Wisconsin Department of Administration
Division of Executive Budget and Finance

Fiscal Estimate - 2023 Session

☒ Original ☐ Updated ☐ Corrected ☐ Supplemental

LRB Number 23-3351/1	Introduction Number AB-0393

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

Fiscal Effect

State:

☐ No State Fiscal Effect
☒ Indeterminate
- ☐ Increase Existing Appropriations
- ☐ Decrease Existing Appropriations
- ☐ Create New Appropriations
- ☐ Increase Existing Revenues
- ☐ Decrease Existing Revenues
- ☒ Increase Costs - May be possible to absorb within agency's budget
  - ☐ Yes ☒ No
- ☐ Decrease Costs

Local:

☐ No Local Government Costs
☐ Indeterminate
1. ☐ Increase Costs ☐ Permissive ☐ Mandatory
2. ☐ Decrease Costs ☐ Permissive ☐ Mandatory
3. ☐ Increase Revenue ☐ Permissive ☐ Mandatory
4. ☐ Decrease Revenue ☐ Permissive ☐ Mandatory

5. Types of Local Government Units Affected
☐ Towns ☐ Village ☐ Cities
☐ Counties ☐ Others
☐ School Districts ☐ WTCS Districts

Fund Sources Affected
☒ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEGS

Affected Ch. 20 Appropriations
20.115 (1)(a); 20.115 (1)(gb)

Agency/Prepared By	Authorized Signature	Date
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Fiscal Estimate Narratives

DATCP 9/19/2023

LRB Number **23-3351/1**	Introduction Number **AB-0393**	Estimate Type **Original**
Description regulating kratom products, granting rule-making authority, and providing a penalty		

Assumptions Used in Arriving at Fiscal Estimate

The proposed legislation increases costs to the Department of Agriculture, Trade and Consumer Protection (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 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. DATCP 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 into DATCP's current licensing software. This would be a significant task and involve information technology developers and contractors 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 an indeterminate, but significant amount of 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 or 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 DATCP exist in current DATCP programs. DATCP 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) 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.

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. 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, DATCP would be forced to allocate staff time and resources to inspect a facility that is already overseen 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 regulate commercial feed licensing, the ingredients used in the feed, the labeling of the feed, and the manufacture of the feed, including the required Good Manufacturing Practices to follow in producing the feed. As written, commercial feed licensees may also be required to obtain a food processing plant license.

Currently, kratom is prohibited from use as a feed ingredient, including use in pet (dog or cat) food or treats. The safety, efficacy and risks of kratom have not been determined 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. Furthermore, the FDA determined that kratom is unsafe as a food additive, and cannot be marketed as a food additive, supplement or drug https://www.fda.gov/news-events/public-health-focus/fda-and-kratom.

The department does not currently register feed products. The creation of a kratom feed product registry will impose significant technical and staff resource demands.

Laboratory methods to analyze products for kratom and to determine safe levels for feed will have to be developed. Further complicating the safety analysis is the variety of potential impacts on the animals consuming kratom feed (e.g. dairy cattle, chickens, felines) and acceptable levels of kratom residues within animal products intended for human consumption (e.g. milk, meat, eggs).

Regulating kratom feed products poses similar challenges as described above for human food products (product registry, standards for testing, enforcement and intrastate commerce). There are no age restrictions for purchasing feed products. Significant outreach will be needed to implement this provision, especially to small retail establishments and individuals offering kratom pet treats for sale at farmers markets or similar venues.

Long-Range Fiscal Implications

Unknown.