SAFE INGREDIENTS & TESTING PROTOCOLS

POWERED BY SORSE™

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INTRODUCTION

– That Looks Healthy, But Is It?

Over the last several years, the food and beverage industry has seen a significant uptick in the public's desire for items that are "healthy" and/or "natural." Unfortunately, this trend has caused confusion and unintended associations between those words and health. Most people don't actually know what makes a food item healthy or natural, which is one reason why an agency like the Food & Drug Administration (FDA) has to step in to assist.

The unfortunate truth is that the "healthiness" of a substance is not binary. Even those most versed in the subject of health and nutrition do not know the effect of a food on health with certainty. The health aspects of a substance (positive and negative) fall on a continuum. Over the last century, there have been large shifts in what constitutes a healthy diet. Chemicals that we recognize as vitamins today were only discovered, isolated, and named in the first decades of the 18th century. It was partly this discovery that paved the way for today's dietary standards and label claims.

The first instance of dietary goals and standards in the United States was in 1977 by a select Senate committee, following public demand after the airing of the CBS documentary "Hunger in America." The initial effort was primarily to combat hunger by providing nutritional guidance to Americans and continuing research in the fields of nutrition and food science. As time progresses, new areas of interest have required new guidance by the FDA and other government institutions around the world.

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– FDA Guidance and Rule Making

Scientific discovery is not the only event that will persuade the FDA to issue guidance in the realm of food safety. Mislabeling and/or falsely making a health claim that can pose a threat to public health will trigger a review of products and services by the FDA. This includes usage of marketing terms that have been buzzworthy in the food and beverage industries, such as "natural." This changing landscape has resulted in the need for the FDA to draft guidance and definitions for what is to be considered "natural." The FDA defines the term "natural" as "nothing artificial or synthetic (including all color additives regardless of the source) has been included in, or has been added to, a food that would not normally be expected to be in that food." In addition to terms such as "natural" or "healthy," there are other buzzwords that have been introduced to the consumer lexicon that have caused further confusion.

Terms like "organic," "all-natural," "superfood," "GMO," "multi-grain," and "grass-fed" are just a few of the many descriptors that producers and advertisers use to grab our attention. These buzzwords are often not an indication of the beneficial properties of the food, and have largely been introduced via anecdotal evidence, arbitrary definitions, and loose correlation. This does not mean it is wrong to use these terms; however, it is important to be aware of the fluidity of government policy and the general public's understanding and assumptions around the terms.

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It is also important to acknowledge that the FDA does not write laws regarding the improper use of terms, buzzwords, and implied claims, but it issues guidance as it receives new scientific research, opinion from industry experts, and public comment. For example, "organic" is one of the more common buzzwords that you see on labels and in advertising – but what does it mean? The FDA doesn't regulate what can be labeled "organic," but the USDA does have standard guidelines that can be found at: **ams.usda.gov/sites/default/files/media/Labeling%20Organic%20Products.pdf**

n addition, most of the synthetic processing aids and artificial ingredients that are allowed in conventional foods are prohibited in organic ones. There are more defined rules around what can be labelled organic and what can't be – but consumers throw around the term loosely, as do some food producers. For example, "grass-fed" is misleading, because while the cows could indeed be eating only grass, that doesn't necessarily mean they are being treated humanely or that they are any healthier for consumers. Some of the most common terms used on food labels that are confusing, misleading, or essentially meaningless are:

- Multi-grain
- No trans fat
- Reduced sodium
- Less fat
- Made with extra fiber

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The first term, "multi-grain," makes no distinction of how many grains, the nutritional content, or the health benefit of consuming multiple types of grain. From these observations, the same logic of extracting meaning (or lack thereof) from marketing terms can be used.

