PJRFSI Cannabis Safety Standard - Manufacturing

Perry Johnson Registrars Food Safety, Inc.

Headquarters – Troy, MI

- Family of 72 companies
- Global Offices in Europe, Asia, and the Americas
- Offering services in both Food Safety and Cannabis Safety.
- Cannabis Safety Standard accreditation in progress

1.
Importance of Food Safety in the Cannabis Industry

Why does it matter?

Why Cannabis Safety?

- Cannabis industry is like the “Wild West” – little regulation and a lack of clear direction
- A cannabis product manufacturing company may have cannabis expertise but haven’t accounted for food safety/product safety

Courtesy Wikimedia Commons

Producer Responsibility

- manufacture product safely
- Implement appropriate controls
- Whole company commitment

Regulatory Responsibility

LARA
LICENSING AND REGULATORY AFFAIRS
CUSTOMER DRIVEN. BUSINESS MINDED.

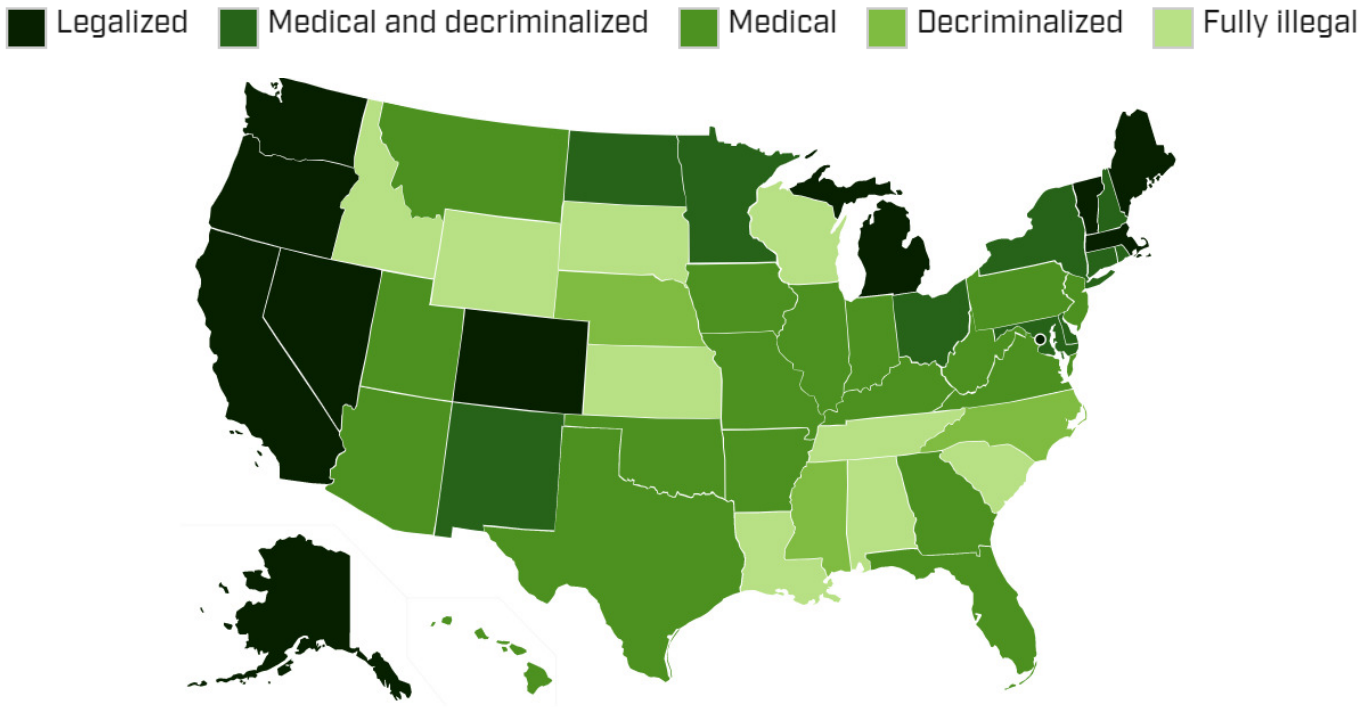
- Includes Federal, State and local agencies
- Setting food safety standards
- Conducting inspections
- Enforcement programs

