FDA U.S. FOOD & DRUG ADMINISTRATION

FDA & TTB Roles in Regulating Alcoholic Beverages

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Applicable Statutes

- Federal Food Drug and Cosmetic Act (FD&C Act)
  - Alcoholic beverages are “Food” per the Act

- FD&C Act requires “food” to be:
  - Safe
  - Handled at all times in sanitary manner as food
  - Contain only safe approved additives
  - Be truthfully and informatively labeled

Applicable Statutes

- Fair Packaging and Labeling Act (FPLA)
  - Applies to consumer commodities including foods
  - Mandates certain labeling requirements
  - Does **not** apply to products covered by the FAA Act (wine, malt beverages, distilled spirits)

- Alcoholic Beverage Labeling Act (ABLA)
  - Requires a specific Health Warning Statement
  - Must appear on all alcoholic beverages containing .5% alcohol by volume and above

Applicable Statutes

- Internal Revenue Code (IRC)
  - Contains excise tax provisions relating to alcohol
  - Gives TTB the authority to oversee the qualification and operation of distilleries, wineries, breweries and industrial alcohol producers and users
  - Assigns some labeling, packaging, bottling and storage requirements

Applicable Statutes

- Federal Alcohol Administration Act (FAA Act)
  - Defines wine, distilled spirits & malt beverages
  - Mandates a federal permit system
  - Specifies labeling requirements for these alcoholic beverages
  - Regulates the marketing and promotional practices concerning the sale of alcoholic beverages

TTB Jurisdiction

- Requires a permit for all producers of alcoholic beverages (other than breweries), importers, and wholesalers.

- TTB responds to and investigates domestic and international consumer complaints about U.S. alcoholic beverage products.

TTB Oversight

- TTB protects the consumer by ensuring the integrity of alcoholic beverage products; prevents unfair and unlawful market activity
- TTB Labs test products for contaminants, adulterants, prohibited ingredients, pesticides, heavy metals, natural toxins, etc.
- Product samples are collected under various TTB programs

FDA Jurisdiction

- FDA regulates everything else:
  - Safety for all alcoholic beverages including:
    - Inspection of facilities, operations and sanitation during processing (GMPs)
    - Assessment of safety for novel processes (synthetic ETOH)
    - Safety of food additives or GRAS substances used in alcoholic beverages
    - Evaluating the risk of any contaminants found to be in alcoholic beverages
    - Enforcement of pesticide residue limitations established by EPA
  - Labeling of non-FAA Act alcoholic beverages

How do FDA and TTB interact?

- Memorandum of Understanding (MOU)
  - Created in 1987
  - Clarifies respective responsibilities of the two agencies
  - Provides a communication & consultation process
  - Both Agencies retain their respective authorities
  - http://www.ttb.gov/main_pages/memo-understanding.shtml

    OR

  - http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116370.htm

How do FDA and TTB interact?

- Under the MOU, TTB, is the agency with the pervasive system of controls:
  - Performs testing of alcoholic beverages
  - Does most of the enforcement
  - Monitors recalls
    - TTB consults with FDA before issuing press releases regarding a health hazard associated with an alcoholic beverage
    - TTB and FDA share testing data and analyses with regards to the product in question

Alcoholic beverages

- An alcoholic beverage is a “food” per 21 CFR 1.227, which states in part, “Examples of food include: ...beverages (including alcoholic beverages and bottled water)”.

- A facility such as a cidery that manufactures alcoholic beverages would have to register with FDA as a food facility (see 21 CFR Part 1, subpart H), unless it satisfies any of the criteria for entities that are not required to register (see 21 CFR 1.226).

Food Facility Registration

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-facility-registration-seventh-edition

FSMA and CGMP & PC rule

(21 CFR part 117)

- Subpart A – General Provisions
- Subpart B – Current Good Manufacturing Practice (CGMP)
- Subpart C – Hazard Analysis & Risk-based Preventive Controls
- Subpart D – Modified Requirements
- Subpart E – Withdrawal of a Qualified Facility Exemption
- Subpart F – Requirements Applying to Records that Must be Established and Maintained
- Subpart G – Supply-chain Program

CGMP & PC rule

(21 CFR part 117)

- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule (aka CGMP & PC rule)

- Modernizes longstanding current good manufacturing practice (CGMP) requirements

- Importantly - establishes new requirements for hazard analysis and risk-based preventive controls.

