

## **DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION NOTICE OF PROPOSED GUIDANCE DOCUMENTS**

Pursuant to section 227.112 of the Wisconsin Statutes, the Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP) is hereby accepting comments on the proposed guidance document:

### **Industrial Hemp Products as Human Food Ingredients**

#### **LOCATION OF PROPOSED GUIDANCE**

Proposed guidance document may be reviewed by accessing:

[https://datcp.wi.gov/Pages/About Us/GuidanceDocuments.aspx](https://datcp.wi.gov/Pages/About%20Us/GuidanceDocuments.aspx)

#### **SUBMITTING PUBLIC COMMENTS**

Public comments on proposed or adopted guidance document may be submitted by accessing:

[https://datcp.wi.gov/Pages/About Us/GuidanceDocuments.aspx](https://datcp.wi.gov/Pages/About%20Us/GuidanceDocuments.aspx)

#### **DEADLINE FOR SUBMISSION**

The comment period will run no fewer than 21 days after the publication of this document in the Administrative Register.

#### **AGENCY PUBLICATION**

The attached guidance document contains statements or interpretations of law under the following applicable provisions of federal law or the applicable state statutory or administrative code provisions: Wis. Stat. ch. 97, Wis. Admin. Code, chs. 22, 70 and 75.

#### **CERTIFICATION**

Pursuant to the authority delegated to me by the Secretary, I have reviewed the attached guidance document or proposed guidance document and I certify that it complies with sections 227 .10 and 227 .11 of the Wisconsin Statutes. I further certify that the guidance document or proposed guidance document contains no standard, requirement, or threshold that is not explicitly required or explicitly permitted by a statute or a rule that has been lawfully promulgated. I further certify that the guidance document or proposed guidance document contains no standard, requirement, or threshold that is more restrictive than a standard, requirement, or threshold contained in the Wisconsin Statutes.



Dr. Steve Ingham

Administrator

Division of Food and Recreational Safety



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## Guidance Document Title: Industrial Hemp Products as Human Food Ingredients

*This guidance document is based on Wis. Stat. § 97.10 Wis. Stat. and chapters ATCP 22, 70 and 75. This document is intended solely as guidance, and does not contain any mandatory requirements except where requirements found in statute or administrative rule are referenced. This guidance does not establish or affect legal rights or obligations, and is not finally determinative of any of the issues addressed.*

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### Overview of Industrial Hemp Program

Industrial Hemp is the plant *Cannabis sativa*, and contains many chemical compounds. Wisconsin statute defines industrial hemp based on the concentration of one particular compound, delta-9 THC. Wis. Admin. Code ch. ATCP 22 specifies that testing of industrial hemp must be in compliance with either Wis. Admin. Code ch. ATCP 22 or another state's industrial hemp pilot program under Section 7606 of the Agricultural Act of 2014. Under that Act, Industrial hemp must be certified to contain not more than 0.3% delta-9 THC on a dry weight basis. Cannabidiol (CBD) is another compound that is found in the flowers of Industrial Hemp. CBD is not believed to be psychoactive and Wisconsin statutes do not specify a maximum CBD level in Industrial Hemp or Industrial Hemp products. Note that CBD derived from the flowers of marijuana is not included in the hemp program and Wisconsin law does not authorize marijuana-derived CBD in the Industrial Hemp program. CBD is under investigation by the US Food and Drug Administration as a drug.

### Industrial Hemp as Food or Food Ingredients

Wis. Stat. § 97.10 prohibits the sale of any food that is adulterated. ATCP 70.08 (Food Processing Plants) requires that ingredients be "...safe, wholesome, and unadulterated..." and "obtained from sources which comply with applicable licensing and inspection requirements." The *Wisconsin Food Code*, which sets requirements in retail food establishments, states that food received by a retail food establishment shall "be obtained from sources that comply with law." ATCP 75 app. § 3-201.11 (A). In that context, "law" is defined as "applicable local, state, and federal statutes, administrative rules, regulations, and ordinances." ATCP 75 app. § 1-201.10.

For foods prepared in Wisconsin and sold only in Wisconsin, *i.e.* not in interstate commerce, food is not considered to be adulterated solely because it contains industrial hemp or an industrial hemp product as long as the underlying industrial hemp meets statutory requirements. Wis. Stat. § 97.02. Therefore, permitted food ingredients include industrial hemp products if all of the following four requirements are met:

- The industrial hemp source of the ingredient has obtained a "fit for commerce" certificate from DATCP or another state's industrial hemp pilot program.
- Processing of the ingredient or food containing industrial hemp is done in Wisconsin by a food processing plant or retail food establishment licensed pursuant to § 97.29 or § 97.30, respectively. Industrial hemp-containing food or food ingredients manufactured outside of Wisconsin cannot be used by Wisconsin food businesses because these ingredients are foods involved in interstate commerce.
- Any packaged foods containing the industrial hemp-derived ingredient are accurately labeled to indicate the presence of each industrial hemp-derived ingredient.
- Sales of the finished foods occur only in Wisconsin.

### Why Can't CBD be Sold Freely Across State Lines?

In addition to THC, industrial hemp also contains the chemical compound cannabidiol (CBD). The U.S. Food and Drug Administration (FDA) has begun investigating CBD as a drug. Any substance which is being investigated as a drug cannot be added to a food which enters interstate commerce. However the FDA has completed its evaluation and approved the use of three industrial hemp products for use as ingredients in human food—hulled hemp seed, hemp seed protein powder, and hemp seed oil—because industrial hemp seeds do not naturally contain THC or CBD. Food & Drug Admin., *FDA Regulation of Cannabis*

*and Cannabis-Derived Products: Questions and Answers*, <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers> (Apr. 2, 2019).

### **Industrial Hemp in Alcohol Beverages**

The Alcohol and Tobacco Tax and Trade Bureau of the U.S. Department of the Treasury, which approves alcohol beverage formulas, has issued an Industry Circular stating that “it will return for correction any applications for formulas containing ‘hemp’ ingredients (other than ingredients derived from hemp seeds or hemp seed oil). Alcohol and Tobacco Tax & Trade Bureau, U.S. Dept. Treasury, Industry Circular No. 2019-1, *Hemp Ingredients in Alcohol Beverage Formulas* (2019).

*Steve Ingham*

*6/12/2019*

Dr. Steve Ingham, Administrator, Division of Food and Recreational Safety

DATE June 12, 2019