

OFFICE OF THE COMMISSIONER
(850) 617-7700



THE CAPITOL
400 SOUTH MONROE STREET
TALLAHASSEE, FLORIDA 32399-0800

FLORIDA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES COMMISSIONER NICOLE "NIKKI" FRIED

December 7, 2021

Mr. John McGuire, State of New Jersey
NCWM Laws and Regulations Committee Chair

Mr. Brad Bachelder, State of Maine
NCWM Specifications and Tolerances Committee Chair

Re: *Cannabis* Agenda Items Submitted by the NCWM *Cannabis* Task Group

Laws and Regulations Agenda Items:

Block 3:

PAL-22.1

PAL-22.2

MOS-22.2

NET-22.1

Specifications and Tolerances Agenda Item:

SCL-22.2

Committee Chairs McGwire and Bachelder,

The Florida Department of Agriculture and Consumer Services (FDACS) is writing this letter in strong support of the *Cannabis* items before your respective NCWM Committees. FDACS has been a leader in regulating the *Cannabis* marketplace over the past three years and has adopted model regulations that have been emulated in part or in whole by other jurisdictions across the nation. We are one of the few agencies to regulate the entire process from seed to sale for human consumption. Since the inception of our *Cannabis* laws in 2019, we have worked with industry leaders; elected officials at the local, state, and federal levels; regulatory agencies at the local, state, and federal levels; and with numerous *Cannabis* trade associations to ensure the establishment of a fair, equitable, and safe *Cannabis* marketplace in Florida.

FDACS has followed the *Cannabis*-related items before your respective NCWM Committees through the four regional association meetings and witnessed the overwhelming support by regulators and industry to move these items forward as "Voting" items. We have also thoroughly read the analysis prepared by NIST OWM as it pertains to these items. While we appreciate the effort that went into the NIST OWM analysis, we respectfully disagree with numerous assertions made by NIST OWM and discovered several inaccuracies in their analysis. We are also disappointed that the NIST OWM analysis and recommendations fall short in the areas of consumer protection, marketplace equality, and regulatory responsibility, which are vital to the establishment of a healthy national *Cannabis* marketplace. It is imperative to note that further delay in the adoption of these standards will force states with active *Cannabis* marketplaces, like Florida, to adopt their own standards in the absence of these NCWM standards. This will only further perpetuate the development of boutique *Cannabis* regulations across our nation and harm this rapidly growing industry.

It is understandable that the *Cannabis* space is new to NIST OWM so there is much they have to learn, but we are concerned the opinions and inaccuracies expressed in their analysis may lead others to also incorrectly understand this industry and will create undue confusion and misperceptions across the board. It is our expectation that the NCWM will actively participate in the growth and evolution of this new industry, but we hope they do not elect to sit passively on the sidelines watching the *Cannabis* industry evolve around (and without) them simply because of these NIST OWM recommendations. We hope that the NIST OWM analysis does not impair the judgement of the Committees to do the right thing and move these scientifically based agenda items forward as “Voting” items into the NCWM Annual meeting in July 2022.

We offer the following detailed narrative in response to the NIST OWM analysis that will hopefully clarify these areas of inaccuracy and misinterpretation.

NIST OWM Analysis Page 17:

- **OUTREACH** – Outreach is a critical and active part of responsible regulation. Numerous national organizations have been consulted by FDACS over the years in the development of regulations. As a result, NIST OWM’s recommendation to develop a strategy to reach out to organizations has been satisfied (noting the organizations listed in the NIST OWM analysis were only examples and not specific targets). The following list is a sampling of organizations that FDACS has worked with over the past few years in the development of regulations.
 - Texas Hemp Growers Association (THGA) <https://txhempgrowersassociation.com/>
 - Hemp Alliance of Tennessee (HAT) <https://www.yourhat.org/>
 - Tennessee Growers Coalition (TGC) <https://tngrowerscoalition.com/>
 - National Hemp Association <https://nationalhempassociation.org/>
 - National Industrial Hemp Council (NIHC) <https://www.nihcoa.com/>
 - National Hemp Regulators Conference (50 State’s Regulators)
 - United States Department of Agriculture (USDA) <https://www.ams.usda.gov/rules-regulations/hemp>
 - United States Drug Enforcement Agency (DEA) <https://www.dea.gov/stories/2021/2021-05/2021-05-14/dea-continues-prioritize-efforts-expand-access-marijuana-research>
 - CannaMommy <https://www.cannamommy.org/>
 - Minorities for Medical Marijuana <https://minorities4medicalmarijuana.org/>
 - National Association of State Departments of Agriculture (NASDA) <https://www.nasda.org/>
 - Global Hemp Association <https://globalhempassociation.org/>
 - Florida Hemp Association <http://flahempassociation.com/>
 - Florida Hemp Council <https://theflhc.org/>
 - Florida Industrial Hemp Advisory Council <https://www.fdacs.gov/About-Us/Advisory-Councils-and-Committees/Industrial-Hemp-Advisory-Council>
 - Individual State’s Departments of Agriculture (many)
 - Hundreds if not thousands of individual businesses too numerous to list here.