– 2016 Definitions of "Healthy" and "Natural"

Generally speaking, the FDA considers the term "natural" to mean that nothing artificial or synthetic (including all color additives regardless of the source) has been included in, or has been added to, a food that would not normally be expected to be in that food. It is important to state that the definition the FDA has assigned to the term "natural" on food labels does NOT have any association with the nutritional, health, and/or safety aspects of the product. While the FDA does not directly make any rules or laws regarding the use of words such as "natural" or "healthy," they do issue guidance documents, as they do for most topics.

In 2016, Consumer Reports® submitted the results of a survey to the FDA calling for clarification on food labeling, safety standards, and consumer expectations. The FDA also received three petitions asking that the agency define the term "natural" for use in food labeling; one citizen petition requested that the agency prohibit the term

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"natural" on food labels. Additionally, the FDA notes that federal litigation involving genetically modified foods and foods containing high fructose corn syrup were contributing factors to the issuing of guidance. In a continued effort to educate consumers and product developers, Consumer Reports gives their own set of recommendations and ratings of labels and claims. This labeling overview can be found at: **consumerreports.org/food-labels/seals-and-claims**

– How to Determine if an Ingredient is Safe for a Product

Determining whether an ingredient is safe is only part of the product development process, but one of the most important. The FDA is the authority for pre-market approval and consideration of foods to be reasonably safe for human consumption based on current scientific evidence/experts in the field. This can happen several ways:

- General Recognized as Safe (GRAS) notice
    - Self-affirmed, scientific procedures or;
    - Experience based on common use in food prior to 1958
- Threshold of Regulation Exemption
- Food Contact Substance Notification

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A searchable database of information on ingredients submitted to the FDA for review by the Select Committee of GRAS Substances is available at: **accessdata.fda.gov/scripts/fdcc/?cat=foodingredpkg&type=basic&search=.** Beyond corroborating the use of a substance as an ingredient or additive, the FDA also determines what type of food it can be added to, how much will be typically consumed by the average American, and potential adverse health effects (acute vs. chronic exposure).

To better understand the regulatory framework of food and beverages in the Unit- ed States, reviewing the role the FDA plays as a public government institution and an overview of the process and the FDA's reach is valuable. The primary role of the FDA is to ensure that the food (apart from those regulated by the USDA) and food contact substances are "safe, wholesome, sanitary, and properly labeled."

Before any ingredient is "free" (without requiring submission and approval) to be added to food, it must undergo a safety review by experts (GRAS panel). The FDA is responsible for regulating and overseeing food, drugs, cosmetics, animal feed, and drugs as a part of the Federal Food, Drug, and Cosmetic Act (FDA&C Act). Additional emphasis should be made on animal feed and drugs, as it is a common misconception that these products are not covered by the FDA but do have risk of entering the human food supply. The FDA separates ingredients into categories such as preservatives, sweeteners, acidulants, etc. presented in the supplementary ingredient function

table provided by the FDA. All health and safety data associated with GRAS notices are freely available as part of the Freedom of Information Act. While the FDA acknowledges the organization cannot keep a complete list of all GRAS substances, they do keep a publicly available database of ingredients and process aids that have been introduced and submitted to the FDA since the FDA&C Act.

If a food and beverage company would like to meet (to the best of their ability) federal and local laws and regulations, they should follow one of these pathways: 1. General Recognized as Safe (GRAS) Notice, 2. Threshold of Regulation Exemption, 3. Food Contact Substance Notification. It is important to note that once a company or organization has fulfilled this requirement, the ingredient in question can be added to food by any company without requiring additional approval while following good manufacturing processes. Some requests become more ambiguous and complicated when a client wishes for a product to be considered organic, natural, kosher, gluten-free, or non-GMO.

– How Does SōRSE Define the Term "Natural"?

Not surprisingly, usage of the term "natural" has caused a large amount of confusion among consumers and industry professionals alike. When consumers see a product prominently labeled "natural," they can make several, often false, assumptions about the product. When a majority of people do not understand a label, or gain false insights

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om said label, companies run the risk of being accused of misleading consumers and misbranding products. In fact, Consumer Reports® again is trying to educate consumers of the lack of meaning the term carries.

