processing is conducted primarily (greater than 75%) for sale directly to consumers from the point of production. Retail food establishments are licensed either by DATCP or one of DATCP's local health department agents (approximately 60 health departments in all major urban areas and nearly all densely populated counties). As written, the legislation would require retail food establishments to obtain an additional food processing plant license, regulated under a different chapter of the Wisconsin Administrative Code (ATCP 70 Wholesale Food Manufacturing, instead of ATCP 75 Retail Food Establishments) in order to process kratom products. Further, the Department would be forced to allocate staff time and resources to inspect a facility that would be better served by the local regulatory agency. Revisions of Wis. Stat. 97, and Wis. Admin. Code chs. 70 and 75 would also be necessary for alignment with the proposed legislation as written. The legislation as written may impose additional costs on DATCP, DATCP's agents, and regulated processors.

By defining kratom products to include products for animal consumption, the legislation intersects with commercial feed regulation. Wis. Stat. § 94.72 and Wis. Admin. Code ch. ATCP 42 cover commercial feed licensing, the ingredients used in the food, the labeling of the food, and the manufacture of the food, including the required Good Manufacturing Practices to follow in producing the food. Further, kratom products may not be used in pet (dog or cat) food or treats at this time. The safety and efficacy of kratom has not been reviewed for use in any animal feed. Reviews are handled through the Ingredient Definitions Committee through the Association of American Feed Control Officials and the FDA as food additive petitions. Available: <https://www.aafco.org/Regulatory/Committees/Ingredient-Definitions>; and <https://www.fda.gov/animalveterinary/developmentapprovalprocess/ucm056809.htm> (last accessed 12/02/2021). As written, commercial feed licensees may also be required to obtain a food processing plant license.

### **Long-Range Fiscal Implications**