www.USHempAuthority.org
info@ushempauthority.org

250 W. Main St., #2800
Lexington, KY 40507

U.S. HEMP AUTHORITY®

TECHNICAL COMMITTEE (TC) MEETING MINUTES

July 30, 2021

Attendance Record:

Name	Company	Stakeholder Group Category	Present
Technical Committee Members			
Ron Conyea	Conyea Farms	Grower	No
Wendy Mosher	New West Genetics		No
Scott Propheter	Pyxus,		No
Blake Ebersole	NaturePro Scientific	Processor/Manufacturer	Yes
Brett Goldman	Ocan Group		Yes
Melody Harwood	Neptune Wellness Solutions		No
Kasey Irwin	Bluebird Botanicals		No
Pamela Baxter	Jushi Holdings	Brand Owner	Yes
Sarah Oxendale	Sarah Oxendale Consulting, LLC		No
John MacKay	Syergistic Technology Assoc.	Science/Research	Yes
Grace Bandong	Eurofins Food Integrity & Innovation	Laboratory/Analytical Expert	No
Andrew Pham	Alkemist Labs		Yes
David Goodheim	Veles Labs	Certification Inspector/Food Safety Expert	Yes
Tim Lombardo	EAS Consulting Group		No
John Morrison	Emergence Farm to Food		Yes
Neda Moss	Alkemist Labs	Legal/Regulatory Expert	Yes
Joy Beckerman	Hemp Ace	Trade/Consumer Advocacy Organization	No
Holly Johnson	American Herbal Products Association		No
Megan Olsen	Council for Responsible Nutrition		Yes
Support Staff			
Marielle Weintraub	U.S. Hemp Authority	USHA Board Member, Ex-officio, non-voting	Yes
Kyle Truesdell			No
Annie Rouse			No
Brooke Parker Robertson		USHA Secretariat, non-voting	No
Katelyn Wiard			Yes
John Atwater	FoodChainID, Certification Service Provider	Ex-officio, non-voting	Yes
Marcia Moll		Observer, non-voting	Yes
Nate Ensrud			Yes
Elizabeth (Beth) Seibert			No

1. Discussion on Potential Revisions or Clarifications to the U.S. Hemp Authority Certification Program Standard

There was only one agenda item or topic for the Technical Committee (TC) meeting, and that was to discuss potential revisions or clarifications to the U.S. Hemp Authority (USHA) Certification Program Standard.

Nate Ensrud and Beth Seibert prepared a PowerPoint presentation (see Attachment 1) describing FoodChainID's (FCID's) perspectives and experiences operating the certification program. The presentation was distributed to TC members in advance of the meeting, and TC members were requested to review the presentation and provide their input on the topic..

Nate Ensrud led the discussion for the meeting indicating that the purpose of the meeting was to have an open discussion regarding the information in the presentation and input received from some TC members in advance of the meeting. Nate indicated that the presentation included topics that FCID wanted to highlight and a proposal to clarify the process that FCID takes to certify program participants. Hopefully, only minor corrections would need to be made to the standard to avoid creating any additional confusion or frustration amongst current program participants. FCID has had sufficient experience running the program to understand the myriad situations that arise which formed the basis of the information in FCID's PowerPoint presentation. During the discussion, Nate indicated that during the discussion they would capture comments and try to drive towards consensus regarding revisions or clarifications that need to be made to the USHA certification program standard. FCID would then put together an updated and complete proposal for how the USHA certification process would operate and what revisions would need to be made to the standard. Any changes to the process or standard would need to be reviewed and approved by the TC members before submitting it to the USHA board for review and approval.

FCID's presentation was focused on processors/manufacturers and brand owners, and not growers, since the latter two groups are ones that have had more interest and participation in the USHA certification program. There is often overlap between processors/manufacturers and brand owners (and in some cases they are same entity) and one goal would be to create a clear separation between certification program requirements/expectations for the two to make sure the USHA certification program is valuable for both parties and to make the certification process more streamlined. Although FCID's presentation was focused primarily on dietary supplement hemp products since these are the most common types of products undergoing USHA certification, Nate indicated the importance of all manufacturers needing to operate from an applicable GMP (as required by applicable regulations) as a baseline for participation in the USHA certification program which ultimately makes the USHA certification program more efficient.