- **SURVEY TO THE STATES** – FDACS submitted a detailed 57-question survey to all 50 states inquiring about all aspects from seed to sale. We received partial or complete responses from many states. It should be noted that several states did not submit complete responses and some states did not respond. FDACS cannot control the number or content of responses.

- **SURVEY TO THE STATES (First Bullet)** – Consultation with agency counsel occurs any time a new addition to the Handbooks enters administrative code or state law. This is part of the normal legal review process, so this isn’t a new scenario resulting from the emergence of *Cannabis*.

- SURVEY TO THE STATES (Second Bullet) – Partial compatibility with state’s laws and regulations is not something unique due to the emergence of *Cannabis*. There are other concepts in the Handbooks that are not under the regulatory authority of some state’s weights and measures laws. The state of Florida is an example. The state of Florida’s Weights and Measures Law does not include taximeters, transportation measurement systems, and equipment used for the purpose of inspecting the accuracy of aviation fuel devices.

Section 531.37(1) of the Florida Statutes reads “Weights and measures” means all weights and measures of every kind, instruments, and devices for weighing and measuring, and any appliance and accessories associated with any or all such instruments and devices, excluding taximeters, transportation measurement systems, and those weights and measures used for the purpose of inspecting the accuracy of devices used in conjunction with aviation fuel.

NIST OWM Analysis Page 18:

- SURVEY TO THE STATES (Third Bullet) – Considering the two previous bullets, state and local jurisdiction’s Offices of General Counsel regularly review rules to determine which standards are permissible for adoption. This is common practice and occurs with each concept introduced into the Handbooks.

Florida excludes taximeters, transportation measurement systems, and those weights and measures used for the purpose of inspecting the accuracy of devices used in conjunction with aviation fuel. This does not mean that these codes need to be removed from the Handbooks simply because Florida’s Weights and Measures Law does not include them.

- SURVEY TO THE STATES (Closing Paragraph) – NIST OWM states there are 19 states that automatically adopt the UPLR in Handbook 130. The table in Section II of Handbook 130, *Uniformity of Laws and Regulations*, does not stipulate “*automatically*” rather it reads “*adopted and updated on an annual basis.*” This would also include non-automatic annual updates. As a result, it cannot be concluded that 19 states automatically adopt this section of Handbook 130 on an annual basis as purported by NIST OWM.
- REGULATORY AUTHORITY (Second Paragraph) – NIST OWM states “*OWM does not agree with the statements that having the authority to recognize moisture loss or gain or test fuel quality allows weights and measures directors to establish a water activity limits [sic].*” These statements were not made (to our knowledge) rather the statements that were made in the *Cannabis* Task Group meetings were made in response to advising statements suggesting that “*we do not regulate quality.*” The response was “*we actually do [regulate quality] in the form of fuel quality*” and further statements were made that “*we regulate moisture loss or gain for other commodities.*” These statements were analogous comparisons demonstrating that the basis for adopting a water activity standard already exists within the Weights and Measures Community and throughout the Handbooks. Water activity is NOT just a **quality** aspect rather it is equally if not more so a **quantity** aspect (revisited in greater detail in subsequent paragraphs).

NIST OWM states “*In most states the authority to promulgate the types of labeling and method of sale requirements included among these proposals is delegated by legislatures to state health departments or to specially created cannabis [sic] regulatory agencies (e.g., Colorado Cannabis, or the Maryland Medical Cannabis Commission.*” NIST OWM provided two examples without specificity as to those boundaries but stated “*most states,*” which implies more than two. We are requesting NIST OWM to provide a specific list of states and their offices. Further, it should be noted that *Cannabis* has a medical space as

well as a non-medical space with medical space(s) housed under state departments of health, but this should not be confused with cannabinoids marketed and sold outside of the medical space, which is a rapidly growing market.

We would ask NIST OWM why the *Cannabis* Task Group was asked to conduct a survey of states to determine if “...state’s weights and measures laws authorize the director to adopt rules and regulations that require ingredient labeling, safety warnings, potency declarations and if they allow the director to establish and enforce water activity limits and verify potency labeling” when NIST OWM previously stated “In most states the authority to promulgate the types of labeling and method of sale requirements included among these proposals is delegated by legislatures to state health departments or to specially created cannabis [sic] regulatory agencies (e.g., Colorado Cannabis, or the Maryland Medical Cannabis Commission.” In one statement NIST OWM is purporting they are unsure who has this authority but in the other statement NIST OWM is purporting that “most states” delegate this authority to the state departments of health.

In NIST’s home state of Maryland, the state’s Department of Agriculture oversees the weights and measures program (including the inspection of motor fuel dispensers) whereas fuel quality testing is conducted by the Maryland Comptroller. According to the table in Section II of Handbook 130 *Uniformity of Laws and Regulations*, Maryland has fuel regulations in force, but not based on NCWM standards. However, this bifurcation of regulatory duties between state agencies in Maryland is not delineated in this table. This leads one to conclude that the “yes*” notation in the table for Maryland is an indication of the state rather than for a single agency within the state. Further, Maryland’s Department of Agriculture is an active participant at the NCWM, but their Comptroller is not. The state of Maryland is not unique to this scenario and one could easily conclude this same paradigm would exist with *Cannabis* regulations as well.