CGMPs

CGMPS in 21 CFR part 117, Subpart B

- Applicable to all food processors, including alcoholic beverage producers
- Are the foundation for safe and sanitary operations
- Failure to comply with CGMPS may render your products adulterated under Section 402(a)(4) of the FD&C Act

Alcoholic beverages

- The CGMP & PC rule contains a **partial** exemption for certain food and alcohol at certain alcohol-related facilities (21 CFR 117.5(i)).

- Two conditions must be met for alcoholic beverages at a facility to be exempt from Subparts C and G of the rule (21 CFR 117.5(i)(1)):

  - "the facility is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury" or "is a foreign facility of a type that would require such a permit, registration, or approval if it were a domestic facility; and"

  - Under the FD&C Act "is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages"

Alcoholic beverages

- Note that the exemption is ***not*** from all subparts of the rule (21 CFR part 117). The following apply to alcoholic beverage facilities, such as wineries :
    - CGMP requirements - Subpart B
    - CGMP-related training requirements - Subpart A
    - CGMP-related records requirements of Subpart F
- Overall: An alcoholic beverage facility, such as a cidery, must ensure that its alcoholic beverage products are **not adulterated** under section 402 of the FD&C Act or **misbranded** under section 403 of the FD&C Act.

Updates to CGMP requirements

- The CGMP requirements in 21 CFR part 117 (mostly in subpart B) generally align with the previous requirements of 21 CFR part 110

- 21 CFR 117 Subpart B addresses allergen cross-contact explicitly in the regulatory text.

- 21 CFR 117 Subpart A mandates training (associated record requirements are in Subpart F).

Common Questions

Q: Can apple drops (i.e., windfalls) be used for hard cider?

A: Yes, there is no explicit restriction from using drops for fermentation. Fermentation breaks down patulin, a chemical hazard that can be increased when using drops for non-alcoholic cider/juice. However, the apples must still be safe and suitable for food use. Apples can be damaged when they drop and are more susceptible to molds and rot.

Common Questions (cont.)

Q: Do production employees at alcoholic beverage facilities need to wear hair/beard nets?

Q: Are separate handwashing sinks required in production areas? Are employees required to use them if they already wash hands in bathroom?

Q: What are requirements for illness reporting?

§ 117.10 Personnel.

The management of the establishment must take reasonable measures and precautions to ensure the following:

(a) ***Disease control.*** Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (*e.g.,* by an impermeable cover). Personnel must be instructed to report such health conditions to their supervisors.

(b) ***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:

(1) 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.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing 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.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or

Common Questions (cont.)

Q: Can unfermented juice be used to sweeten or back blend hard cider?

A: Juice added after fermentation, or that is not otherwise fully fermented, is subject to the juice HACCP regulations. The facility can purchase juice that has already been commercially produced and add it to hard cider after fermentation, and they would not be a juice processor subject to HACCP. If the operation produces the juice themselves, the juice is subject to juice HACCP

21 CFR part 120

Common Questions (cont.)

- ***Is juice used in alcoholic beverages (e.g., wines, alcoholic cider) covered under the regulation?***

It depends. The regulation applies to any unfermented juice that is added to an alcoholic beverage (e.g., wine or cider) as an ingredient to adjust flavor or sweetness and retains and expresses its organoleptic (e.g., color, taste) and nutritional characteristics in the finished beverage (§120.1(a)). The regulation does not apply to juice used solely as a starting material for a fermented alcoholic product that is fermented such that the organoleptic and nutritional characteristics associated with the juice are modified to the extent that the original juice becomes an alcoholic beverage and is no longer recognizable as juice at the time processing is complete (comment #5, 58 FR 2897 at 2899; §101.3(k)).

Common Questions (cont.)