John Atwater interjected that today's discussion would not be focused on the glossary of terms since that will be addressed by the TC member subgroup that will be reviewing the American Herbal Product Association's (AHPA's) hemp lexicon and submitting its report to the rest of the group at a later date. However, John indicated that one term that should be clarified was the term "processor," and that he preferred using just the term "manufacturer" or "packager." Ultimately, it was determined that a "processor" was an "ingredient manufacturer," and that the term "processor" could be dropped and clarification added to the certification program standard to differentiate between an ingredient manufacture that needs to follow 21 CFR 117, and a finished product manufacturer, such as a dietary supplement manufacturer that needs to follow 21 CR 111.

Additional topics discussed that are included in the FCID presentation are what types of items cannot be certified and accurate definitions for all of the items, such as synthetic cannabinoids. Marielle made the point that we should continue to emphasize that we will not certify products for the intoxicating effect such as products containing delta-8, delta-10 THC, and others that are much worse. Blake raised the question of whether a company manufacturing, for example, a delta-8 product, could still get certified for products that are suitable for USHA certification; the answer was, yes, with the caveat that the manufacturer would have to have a validated cleaning procedures and acceptable analytical testing procedures with acceptable list of target analytes and detection limits to ensure the prevention of cross-contamination, all of which would need to be audited by FCID. It was also noted that as part of the USHA certification program standard compliance to all local, state and federal regulations is a requirement that would need to be met in all cases. Nate

indicated that auditing compliance to all applicable regulations is not part of a typical FCID USHA audit, nor would it be feasible to do so in the short amount of time allotted for an audit, and that this matter is only addressed by FCID if they happen to identify non-compliance to applicable regulations during the course of an audit.

The next topic of discussion concerned the requirement to use of ISO 17025 accredited laboratories and whether or not other appropriate laboratory qualification procedures would be acceptable if a certification program participant were not using an ISO 17025 accredited laboratory. Pam Baxter indicated that ISO 17025 accreditation is not necessarily a full-proof way of qualifying a laboratory, but it does serves as a good baseline that a laboratory has been audited and has learned important aspects of operating a laboratory in the process of getting accredited, and that it should be a minimum requirement. It was highlighted that fit-for purpose testing was important not only for testing cannabinoids but also contaminants such as pesticides and elemental impurities (aka heavy metals). Nate mentioned that if the laboratory does not have ISO 17025 accreditation or some type of 3rd-party audit that demonstrates the laboratory is using fit-for-purpose test procedures, that could be a barrier to certification, causing delays and much effort for both FCID and certification program participants due to the difficulty of obtaining the necessary information from laboratories. If FCID needed to conduct an independent audit of the laboratory and ensure that it is using a validated test procedure, that would add to the cost of participating in the program. It was determined that ISO 17025 accreditation for cannabinoid testing was important (and is required in most states), and that for other tests, ISO 17025 accreditation or some evidence of an independent 3rd-party audit of the laboratory by a reputable auditing body would be sufficient. The possibility of USHA conducting laboratory certification at a lower cost was mentioned as a potential solution and opportunity.

Next, the timelines for certification and renewals was discussed. The goal was to communicate clear expectations to program participants regarding the time needed for each step of the certification process and the type of information needs to be submitted for review to avoid the current situation in which FCID receives incomplete information from program participants in a piecemeal fashion. The timeline for starting certification would begin once the program participant submits all the required information.

As an example of more clarifying information to be included in the standard, evidence for GMP compliance could be demonstrated by providing a copy of a GMP certificate from a reputable 3rd party auditing body, along with a copy of the audit report and evidence of acceptable corrective action taken for any nonconformities identified during the audit. If such documentation cannot be provided, FCID would need to conduct a GMP audit, separate from the USHA certification process. Applicable GMP compliance would be a minimum requirement for participation in the USHA certification program. Nate indicated that FCID was recommending dropping the 1-day USHA audit in lieu of acceptable evidence of GMP compliance and that FCID would conduct USHA-focused on-site audits (1) when the company to be audited does not want to release information to FCID electronically and would prefer FCID to review the documentation on-site, or (2) when FCID staff uncover matters of concern during review of product documentation that warrants an on-site audit.