- REGULATORY AUTHORITY (Third Paragraph) – While consultation with a jurisdiction’s legal counsel, as suggested, is a routine process (and not unique to these proposals) the proposed language by NIST under “*Current Authority in Weights and Measures Law*” creating a **Section 11. Powers and Duties of the Director** is acceptable, with changes as noted in later in this document.

NIST OWM Analysis Page 19:

- WATER ACTIVITY (First Bullet) – While the statement that “*water activity is different from water content (or moisture content) ...*” is not inaccurate, it is incomplete. Water activity is overlapping with moisture content as it results in a stable moisture content.
- WATER ACTIVITY (Second Bullet) – While water activity is important to the food industry, it is a scientific principle used by the food industry, but not relegated only to the food industry. A common definition of water activity that can easily be found on the internet is “***Water activity (a_w) is the partial vapor pressure of water in a solution divided by the standard state partial vapor pressure of water.***” This scientific principle is used to help control the growth of microorganisms, which is critical to the food industry, but it can apply to any industry (e.g., *Cannabis*).
- WATER ACTIVITY (Third Bullet) – NIST OWM states “*The only reason weights and measures officials are concerned with moisture content is in determining whether variations in the net weight of packaged goods due to the loss or gain of moisture are reasonable.*” We would not agree with this statement as weights and measures officials are also concerned that moisture is not substituted for product when traded in commerce, unbeknownst to the purchaser. For example, adjustments are made for glazing on seafood, meat, and poultry in Handbook 133 as there are known practices that add excess ice on select commodities resulting in consumers paying per-pound seafood prices for ice. In the *Cannabis* industry

“diversion” is a similar fraudulent tactic used by unscrupulous businesses to adjust the water weight in their favor and thus, alter the actual weight of *Cannabis* being traded.

- WATER ACTIVITY (Fourth Bullet) – NIST OWM makes several statements in this paragraph that are not germane to the proposal and are believed to be a source of much confusion.

NIST OWM states “*FDA further explains that ‘most foods have a water activity above 0.95 and that will provide sufficient moisture to support the growth of bacteria, yeasts, and mold. The amount of available moisture can be reduced to a point which will inhibit the growth of the organisms.’*” This last sentence is the exact intent of the proposed water activity standard of 0.60 +/- 0.05 for *Cannabis*.

NIST OWM states “*FDA explains that if the water activity of food is controlled to 0.85 or less in the finished product, it is not subject to the FDA regulations.*” FDA does not regulate *Cannabis* currently, therefore the NIST OWM statement is moot.

The same statement by NIST OWM also references “*finished products*” which **are not** the subject of this proposal. This proposal **does not** apply to finished products, rather it **only** applies to *Cannabis* plant material, whether intended to be a food or non-food product. Therefore, there would be **no change** to any application of water activity to food products currently under FDA jurisdiction.

NIST OWM references 21 CFR Part 113 and 114, which apply to acidified foods. *Cannabis* is not an acidified food. If *Cannabis* were to be added to acidified food products it would not be subject to this water activity requirement and it would be subject to the water activity requirements currently in use for processed food products.

- WATER ACTIVITY (First Paragraph, Without Bullets) – NIST OWM requests “*...that the Committee or Cannabis TG provide a document that includes specific citations to the studies and references or to the industry standards (e.g., ASTM) and the recommendations of the U.S. Pharmacopeia...*” These references were provided with the Form 15 submission by the NCWM *Cannabis* Task Group and have been available for review since submission.
- WATER ACTIVITY (Second Paragraph, Without Bullets) – NIST OWM states “*...OWM recommends that the proposal be amended to include suitable storage temperature and humidity limits wherever unprocessed cannabis [sic] is sold or ownership transferred.*” We would not recommend that these specifications include control limits such as temperature and humidity. Climates vary significantly across the nation and further, regulators typically don’t prescribe *how* to meet a regulation rather they ensure that the regulation is satisfied. Prescribing *how* a regulation will be satisfied has the potential to lead to liability claims and costly lawsuits should the prescribed steps not yield the intended outcome. It is typically up to the regulated entity to determine *how* they maintain compliance. Further, ASTM International is in the process of developing environmental standards for *Cannabis* processors related to humidity and temperature to ensure the water activity is 0.60 +/- 0.05. As a result, such limits will be available soon.

NIST OWM Analysis Page 20:

- WATER ACTIVITY (Third Paragraph, Without Bullets) – NIST OWM recommends adding a statement that the water activity limits proposed only apply to *Cannabis*. We believe this was clear in the initial drafts as it is the intent of the water activity proposal, but further clarification would be acceptable.

“WHEN UNPROCESSED CANNABIS IS SOLD, OR OWNERSHIP TRANSFERRED” (First Paragraph) – NIST OWM asks “*...the Cannabis TG or Committee provide examples of how an inspector is to enforce the water activity requirement without interfering with a commercial transaction.*” If an inspector elected to

test water activity in the field they would acquire (either through purchase or if they have the authority to obtain without purchase) a product sample and proceed with the testing. For example, inspectors collecting fuel samples either buy or under proper authority acquire without payment a product sample and either screen it in the field or send it back to a laboratory for testing. The same scenario would exist for water activity testing.