It is for these reasons that SōRSE Technology seeks to be fluent in the regulatory environment and be capable of adjusting formulations and testing requirements as new guidance and regulations are drafted. SōRSE Technology recognizes that consumers often do prefer products that are marketed with buzzwords, but at the same time recognizes they can hold almost no meaning. A label characterizing a product as "natural" alone makes no distinction regarding the use of pesticides, animal feed and treatment, genetic engineering, or health benefits of a product. In fact, an animal product can legally be labeled "natural" without repercussions, even if it has been treated with drugs from antibiotics, growth hormones, or steroids.

SōRSE Technology has formulated its products in an effort to not mislead customers. When deciding which product offerings to classify as "natural" or "all natural," SōRSE Technology applies the following internal definition to either term interchangeably:

"A inished product derived from naturally occurring raw materials that were processed without modifying the native chemical structure of any of the raw materials."

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While we make every effort to remain up to date with federal definitions and guidance on the term "natural," it will ultimately be the responsibility of the customer to obtain independent regulatory and legal advice regarding the usage of ingredients alongside a natural label or other ingredient claim.

– SōRSE Testing and Analytics

All ingredients in THC Essentials products powered by SōRSE are well-known in the industry with one exception: cannabinoid extracts. Since cannabis extract comes from agricultural material, not only does one have to look at the risks associated with the extract (including method of extraction), but also with the plant itself. With the plant, there may be heavy metals absorbed, pesticides, pathogenic bacteria, and the potential for molds to grow and produce a mycotoxin that can harm humans. With the extract, one will have to look at what solvents are used and see if there are any residues left over from those processes. Testing for all of these risks is important, along with defining what levels would require action on our part. Overall, SōRSE Technology uses information from Washington, California, and Colorado cannabis laws to help guide what potential risks are being looked at in the world of cannabis extracts, and SōRSE Technology does not use any raw materials that fall outside the specifications. SōRSE Technology is also a pioneering member of the Cannabis Analytical Science Program discussed in detail below. SōRSE Technology routinely tests for total cannabinoids of interest, potency, microbial contaminates and solvents in their finished products. This is the information

