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U.S. HEMP AUTHORITY®

TECHNICAL COMMITTEE (TC) MEETING MINUTES

September 10, 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,		Yes
Blake Ebersole	NaturePro Scientific	Processor/Manufacturer	Yes
Brett Goldman	Ocan Group		No
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	No
Tim Lombardo	EAS Consulting Group		Yes
John Morrison	Emergence Farm to Food		Yes
Neda Moss	Alkemist Labs	Legal/Regulatory Expert	Yes
Joy Beckerman	Hemp Ace	Trade/Consumer Advocacy Organization	Yes
Holly Johnson	American Herbal Products Association		Yes
Megan Olsen	Council for Responsible Nutrition		No
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	Yes
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			Yes

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 continue the discussion on the potential revisions or clarifications to the U.S. Hemp Authority (USHA) Certification Program Standard.

John Atwater started off the meeting by mentioning that the level of changes, i.e., major or minor, would determine whether the next version of the certification program standard would be version 3.1 or 4.0. Next, Nate Ensrud summarized some of the highlights from the previous meeting, especially the baseline requirement for demonstrating applicable GMP compliance based on the type of product manufactured, prior to entering the program. There were two areas that required further discussion, namely (1) requirements for testing for raw materials and finished products, including ISO 17025 accreditation requirements for laboratories and acceptable reduced testing programs, and (2) the impact of nonconformities (major and/or minor) on the status of certification. Currently, details related to these topics are not specifically described in the standard, so the goal would be to make updates to the standard to provide these details.

First, Marielle Weintraub and Joy Beckerman discussed the current requirements for laboratories needing to have a DEA license for conducting testing of cannabis products. Joy indicated that the DEA has extended the enforcement flexibility allowing non-DEA registered labs to conduct testing on hemp until January 2023.

Regarding ISO 17025 accreditation requirements, Joy indicated that multiple states, including big important states, require it, but that the USDA does not require it but strongly encourages compliance to the ISO 17025 standard. It was determined that the USHA certification program standard should indicate that ISO 17025 accredited labs need to be used if required by the state in which the product is being manufactured and sold, otherwise, for raw materials or in-process materials, a reputable lab can be used. However, for finished product testing the USHA certification program standard should require labs to be ISO 17025 accredited, given the likelihood that it will become a standard requirement nationally in the future.

One caveat regarding the use of an ISO 17025 accredited lab to conduct finished product testing is that if the finished product manufacturer is conducting finished product testing in their in-house laboratory, they do not need to be ISO 17025 accredited (although it is recommended that they be), the in-house lab must demonstrate on an acceptable reduced testing basis (at minimum on an annual basis), that the in-house lab gets comparable results to that obtained by an ISO 17025 accredited lab.

Nate provided a PowerPoint slide listing the potential tests for raw materials and finished products; this slide was used to help direct the discussion in determining what tests should be required for (1) a grower's botanical ingredient, (2) a manufacturer's raw botanical extract, and (3) finished hemp products. Marielle suggested that the group develop a list of required tests and recommended tests for each of the three product types. The discussion was focus solely on hemp ingredients and finished product, and not non-hemp ingredients that should be covered be standard GMP requirements. After much discussion, the group came up with the following list of tests required for the three product types.

Grower's Hemp Plant Material	Manufacturer's Hemp-Derived Ingredients	Hemp Finished Product
Required Tests		
Cannabinoids (including THC)	Cannabinoids (including THC)	Cannabinoids (including THC)
-	Hemp-Derived Ingredients ¥	Hemp-Derived Ingredients ¥
-	Residual Solvents	Residual Solvents
Pesticides	-	Pesticides
Elemental Impurities	-	Elemental Impurities
-	-	Microbiological Contaminants
-	-	Mycotoxins
Optional Tests*		
-	Pesticides	-
-	Elemental Impurities	-
Microbiological Contaminants	Microbiological Contaminants	-
Mycotoxins	Mycotoxins	-

* Note that the optional tests listed may be required depending on requirements of the state in which the product is manufactured or sold and/or of the buyer. Also, one must test for those contaminants that are liable to be present.

¥ If making certain quantitative label claims for any hemp-derived constituents (e.g., terpenes), testing for those constituents is required.