Additionally, it is not reasonable to interpret the language to indicate an inspector must wait until a commercial transaction is completed before determining compliance. State laws typically include the offering for sale under the definition of “selling.” However, inclusion of “offering for sale” would be acceptable.

We would offer a slightly modified version of NIST OWM proposal in 2.XX.X.

2.XX.X. Water Activity-When unprocessed Cannabis, is kept, offered, or exposed for sale, sold, bartered, or exchanged, or ownership transfers, the water activity shall be 0.60 (\pm 0.05). Unprocessed Cannabis is in compliance with this requirement unless the water activity is less than 0.55 or greater than ~~and~~ 0.65.

- **CONFLICT IN LAW OR REGULATION** – NIST OWM raises the concern for potential conflict between weights and measures authorities and the jurisdiction having authority, if any. This is no different than any other regulation introduced into the Handbooks. At present, almost every state has different rules and regulations pertaining to *Cannabis* products. Also, as referenced earlier, Florida adopts Handbook 44, which includes taximeter and GPS codes, but Florida Law specifically excludes “...taximeters, transportation measurement systems, and those weights and measures used for the purpose of inspecting the accuracy of devices used in conjunction with aviation fuel.” from weights and measures authority. That stated, incorporation of a note as proposed by NIST OWM would be acceptable, with slight modification.

NOTE: Conflict of Laws and Regulations. – If any particular provision of the requirements in this section or subsection (include the section or subsection here for exactness) are found to conflict with existing ~~federal or~~ state laws or regulations (i.e., sale of ~~Cannabis cannabis~~ is prohibited) or local ordinances relating to the definition, labeling, potency or other requirements for ~~Cannabis cannabis~~ or ~~Cannabis cannabis~~ containing products, the enforcement of such provisions shall be permanently suspended. Such suspension shall not affect the validity or enforcement of the remaining provisions of any other requirement in this regulation.

- The word “federal” would not be acceptable since many of these products are currently “prohibited” at the federal level.
- The words “local ordinances” would not be acceptable since many regulations are pre-empted to the state agency having jurisdiction, not the reverse, and local jurisdictions typically do not have legal authority to supersede state authority.

NIST OWM Analysis Page 21:

- **CURRENT AUTHORITY IN WEIGHTS AND MEASURES LAW (First Paragraph)** – NIST OWM states “*The survey may also reveal that a director has advisement from legal counsel that the State’s weights and measures law does not give the state director authority to regulate the types of cannabis [sic] labeling.*” While this legal review takes place any time a rule is promulgated (i.e., it is not unique to *Cannabis*) and the survey is not necessary to initiate this process, the proposed language would be acceptable with the following modifications.

Section 11. Powers and Duties of the Director

The Director ~~may shall~~:

(r) for Cannabis and Products Containing Cannabinoid(s)

(1) Prescribe by regulation:

i. reasonable variations in quantity caused by the loss or gain of moisture during current good distribution practice or by unavoidable deviations in current good manufacturing practice and procedures for moisture determination;

ii. labeling requirements for and defining reasonable variations in water activity that occur in current good manufacturing practice and current good distribution practice and procedures for the measurement of water activity;

iii. labeling requirements for and define reasonable variations in levels of cannabinoid~~s: delta-9 THC, delta-8 THC (potency)~~ that occur in current good manufacturing practice and current good distribution practice and procedures for the measurement of potency; and

iv. packaging and labeling requirements that may include, among other requirements, the characteristics of the packaging (e.g., color) and type of packaging (e.g., tamper evident, childproof, ~~product stabilization~~), requirements for identity, ingredients, product lot code and date of packaging, contact information of the packer, special symbols or warnings, and potency. The requirements may also include prohibitions on packaging that may be misleading or confusing.

(2) The Director may prescribe by regulation, programs that utilize accredited testing laboratories and may enter into agreements to utilize conformity assessment programs and other technical services to ensure compliance with any of the prescribed requirements.

- The power of the director should not be a “shall” rather it should be a “may” as it will not necessarily be applicable in every jurisdiction.
- It is not recommended to list the types of cannabinoids rather it is important to leave them generally categorized as “cannabinoids” since the market is constantly changing as are the cannabinoids being sold.
- The term “product stabilizing” was added as products containing cannabinoids have both a thermal sensitivity and photosensitivity.
- CURRENT AUTHORITY IN WEIGHTS AND MEASURES LAW (Fourth Paragraph) – NIST OWM suggests that home deliveries of commodities and internet sales have increased as of late. While we agree with this observation, it is not unique to *Cannabis* products. This increase has been observed across all product and service sectors from home restaurant or grocery delivery to non-food products to third-party online ordering of products.