The concern was raised that some brand owners might have a contract manufacturer that does not want to release information for review, namely product formula information. Nate indicated that if we can get a copy of the hemp/CBD ingredient and finished-product specifications, test results, review their supplier qualification program for hemp/CBD ingredients, and a redacted copy of the product formula. Marcia Moll indicated that FCID has strengthen their Non-Disclosure Agreement (NDA) to help better protect contract manufacturers. Marielle emphasized the need to provide this clarifying information in the standard, but that there needed to be a way to address a situation in which a contract-manufacturer is using another contract-manufacturer. It was suggested that it would be helpful to talk to the some of the contract manufacturers that are reluctant to release information to better understand their concerns to help address the problem.

Nate highlighted the importance of making sure FCID knows all about the manufacturers and packager/labelers involved in manufacture a hemp/CBD product to be certified and that FCID has revised the application to help with that effort.

Nate indicated that the FCID presentation provide a list of items that FCID considered to be important for processors and brand owners. Marielle indicated that in some cases, program participants are still learning about GMP expectations and may not know enough to provide adequate information for a particular requirement such as sampling and testing plans or specifications, and that it would help if FCID could provide guidance. Nate indicated that training and certification need to be separate activities, but that FCID does have training division that can help with that request. Marcia Moll mentioned the SIDI (Standardized Information on Dietary Ingredients) protocol that provides good guidance on specifications and emailed a link below to the information to the TC members after the meeting.
(https://sidiworkgroup.wildapricot.org/resources/Documents/DRAFTComponentSupplierQualificationGuideline_SIDIWorkGroup_April2012.pdf)

The last topic of discussion concerned testing of ingredients and finished products. It was mentioned that some testing can be done at the ingredient stage that may not need to be performed at the finished product stage so long as it was found at acceptable levels and the manufacturing process cannot introduce that contaminant into the product. It was mentioned that the testing that needs to be performed needs to be based on several factors such as product type, product intended use, and potential contaminants (e.g., mycotoxins) and that all these factors need to be taken into account and the required testing needs to be specified on the ingredient or finished product specification. It was also mentioned that some states have specific requirements for testing for a particular contaminant (e.g., mycotoxins) that need to be met regardless of product type, and that testing for any particular parameter should not be considered optional but should be determined based on a myriad of factors.

ACTION ITEM 1: FCID staff will take back all of the comments provided before and during the meeting and prepare a revised version of the information in the presentation to send to TC member for further discussion at the next TC meeting.
Due date: ASAP, and several weeks before the next TC meeting.

ACTION ITEM 2: TC members to provide written comments regarding revisions and clarification needed in the standard for further consideration and discussion and to contact FCID staff directly with any questions or concerns as needed.
Due date = As needed and several weeks before the next TC meeting.

2. Next Meeting

The AHPA lexicon discussion subgroup will meet prior to the next TC meeting and will submit its findings to the TC members prior to the next TC meeting. The next TC meeting is expected to be in September.

ACTION ITEM 3: Brooke to set up a doodle poll for the next quarterly TC meeting to discuss clarification and revisions to the USHA certification program standard.
Due date = ASAP.

Attachment 1: FoodChainID PowerPoint presentation entitled, "US Hemp Authority Technical Refresh: Providing Clarity and Alignment (July 2021).