TESTING & STANDARDS

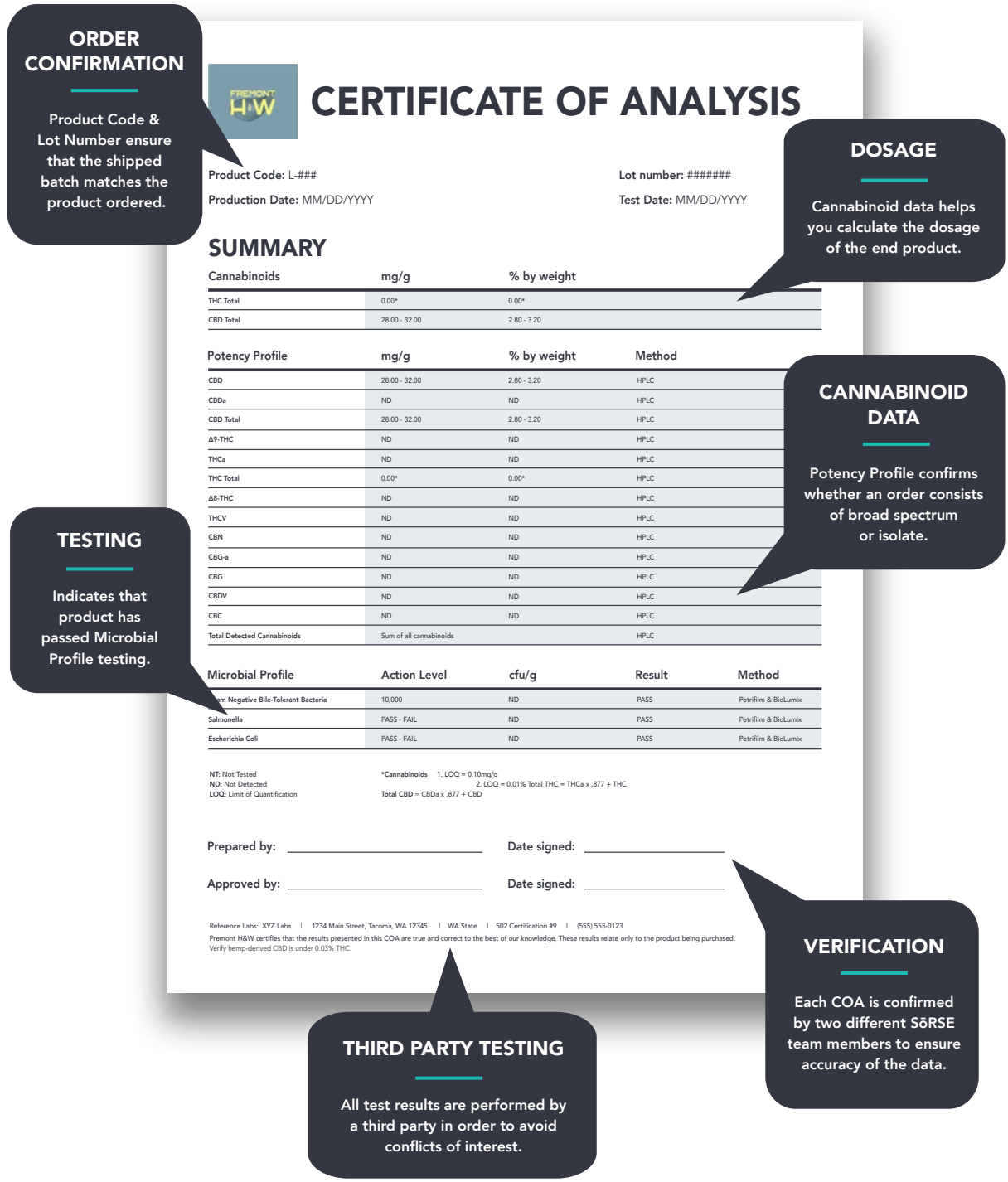

Figure 1: Example of COA structure and what to look for.

that goes on Certificate of Analysis, which they share with their customers, because that is the information they need in order to use SōRSE Technology's product. SōRSE Technology also analyzes the distribution of particle sizes in the emulsion and the turbidity of the product, and we track these tests over time to help define the quality of our product. Utilizing the analytical techniques at their disposal, SōRSE Technology has been able to define minimum quality control measures beyond standard FDA guidance on food ingredients, additives, and process aids. Some of these test results aren't passed on to all of their customers, but the tests are routinely performed to help better understand what is happening to their product over time, to make recommendations to clients, and to assure accurate labeling and dosing.

– What Product Testing Should Be Done?

While there is no regulatory guidance for THC containing products from the federal government, that doesn't mean there won't be in the future, with legalization and decriminalization legislation sweeping across the United States and full adult use legalization in Canada. As of March 2021, there are 27 states and the district of Colombia with some form of decriminalization, with a further 14 legalizing adult recreational use. With each state, territory and nation comes variations in policy. Inconsistent and contradicting regulatory standards could easily lead to quality and safety deficiencies that could have otherwise gone unaddressed under current local regulations.

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Following the passage of the 2018 Farm Bill, AOAC International launched the Cannabis Analytical Science Program (CASP) to discuss and develop standard methodologies and performance requirements for testing of cannabis and hemp products. Included in This includes products containing psychoactive cannabinoids and those that remain subject to the Controlled Substance Act such as Δ9-THC, the most prevalent psychoactive cannabinoid.