NIST OWM Analysis Page 22:

- CURRENT AUTHORITY IN WEIGHTS AND MEASURES LAW (Fifth Paragraph) – NIST OWM notes that they often hear “weights and measures plays catch-up instead of actively participating in the development of new areas of commercial weighing and measurement.” While we agree with this statement, we believe it is for different reasons. NIST OWM points to electric vehicle charging systems and GPS transportation systems. We believe these are two areas that the weights and measures community fell behind with the development of regulations and had to play “catch up” rather than actively participating in the development of these new areas to ensure timely development of standards. Delaying adoption of

standards until “perfected” or “just right” does not provide leadership or marketplace supervision. During this time an industry moves forward and evolves without contribution from the weights and measures community, thus jeopardizing consumer protection and marketplace equity by vacating regulatory responsibility. We believe it is prudent to protect an industry and consuming public through the adoption of standards at a much earlier stage than has been observed for other sectors, such as electric vehicle charging systems, GPS transportation systems, and compressed and liquefied natural gas (CNG/LNG). Further studies following the adoption of standards are certainly encouraged, but they should not delay the adoption of standards. Should these *Cannabis* items not be taken up for a vote at the next NCWM Annual Meeting in July 2022, the earliest possible time these regulations could be incorporated into print would be 2024 (and we don’t need to remind readers this was written in 2021).

- CURRENT AUTHORITY IN WEIGHTS AND MEASURES LAW (Sixth Paragraph) – NIST OWM states “*Most states that have a Department of Agriculture also have a state chemist and seed control laboratory, that have regulatory authority to prescribe net quantity of contents requirements.*” This statement is confusing as authority is typically given by a legislature to an agency and not to a specific position or to a specific laboratory. We are unaware of any seed laboratories that oversee net contents of packages. We are also aware there are myriad configurations throughout the country but in Florida, the remainder of this paragraph is not relatable.

NIST OWM Analysis Page 23:

- CANNABIS FORMATTED AS ITALICIZED TEXT (First Paragraph) – NIST OWM notes “*Within the proposed section title, the term Cannabis is italicized.*” This topic was heavily discussed within the *Cannabis* Task Group. The difficulty is that different states use different terminology to describe plants and products containing more than or less than 0.3% Total Delta-9 THC. For example, California prohibits use of the term “marijuana” whereas states like Florida have it incorporated into their statutes. California in turn uses “cannabis,” a common word with no taxonomic basis. In attempts to find common terminology that would not conflict with state’s terminology across the board, the taxonomic term of “*Cannabis*” was selected as it applies to all states and represents plants, whether they contain more than or less than 0.3% Total Delta-9 THC. The capitalization and italics are taxonomically correct whereas the lower case “c” and non-italics represent the common name that has no taxonomic meaning for products or plants containing more than 0.3% Total Delta-9 THC (i.e., “marijuana” in other states). If the NCWM Membership elects to use the lower case, non-italicized “cannabis” form, then caution should be taken, particularly when considering legal challenges as the two forms of the same word have different scientific and accepted meanings.
- B3: PAL-22.1 – The language proposed by NIST OWM on lines 12-15 is acceptable.

NIST OWM Analysis Page 24:

- B3: PAL-22-2 – NIST OWM proposes to eliminate the proposed wording “~~...with the exception of commodities listed under Section 10.9 Textile Products, Threads and Yarns and other non-food products not intended for human or animal application,...~~” It should be noted that this would then apply to all non-food products which was not the intent of this proposal. The intent of the proposal was to apply to food products and select non-food products, but not to all non-food products.
- “Shall Bear on the Outside of the Package...” - NIST OWM asks for clarification of the intent of the statement “*shall bear on the outside of the package.*” The outside of the package means it cannot appear on the inside of the package. By applying the statement on the outside of the package it is then accessible to the potential purchaser before making the purchase versus after making the purchase and opening the package. The phrase is general enough that it is silent regarding peel away labels, which are

located on the outside of a package. More specific or detailed information to clarify could possibly be acceptable.

NIST OWM Analysis Page 25:

- “Contains Cannabis” – In response to NIST OWM’s comments regarding product identity and ingredients, *Cannabis* may be an ingredient, or it may not be an ingredient, depending on the product. We believe the word “*Cannabis*” on the package, if used in the right context, provides adequate declaration as to the content as well as the identity. It should be noted that some states have minimum age requirements for the purchase of *Cannabis* products as well.
- “Will placing the Delta-9 THC potency information on the bottom of the package or bottle be permitted?” (First Paragraph) - NIST OWM asks if the potency declaration will be allowed to appear on the bottom of the package. Placement of information on the bottom of packages is generally not acceptable in the weights and measures community. Placement of the potency information on the bottom of the package would not be acceptable to us and further clarification may be acceptable.
- “Will placing the Delta-9 THC potency information on the bottom of the package or bottle be permitted?” (Second Paragraph) - NIST OWM asks if the intent of the proposal is to only apply to food product and not to non-food products. A simple delineation would be nice, but as mentioned earlier, the proposal would apply to food products as well as some non-food products, such as lotions, creams, and other products intended for non-ingestible human consumption.
- “Will placing the Delta-9 THC potency information on the bottom of the package or bottle be permitted?” – NIST OWM’s suggested language in lines 32-40 would be acceptable with the following modifications.