- FDA's 2001 Juice HACCP Regulations, Questions and Answers

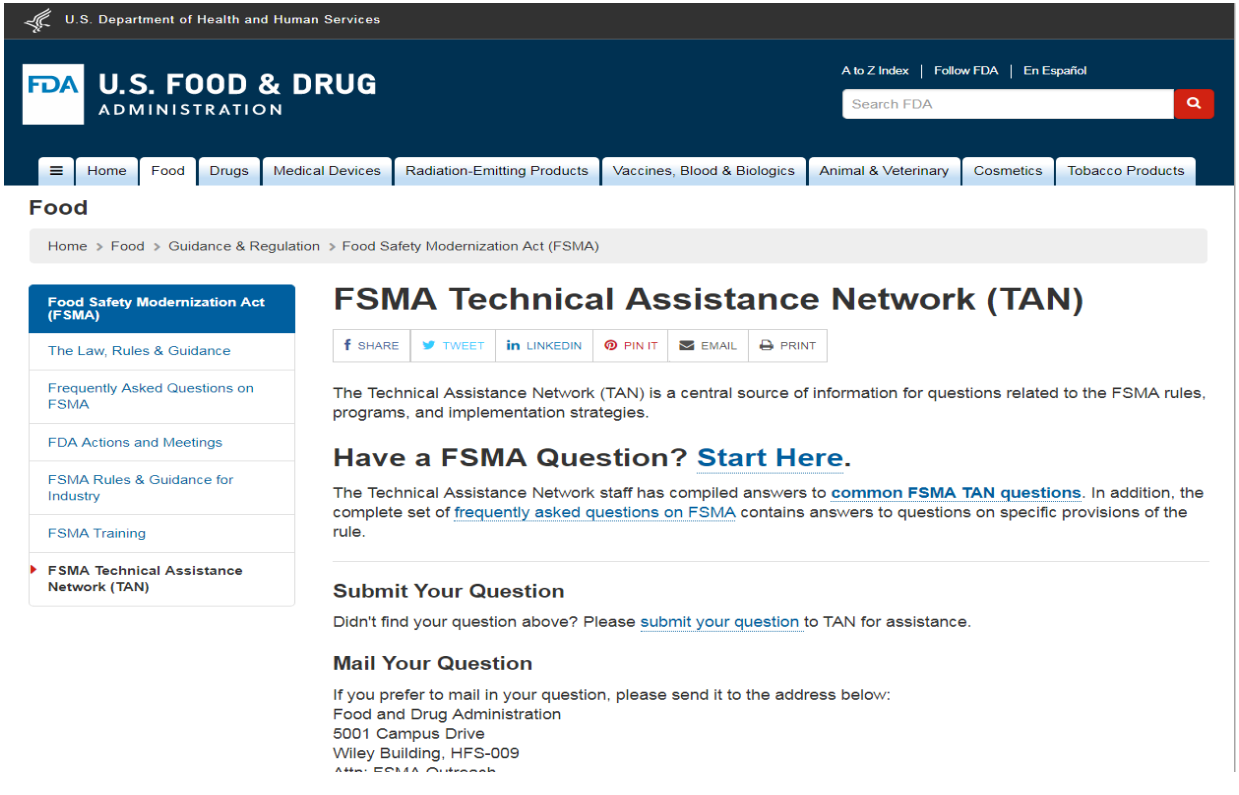
- FDA's 2003 Juice HACCP Regulations, Questions and Answers

FSMA Technical Assistance Networks

FDA Technical Assistance Network (TAN), access the following link – https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm

FSMA Technical Assistance Network (TAN) Inquiries Report

https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm498163.htm



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Summary

- The U.S. has several agencies that regulate alcohol beverages to ensure their conformity with U.S. laws and regulations:
  - TTB, part of the U.S. Department of the Treasury
  - FDA, part of the U.S. Department of Health and Human Services.
  - Other federal, State and local agencies also play a role.

The combined efforts of TTB, FDA and other agencies provide a thorough and effective regulatory control over alcohol beverages in the U.S.

The U.S. Government's approach is to build safety into the alcoholic beverage products through a multifaceted approach, including permitting, formulation/labeling approvals, CGMPs & inspections.

Questions?