Within CASP, several working groups have been formed that include members of SōRSE Technology, GW Pharmaceuticals, PerkinElmer, and MilliporeSigma, among other industry leaders. Currently, five AOAC working groups are developing standards for analytical methodology under CASP:

1. Microbial Contaminants
2. Chemical Contaminants
3. Cannabinoids in Consumables
4. Training and Education
5. Proficiency Testing

One of the invaluable tasks of the working groups is to develop Standard Method Performance Requirements (SMPR®). Consensus on performance requirements of a method is critical for successful method development. The process of drafting an SMPR

usually requires several months, and several meetings and conference calls. An SMPR drafted by a working group is presented to a stakeholder panel. A stakeholder panel may revise, amend, or adopt a proposed SMPR on behalf of AOAC.

SōRSE Technology and the Quality Analytics group have been heavily involved in this process and are willing to conduct any testing that has been found to play a role in consumer health, safety, and comfort with safeguards in place for products and ingredients.

– Challenges That Cannabis Testing Labs Face, and How Manufacturers Should Select Third-Party Testing Labs

Testing of cannabis products is still in its infancy in much of the world and is plagued by inconsistent testing and difficulties in reproducibility, inconsistent methodologies, and often unknown product formulation that only further complicate analysis. Additionally, variations in the product matrices (i.e. is the cannabinoid in a solid matrix such as a chocolate or other confectionary versus a liquid matrix like a beverage) often require different preparation and analytical methods. The proprietary aspect of many product formulations adds an extra layer of complexity.

For example, recovery of cannabinoids from a high sugar beverage with a lot of flavors and ingredients will be variable depending on method. The likelihood of variability in retrieval of the analyte of interest (Δ9-THC, CBD, etc) increases among

different processing methods. Inter-laboratory reproducibility can also be significantly impacted by sample processing. For example, a beverage with no sugar and minimal other ingredients may require less processing and clean-up than a beverage with a large amount of sugar, dissolved solids, and other ingredients.

In order to assure the most accurate and consistent testing results, a relationship should be made between manufacturers and third-party testing labs. Please see the Addendum at the end of the paper for questions to ask third-party labs.

– What Ingredients to Avoid, and FDA Guidance in 2021

Nutritional recommendations are fluid and regularly changing as new research comes to light. While the list of diets and foods trends that humans are exposed to is ever-growing, our understanding of the human diet is an incredibly complex subject with no quick answers. Current guidelines to a healthy diet include the following recommendations from the U.S. Departments of Health and Human Services:

1. Follow a healthy eating pattern across the lifespan. All food and beverage choices matter. Choose a healthy eating pattern at an appropriate calorie level to help achieve and maintain a healthy body weight, support nutrient adequacy, and reduce the risk of chronic disease.

2. Focus on variety, nutrient density, and amount. To meet nutrient needs within calorie limits, choose a variety of nutrient-dense foods across and within all food groups in recommended amounts.

3. Limit calories from added sugars and saturated fats and reduce sodium intake. Consume an eating pattern low in added sugars, saturated fats, and sodium. Cut back on foods and beverages higher in these components to amounts that fit with in healthy eating patterns.

4. Shift to healthier food and beverage choices. Choose nutrient-dense foods and beverages across and within all food groups in place of less healthy choices. Consider cultural and personal preferences to make these shifts easier to accomplish and maintain.

5. Support healthy eating patterns for all. Everyone has a role in helping to create and support healthy eating patterns in multiple settings nationwide, from home, to school, to work, to communities.

– Expected Test Results

The SōRSE Technology Platform uses only food grade materials from distributors and producers who have been vetted for quality consistency and compatibility with

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products. To ensure a consistent, safe, and stable product, SōRSE Technology utilizes third party analytical testing and internal verification.

SōRSE Technology only processes their products in audited food facilities that meet Global Food Safety Initiative standards. These standards are set to assure food safety that is achieved through continuous improvement activities and truly meet the needs of SōRSE Technology's international customers.