10.XX. Cannabis and Cannabis-Containing Products – Any Cannabis or Cannabis-containing products *intended for human or animal consumption or application*, shall bear on the outside of the package the following:

(a) On the principal display panel

(i) The statement “Contains Cannabis.”;

(b) On any panel or surface of the package

(ii) The statement “Contains more than 0.3% Total Delta-9 THC” or “Contains 0.3% Total Delta-9 THC or less.”; and

(iii) A declaration of the *quantity number* of milligrams of each marketed cannabinoid per serving or application.

NIST OWM Analysis Page 26:

- “Will placing the Delta-9 THC potency information on the bottom of the package or bottle be permitted?” (First Bullet) – Please refer to comments provided on Page 8 of this document for “CANNABIS FORMATTED AS ITALICIZED TEXT (First Paragraph).”
- “Will placing the Delta-9 THC potency information on the bottom of the package or bottle be permitted?” (Second Bullet) – NIST OWM recommends using “*quantity in*” instead of “*number of.*” This proposed change would be acceptable.

- TEST METHODS (Lines 9-16) – NIST OWM suggests “...*the Committee provide information on the acceptable test methods to be used for enforcement.*” This is not practical and not typical for many test methods of this nature. Typically, regulators do not prescribe test methods since multiple acceptable methods often exist. Prescribing test methods can open the door for potential bias toward a particular vendor, which is prohibited in government procurement (at least in Florida). In the *Cannabis* space there are two common types of instruments that can be used to determine the cannabinoid content of a product. Gas Chromatography (GC) and Liquid Chromatography (LC) are the two main techniques used, but there are variations within each (e.g., detectors, columns, etc.). Currently, AOAC is the only consensus organization that has published a viable testing method. Other testing methods are in the developmental stage but may not be the same once published. We would encourage labs to use test methods that have been developed by consensus organizations, much in the same way in the motor fuel sector. It should also be noted that the situation FDA outlined was already known and previously observed in states that currently test *Cannabis* products for cannabinoid content. The proposal requiring the declaration of cannabinoid type and concentration allows the regulatory community to hold the responsible party accountable and act if the product does not meet the labeling claims. When the cannabinoid content deviates from labeling claim it tends to be from one of four categories.
 1. Heterogeneity in processing
 2. Laboratory deviations
 3. Thermal or photo-degradation over time
 4. Fraud
- B3: MOS-22.2 – “*OWM recommends that the Committee move only partial sections of this proposal forward as a Voting Item. The Committee will need additional time to address the requirements for limits on water activity...*” This statement highlights a critical philosophical disagreement between NIST OWM and many regulatory agencies. This recommendation by NIST would let the market continue unchecked and essentially unregulated in this regard while studies are conducted. This would allow fraud to perpetuate, substandard products to enter the market, and consumers and businesses to be financially harmed while these additional studies are being conducted and additional information is being gathered. An alternative approach that would protect the consumers and businesses would be to move these items forward as “Voting” items, so they can be introduced into regulations and simultaneously conducting any desired additional studies and gathering any desired additional information. The NIST OWM philosophy to wait versus placing established consensus-based regulations into the handbooks is not one that we share. The *Cannabis* market has already been highly active for 3-5 (or more) years, depending on the jurisdiction, and failing to move these items forward with a “Voting” status now would result in the year 2024 being the earliest possible time they could make it into print. This would allow an unchecked market for 6-8 (or more) years before weights and measures regulations would be introduced to regulate the market. We can’t speak for other states but if these items do not move forward with a “Voting” status, Florida will look to adopt their own regulations, which has been echoed by other jurisdictions as well.

NIST OWM Analysis Page 27:

- B3: MOS-22.2 (First Full Paragraph) – NIST OWM states “...*water activity is associated with product quality.*” This statement is only partially accurate as water activity is also associated with **quantity**, by keeping the moisture content stable. NIST OWM adds emphasis (**bold** and underline) to the word “**quantity**” throughout the paragraph. Since water activity keeps the moisture content constant, thus also affecting **quantity**, we would agree with lines 7-16 of this paragraph. If you don’t control the moisture content you allow for “diversion”, which is a technique currently used by unscrupulous

businesses to manipulate the amount of *Cannabis* sold and allows for deception and fraud to perpetuate in the marketplace. In this paragraph, NIST OWM, once again, tethers water activity to traditional food products, which is not applicable to the water activity proposal.

- **B3: MOS-22.2 (Second Full Paragraph)** – NIST OWM states “*The Committee should request the NCWM Cannabis TG and the cannabis [sic] industry, and trade associations provide scientific studies and other information to justify and validate the limits of water activity requirements stated within the proposal. The Committee can have the data evaluated by a qualified panel of experts who could also assist in developing the justifications and technical language in the regulations.*” This process as prescribed by NIST OWM would take multiple years and during this time *Cannabis* products on the market would go unregulated. In our opinion, this is not a responsible approach to ensure fair and equitable trade practices in the marketplace nor does it help protect consumers and businesses. Further, ASTM International D37 Committee on *Cannabis* has nearly 1,000 members and the very same water activity standard in these proposals was vetted out through their consensus process and determined to be the best water activity for *Cannabis* plant material. We would argue that nearly 1,000 industry members would more than satisfy the request for input from the *Cannabis* industry and trade associations to justify and validate the limits of the water activity requirement proposed in this item. We would also argue that this would also satisfy NIST OWM’s request to have “*...growers, packers, distributors, retailers, and other stakeholders have adequate notice and an opportunity to comment on the water activity limits...*” This is the primary composition of the nearly 1,000 members of ASTM International’s D37 Committee on *Cannabis*.