US Hemp Authority Technical Refresh: Providing Clarity and Alignment

July 2021

FOODCHAIN ID®
Seeing Food Clearly

Overview

- The majority of interested participants are Processors or Brand Owners
- Brand Owners derive the most value from the ultimate use of the Certification on the product label
- Processors are most responsible for ensuring a quality product is delivered to consumers
- Clearly communicating the requirements at each step in the manufacturing process will help companies get certified quicker
- The overarching principle is ensuring a GMP baseline is in place, then focusing on hemp/CBD components of a good GMP program more closely

General Items

- Update definitions and eliminate use of related terms (ie, processor, manufacturer, operator, co-packer, co-manufacturer, supplier).
- Include more comprehensive list of items that can't be certified. Suggested:

a. Synthetic Cannabinoids
b. Biosynthetic Cannabinoids
c. Bioengineered Hemp
d. Delta 8
e. Smokable or Vaping products
f. Animal feed
g. Single-source nutritional products
h. Pet products containing a nutrition facts panel

- Align on inspection requirements and clarify throughout
- Update all lab references to require ISO17025 and remove lab qualification
- Specify timelines for certification and renewal

Processors AND Brand Owners: Manufacturing Baseline

- ALL manufacturers making any supplement product for USHA certification must:
  - Have a GMP certificate from an appropriate 3rd party certifier (latest audit report will be reviewed);
  - If not, FCID will conduct a full GMP audit
  - For Processors of food products, a GFSI audit is appropriate
  - For Processors of cosmetics, a GMP audit is appropriate
- If a Brand Owner is using an USHA-certified processor, then only the items on the Brand Owner list will be reviewed during product certification
- If a Brand Owner is using any non-USHA-certified processors, then the items on the Processor list will also be requested
- Both Processors and Brand Owners should have a co-manufacturer approval process (if they're using co-mans)
- Brand Owners must clearly identify who is manufacturing/packaging each product submitted for certification

FOODCHAIN ID®
Seeing Food Clearly

Processors – Core Items Reviewed

- Ingredient Supplier Approval Program
- Ingredient Specifications for hemp and CBD ingredients
- Testing program for incoming hemp and CBD raw materials and finished products
- ***Date/Lot Code process (reviewed for both Processor and Brand Owner)***
- ***Contract Manufacturer Approval Program (reviewed for both Processor and Brand Owner)***
- ***Finished Product Specifications (reviewed for both Processor and Brand Owner)***

Items that may have been requested previously that won't be reviewed:

Labels and marketing materials (requirement for Brand Owners); Lab qualification program (ISO17025 as baseline)

FOODCHAIN ID®
Seeing Food Clearly

Processors: Ingredient Supplier Approval Program

- How you choose a supplier;
- Ongoing review/annual requalification of supplier;
- How you ensure information is accurate, i.e., conduct onsite inspections, request inspection reports;
- Review of sampling and testing plans;
- Documents requested to ensure supplier/ingredient meets safety, food and other requirements;
- Rating supplier performance;
- Ensuring purchase from approved suppliers only;
- Ensuring exclusion of prohibited materials (synthetic, mimetic, bioengineered cannabinoids);
- Maintaining an Approved Supplier list and process for removal.

FOODCHAIN ID®
Seeing Food Clearly

Processors: Ingredient Specifications

- Written specifications for all ingredients (we will review hemp and hemp-derived only)
- Testing of incoming hemp and CBD raw materials
  - Heavy metals
  - Pesticides
  - Residual solvents for extracts
  - THC
  - CBD (optional)
  - Microbial (optional)
- Documented release of raw materials based on specifications

FOODCHAIN ID®
Seeing Food Clearly

Processors AND Brand Owners: Finished Product Specifications

- Written specifications for all products
  - Includes formula, manufacturing requirements, etc.
  - This is the key communication between manufacturer and brand owner on product requirements
- Finished product testing (can be done by processor or brand owner; testing must be done by an ISO17025 accredited lab and if testing is done in manufacturer's in-house lab, brand owner must have verification program)
  - CBD
  - THC
  - Microbial
  - Heavy metals (optional)
  - Pesticides (optional)
- Documented release of finished products based on specifications

FOODCHAIN ID®
Seeing Food Clearly

Brand Owners – Core Items Reviewed

- ***Date/Lot Code process (reviewed for both Processor and Brand Owner)***
- ***Contract Manufacturer Approval Program (reviewed for both Processor and Brand Owner)***
- ***Finished Product Specifications (reviewed for both Processor and Brand Owner)***
- Labels and Marketing materials including website
- Finished product test results

FOODCHAIN ID®
Seeing Food Clearly