COLORADO
Department of Revenue
Enforcement Division

HACCP INTERNATIONAL FOOD SAFETY PROGRAMMEN CERTIFICATION

BUREAU OF CANNABIS CONTROL
CALIFORNIA

Marijuana Legality by State



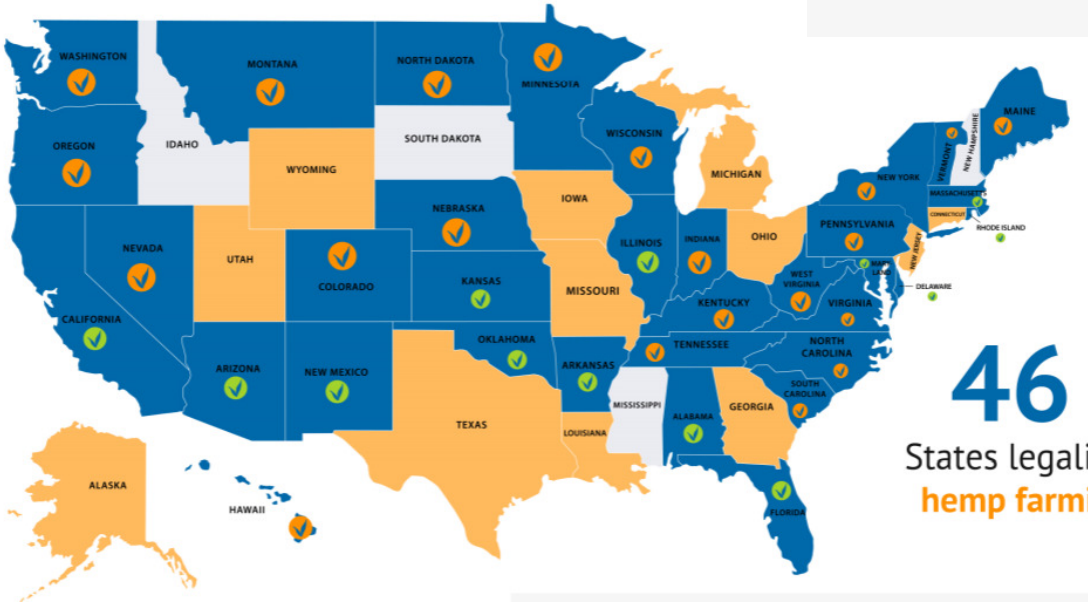
Courtesy of DISA Global Solutions https://disa.com/map-of-marijuana-legality-by-state

Hemp Legality by State

New states which started in 2019 (13 states)

States which grew hemp in 2018 (21 states)

States with enacted hemp legislation (46 states)



46
States legalized
hemp farming

https://www.votehemp.com/u-s-hemp-crop-report/

Cannabis Food Safety Regulation

- Not federally regulated by FDA or USDA
- Food safety standards are developed state by state
- Enforced through state divisions

Types of Regulation

Varies by State

- Colorado – Colorado Health Dept
- California and Oregon – 3 different agencies
- Florida – Dept of Health (Office of Medical Marijuana Use)
- Nevada – Dept of Taxation
- Michigan – LARA/BMR

Cannabis Food Safety

- High numbers of immunocompromised, young, elderly, or otherwise vulnerable persons are consumers of medical cannabis products.
- Inappropriate levels of CBD or THC may cause unintentional, unwanted effects.