In this paragraph NIST OWM cites “criminal” penalties related to water activity. NIST OWM should understand that the weights and measures regulatory community typically relies on civil remedies to address violations and rarely do they move into the criminal realm. Tools typically used by weights and measures officials are in the form of stop sale and stop use orders as well as administrative fines. Sometimes injunctions are necessary in extreme cases and only in rare occasions are criminal penalties pursued, which are typically handed to the Attorney’s General or State Attorney’s Offices for prosecution. In the *Cannabis* trade, criminal penalties arise typically from the level of THC found in products. Beyond the issuance of a stop sale order and potentially an administrative fine for high THC content found in commercially available products, any further handling would be by the state’s Attorney’s General or State Attorney’s Offices or at the federal level, by the Drug Enforcement Agency. In short, discussion combining criminal penalties with water activity is not applicable and only confuses the matter for those learning this sector.

- **B3: MOS-22.2 (Third Full Paragraph)** – NIST OWM suggests developing guidance and procedures for sampling and testing related to water activity. NIST OWM also mentions that states metrology labs will need to be trained and equipped to certify devices used in the field. It should be noted that there are currently field screening units (e.g., octane) that are not certified by NIST’s metrology lab. Further, there are other laboratory tests that NIST’s metrology lab does not certify, specifically pertaining to vehicular fluids and fuels. The test procedures for a water activity meter are straight forward and simple. A basic description of those procedures has been provided for a measure of clarity.
 1. Take an aliquot of *Cannabis* plant material (e.g., a “pinch”),
 2. Place it in the sample compartment,
 3. Close the lid,
 4. Press the button, and
 5. Read the screen.

Laboratory instruments should always be sent back to the manufacturer periodically for proper diagnostics and recalibration, if necessary, but not to a NIST laboratory as they are not certified by vendors to perform this type of proprietary work. This is, of course, is recommended for all types of similar instrumentation. This statement should not be confused with the necessity for the NIST metrology lab's certification of weights and measures artifacts.

- B3: MOS-22.2 (Fourth Full Paragraph) – NIST OWM recommends that the NCWM *Cannabis* Task Group be placed under PALS so it can be “better led.” We do not believe that the *Cannabis* Task Group should be a Focus Group under PALS as the topics within the *Cannabis* sector extend well beyond just packaging and labeling. The *Cannabis* sector is fast-moving and rapidly developing so we believe the future of the NCWM *Cannabis* Task Group will be long standing and widespread, far beyond the scope of PALS. We do agree; however, that PALS will play an integral role in certain aspects of the NCWM *Cannabis* Task Group's work.

NIST OWM Analysis Page 28:

- B3: NET-22.1 – NIST OWM recommends changing the title of this item to read “**Section 1.2.6. Deviations Caused by Moisture Loss or Gain and 3 Section 2.3.8. Table 2-3 Moisture Allowances.**” We believe this would be an acceptable change.

NIST OWM Analysis Page 29:

- B3: NET-22.1 (First Bullet) – NIST OWM has stated that moisture allowances cannot be arbitrary and must be backed by a scientific study, citing *Cook Family Foods, Ltd. v Voss* (1991). After reviewing this filing, it is clear the court opined that a moisture allowance must follow due process, but it was silent as to requiring a scientific study. According to the filing, state inspectors were arbitrarily applying moisture allowances, if applying one at all, based on their judgement when conducting on-site inspections. This resulted in an arbitrary application of moisture allowance to packages, which did not follow due process. The state contended that setting a constant moisture allowance without scientific data would be subjective (this statement was made by the state during deposition and quoted in the case but was not a statement rendered by the judge). The court noted that the businesses impacted by the state's approach had no way to know in advance of the requirement they had to meet, thus due process had not been followed. However, the court did not state that a moisture allowance must be based on a scientific study. Due process may involve a scientific study but does not require a scientific study to be performed in advance of the adoption of a standard. Thus, NIST OWM's contention that the court ruled a moisture allowance must be based on a scientific study is incorrect.
- B3: NET-22.1 (Second Bullet) – Continuing the thought in the previous paragraph, NIST OWM goes on to state “*If the studies are not done in a way that is scientifically valid, which represents real world conditions, and reflects the typical packaging and shelf-life of products, they will NOT protect consumers or packers. They will also not ensure inventory or taxes are accurately maintained.*” We would not fully agree with this statement. Any moisture allowance is applied on top of the maximum allowable variation (MAV) and thus constitutes a more relaxed limit, based on accounting for moisture loss or gain. Additionally, NIST OWM's comment concentrates solely on the accuracy of the measurement rather than factoring in precision, which is equally as critical. So long as the allowance is constant a level of balance will be maintained. Concentrating on accuracy only would have more merit if the allowance was only for loss or only for gain; however, the proposal includes moisture loss and gain, thus allowing for a level of overall balance to be maintained. Therefore, NIST OWM's contention in this paragraph are incomplete and do not convey an accurate picture of the impact of this proposal.