The issue of ensuring compliance to state requirements was discussed. Since testing requirements may vary depending on the state(s) involved, if the USHA staff need to verify that the appropriate testing is being done, state by state, that would add to the amount of time, effort and cost needed to audit and ultimately certify the finished product. Rather than have USHA staff verify the accuracy of the information, on a state by state basis, a potential solution would be for the certification program participant to demonstrate how they accurately determined what testing was needed based on state law for all states of interest. In the case of the state verification recognition program that USHA is pursuing with various states, USHA staff would likely need to verify the accuracy of the information and there would likely be an upcharge for that. Another option would be to make the testing requirement the most rigorous one that currently met all state requirements (NY, CO, CA, FL were mentioned as states of primary concern).

It was discussed that reduced testing on a rotational basis can be performed so long as it is supported by scientific justification, for example, supplier qualification (for raw materials), process verification, in-process controls, and statistical analysis of an adequate quantity of historical test data (for finished product). However, some tests may be required on a lot by lot basis, based on state regulations and/or required for contaminants that are liable to be present.

The topic of verifying all quantitative claims for all ingredients on the product label, or testing for NLEA nutritional food claims was discussed. Most of the members thought that the USHA certification program should be focused on hemp and hemp-derived ingredients, and that although testing for quantitative claims for non-hemp derived ingredients may be a regulatory requirement, that is not the focus of the USHA certification program, and that those testing requirements should have been addressed by the auditing body that certified the company for applicable GMP compliance.

That lead back to a discussion of what was required to demonstrate compliance to GMPs. Marielle was concerned that it would be too much to expect manufacturers to be GMP certified to begin with in order to

get USHA certified. She indicated that USHA expected GMP compliance, but not GMP certification. John indicated that there needed to be some an independent 3rd-party audit to demonstrate GMP compliance which would apply to manufacturer of the product and not necessarily the brand owner, unless they were also the manufacturer. Nate indicated that the company would not need to be GMP certified, but that FoodChainID (FCID) could conduct a GMP audit that would be separate from the USHA product certification. Also, if FCID were conducting the GMP audit, they would be able to conduct the audit with a focus on hemp and hemp-derived ingredients/products, as well as other non-hemp-derived ingredients to a lesser extent. Nate indicated that FCID discovered that conducting a 1-day USHA audit was not sufficient to be able to determine that a manufacturer was GMP compliant, and that typically GMP audits are 2- to 3-day audits depending on the size of the manufacturing operation. The primary objective of having demonstration of GMP compliance was to minimize the amount of work that FCID staff need to do regarding basic foundational GMP requirements so that they could focus on hemp-related concerns. The concern was that FCID staff had to address basic GMP compliance issues with companies that involved a lot more work than what was covered by the current cost/price for participating in the USHA certification program. Marielle indicated that if we have this requirement, then we are going from version 3.0 to 4.0 and would need to hold public commentary. Joy and Marielle expressed concern that this GMP certification or audit requirement might prevent small companies from participating in the USHA certification program. Ultimately, it was more or less concluded that a manufacturer could demonstrate GMP compliance either with a 3rd party audit certification, or FCID could conduct a GMP audit with a focus on hemp-derived ingredients and products and that the length of the audit would be based on the size of the manufacturing operation.

Nate concluded the meeting by thanking everyone for the constructive input and discussion and indicated that he would get together with John Atwater to compile notes and determine next steps to continue our efforts in revising the USHA certification program standard to bring clarity and transparency to the program requirements. Nate asked everyone to email him any topics in the standard that we have not yet discussed that they thought needed to be addressed so that we could make sure that we address them. Joy mentioned the need to no longer identify THC as simply THC, but rather identify it more specifically, e.g., delta-9 THC, delta-8 THC, and total THC.

ACTION ITEM 1: Nate and John to compile comments from the meeting and determine the next steps to continue our efforts in revising the USHA certification program standard to bring clarity and transparency to the program requirements. This will include drafting suggested revisions to the USHA certification program standard for the TC members to review prior to the next technical committee meeting.
Due date: Two week before the next TC subcommittee meeting.

2. Next Techinical Committee Meeting

The next technical committee (TC) meeting will meet preferably in early November after FCID staff draft suggested revisions to the USHA certification program standard. TC members will be asked to review the draft revised standard prior to the next meeting and will be given a copy of the revised standard at least two weeks prior to the next TC meeting to provide them ample time to review the suggested revisions. During the meeting, the TC members will need to determine, based on the proposed revisions, whether the standard will change from version 3.0 to 3.1, or from version 3.0 to 4.0.

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