Cannabis Recalls

- Cannabis and cannabis products can be recalled
  - Molds and yeasts
  - Pathogens
  - Pesticides
  - Heavy-metals

Raw Material Concerns

- Mycotoxins
  - Aflatoxins
  - Ochratoxins
- Pesticides
  - Approved vs. unapproved
  - Regulations
- Chemical Residues
- Contamination
  - Water
  - Pests
  - Humans

Food Safety-Related Concerns

- Food Allergens
  - Animal products
  - Nuts
  - Soy/wheat
- Bacterial contamination
  - *E. coli*
  - *Salmonella*

Cannabis Packaging

- Adherence to current Cannabis packaging requirements
- Types of packaging used
- Proper packaging storage
- Proper labeling
  - THC level of product
  - Name & address of production facility
  - Name of the infused product and ingredients by descending weight
  - Product cannot be a shape, color, package, or labeled to appeal tc minors age 17 and under
  - Child-resistant packaging

2.
Cannabis Certification

Audit Types and Steps to Certification

Third Party Certification

- Provides audits and certifications outside of regulatory requirements
- Based on a recognized set of food safety standards such as Good Manufacturing Practices or HACCP (Hazard Analysis and Critical Control Points)

Types of Food Safety Audits

- PJRFSI Cannabis Safety Standard
- GFSI benchmarked food safety audits
  - SQF allows audits for cannabis edibles within Canada only
  - BRC allows cannabis products as long as they are food products (no smokable or topical products)
  - FSSC and does not recognize Cannabis products in scope

Photo courtesy GFSI

Benefits of Certification

- Mitigate risks to public health and safety
- Promote your products with an added layer of confidence
- Increase consumer confidence
- Stay ahead of the competition when it comes to government requirements
- Reduce recalls and save money

Pending Letter
(sample)

Perry Johnson Registrars Food Safety, Inc.

Date
Site Address

Dear Name,

We at Perry Johnson Registrars Food Safety Inc. appreciate the opportunity to serve as your partner as you progress toward becoming a certified SQF Supplier. As detailed in your Certification Agreement, we will audit your Cannabis Safety System and your facility listed at the address above to the PJRFSI Safety Standard.

This letter confirms that you anticipate completing your Cannabis Safety certification with Perry Johnson Registrars Food Safety Inc. by the [target date].

Following the facility audit, you will have up to 30 days to close out any documented nonconformities. Provided you achieve the minimum compliance grade, we will register you as a Certified Cannabis Safety Operation within 45 days of your facility audit date. This timeline may be shortened if you are able to close out all non-conformities earlier than the due dates. After the certification decision has been made, you typically receive your official, signed certificate within two weeks.

Please feel free to contact me by email or at 1-800-800-7910 if you have any questions about the next phase of your certification process. We look forward to being of service to [company name].

Kind Regards,

Working with an accredited Certification Body

Shows commitment to employees, stakeholders, and potential customers

Steps to Certification

Contract with PJRFSI

PJRFSI provides a free quote for certification. PJRFSI can also provide a pending letter of certification
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Schedule Audit

Our team of schedulers will coordinate your audit with your assigned auditor.

Pre-Assessment

PJRFSI can conduct an optional pre-assessment audit prior to the certification audit to identify any gaps in your program

Conduct Audit

Your auditor will conduct the audit onsite at the facility. They will go through the requirements, review records, interview employees and review your documents for conformity.

Corrective Actions

Implement corrective actions within 30 days for any identified non-conformities

Certification

PJRFSI Issues a certificate. Certification is valid for 1 year.
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3.
PJRFSI Cannabis Safety Standard

PJRFSI Cannabis Safety Standard

- Applicable for Cannabis product manufacturers including hemp, CBD, and marijuana infused products
- Based off of the Federal Government's 21 CFR 117 Subpart B Good Manufacturing Practice
- State-specific requirements

How to be Audit Ready

- Pre-assessment
- Review and implement Requirements
- Train Employees
- Internal Audit
- Implement Corrective Actions

Excerpt from the Standard

- Part 1 - 21 CFR Part 114 GMP

1.0 Personnel (117.10) .....

2.0 Plant and Grounds (117.20) .....

3.0 Sanitary Operations (117.35) .....

4.0 Sanitary facilities and controls (117.37) .....

5.0 Equipment and Utensils (117.40) .....

6.0 Processes and controls (117.80) .....

7.0 Warehousing and Distribution (117.93) .....

8.0 Defect Action Level (117.110) .....

US State Cannabis Regulations .....