- B3: NET-22.1 (Third Bullet) – If procedures need to be modified in Handbook 133, we’re confident the NCWM *Cannabis* Task Group would be willing to address this, but we cannot speak for the Task Group.
- B3: NET-22.1 (Fourth Bullet) – Inspectors have traditionally used sample error limits and the concept of predominance to prevent facilities from “just underfilling” all packages. This is not a new concept created by this proposal rather it has permeated the industry for generations by unscrupulous vendors in all sectors.
- B3: NET-22.1 (Fifth Bullet) – NIST OWM states “*Under this moisture allowance approach inspectors will not be able to take enforcement actions as they currently do when using NIST Handbook 133.*” I would note that most jurisdictions (if not all) rely on their statutory penalty authority and structure when determining enforcement actions. Handbook 133 (nor any other of the Handbooks) do not supersede state law or jurisdictional codes.

NIST OWM further states “*Since the 1970s weights and measures has treated overweight and overfilled packages as being acceptable because overpacking is limited by the packer for economic reasons.*” While this may be the case, *Cannabis* is a new commodity type in its overall scope and the approach used in the 1970s are not necessarily indefinitely applicable. Fifty years of market evolution forces us to revisit, review, and revise philosophies and approaches.

NIST OWM also states “*They will also determine if the packer is following current good manufacturing and distribution practices, obtain other information, and then make a determination that the overfilling or underfilling were reasonable or not.*” This approach by NIST OWM speaks to the very concern the court expressed in the *Cook Family Foods, Ltd. V Voss* (1991) case regarding subjectivity. The inspector should not “*then make a determination that the overfilling or underfilling were reasonable or not.*” This subjectivity is the exact reason why a standard should be put in place.

- B3: NET-22.1 (Sixth Bullet) – NIST OWM recommends “*the state directors be surveyed (see OWM comments on Block 3) to determine if they intend to have their inspectors take enforcement action on overweight packages of cannabis [sic].*” While surveys are typically informative, they are not a requisite to the establishment of a standard. As has been mentioned previously, there is no known jurisdiction that adopts and enforces every aspect of any Handbook. This is left to the individual jurisdiction to ensure compliance and compatibility with their codes and laws. Further, diversion with *Cannabis* plant material is unique to this commodity and prompts the adoption of an overfilling limit, consistent with a controlled water activity.

NIST OWM Analysis Page 30:

NIST OWM further states that “*OWM has not heard of any recent cases where overfilling has been an issue.*” As has been noted by NIST OWM, *Cannabis* has yet to have federal regulations promulgated and thus, NIST OWM has not had experience with such products. Again, diversion is a known tactic to evade taxes as well as “launder” THC-containing *Cannabis* into the underground markets.

- B3: NET-22.1 (Seventh Bullet) – NIST OWM states “*OWM recommends that the Committee study the idea of changing this approach and have the MAV values apply to both positive and negative package errors when packaged cannabis [sic] is being tested.*” We would agree that the MAV should apply in both the positive and negative directions.
- B3: NET-22.1 (Eighth Bullet) – NIST OWM “*encourages the Committee to consider conducting a broad long-term study in cooperation with the cannabis [sic] industry to determine if the 10 percent MAV packages under 36 g is appropriate for application to cannabis [sic] packages.*” We would not be

opposed to additional studies being conducted in the *Cannabis* or other realms, but we do not believe waiting until such additional studies are conducted before the adoption of these established scientific standards is being responsible to consumers, businesses, or the market in general.

I would like to conclude by reiterating the need to understand that further delay in the adoption of these *Cannabis* standards will force states with active *Cannabis* marketplaces, like Florida, to adopt their own standards in the absence of these NCWM standards. This will only further perpetuate the development of boutique *Cannabis* regulations across our nation and harm this rapidly growing industry.

We appreciate the input by NIST OWM and encourage NIST OWM staff to continue their learning and education of this new market sector. We also encourage NIST OWM to fully understand how we must evolve and rapidly respond to emerging sectors to ensure the weights and measures community remains relevant, promotion of marketplace equality, and protection consumers in this and all other market sectors.

Again, the Florida Department of Agriculture and Consumer Services strongly supports the *Cannabis* proposals before the Specifications and Tolerances Committee and the Laws and Regulations Committee and encourages the Committees to move all items forward with a "Voting" status out of the NCWM Interim Meeting and into the NCWM National Meeting in July of 2022. I would be happy to discuss further any of these comments with either of both of you, if desired. I can be reached at (850) 631-1569 or at Holly.Bell@FDACS.gov.

Sincerely,

DocuSigned by:



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Holly Bell

Director of *Cannabis*