- Part 2 – State Requirements

Excerpts from the Standard - Part 1

- 1.0 Personnel
- 2.0 Plants and Grounds
- 3.0 Sanitary Operations

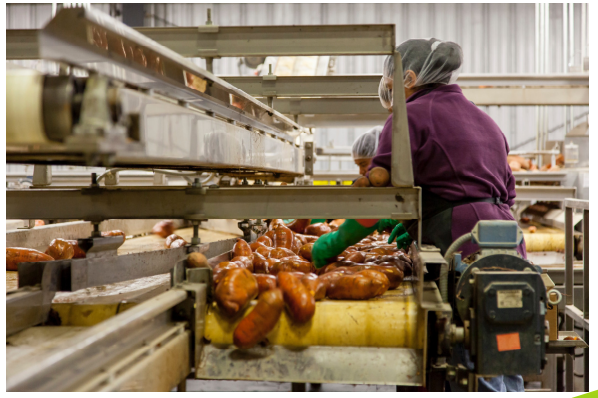
Excerpts from the Standard – Part 1

1.2 Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include:

- Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food contact surfaces, or food-packaging materials.
- Maintaining adequate personal cleanliness.
- Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate handwashing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
- Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.
- Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.
- Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.
- Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

Excerpts from the Standard – Part 1

- 4.0 Sanitary facilities and controls
- 5.0 Equipment and Utensils
- 6.0 Processes and controls



Excerpts from the Standard – Part 1

5.0 Equipment and Utensils (117.40)

5.1 All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.

- Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.
- Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.
- Food-contact surfaces must be corrosion-resistant when in contact with food.
- Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.
- Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.

Excerpts from the Standard – Part 1

- 7.0 Warehousing and Distribution
- 8.0 Defect Action Level

Excerpts from the Standard – Part 1

7.0 Warehousing and Distribution (117.93)

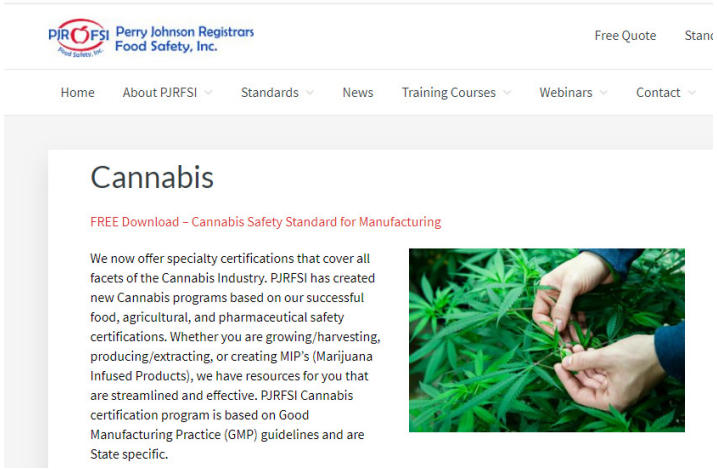
7.1 Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

Excerpts from the Standard Part 2

- State Specific Cannabis Rules

Download the Standard

- We are offering a free download of the standard from our website



- http://www.pjrfsi.com/cannabis-safety-standard-for-manufacturing/.

Webinar Series

- PJRFSI Cannabis Safety Standard – Growers Sched
  Jan 10, 2020 at 2:00pm EST
- PJRFSI Cannabis Safety Standard – Retail
  TBA 2020
- For more info you can email customerservice@pjrfsi.com

Thank you!

Any questions?

Perry Johnson Registrars Food Safety, Inc.

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www.PJRFSI.com