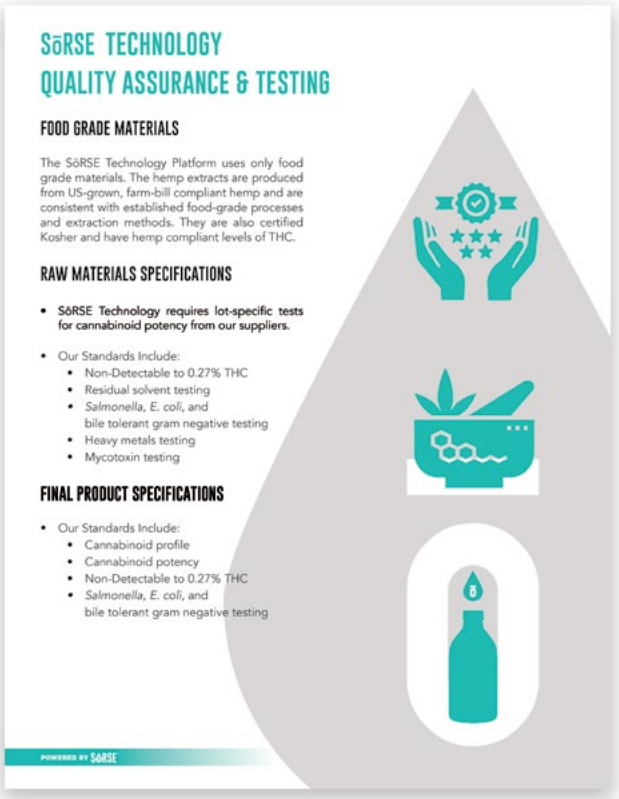

Figure 2: Example of Quality Assurance testing standards from SōRSE.

CONCLUSION

– Conclusion

A safe product that meets a company's needs is a central focus of SōRSE Technology. SōRSE Technology does not use ingredients that were produced using modern biotechnology. SōRSE Technology follows the USDA guidance and definition of bioengineered ingredient (7 CFR §66.1) as a "substance that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature." The USDA also maintains a List of Bioengineered Foods (7 CFR §66.6). When possible, SōRSE Technology does not use ingredients derived from agricultural products found in the List of Bioengineered Foods. Should we need to use an ingredient derived from a food on the list, we will be sure to source a non-bioengineered strain.

Additionally, SōRSE Technology is aware of California Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986. The Act provides a chemical list of substances known to the State of California to contribute to cancer or reproductive toxicity. None of the substances listed by the State as a possible cause of cancer are added to SōRSE Technology's products, nor do they believe that any non-naturally occurring chemical substances listed under this legislation are present in the products. The complete list can be found at **oehha.ca.gov/proposition-65/proposition-65-list**

CONCLUSION

Beyond bioengineered foods and Prop 65 substances, SōRSE Technology has also conformed to the FDA Food Safety Modernization Act (FSMA) and has taken necessary steps to offer Kosher, allergen-free, and natural label compliant products. SōRSE Technology's other GMP (Good Manufacturing Practice) Production Standards include: Certificate of Analysis (COA), GRAS (Generally Recognized as Safe) ingredients, and SQF (Safe Quality Food). Whether the goal is a clean label that can honestly be branded "natural" without misleading consumers, or focusing on a safe, consistent, and shelf stable product displaying Kosher certification, SōRSE is the solution.

REFERENCES AND USEFUL LINKS

U.S. Senate Select Committee on Nutrition and Human Needs. Dietary Goals for the United States, 2nd ed. Washington, DC, U.S. Government Printing Office, 1977.

https://oehha.ca.gov/proposition-65/proposition-65-list

https://www.ams.usda.gov/sites/default/files/media/Labeling%20Organic%20Products.pdf

https://www.accessdata.fda.gov/scripts/fdcc/?cat=foodingredpkg&type=basic&search=

Food Label Guide

http://sorsetech.com/wp-content/uploads/2020/02/Food-Label-Guide-1.pdf

Labeling Organic Products

http://sorsetech.com/wp-content/uploads/2020/02/Labeling-Organic-Products.pdf

If Two Products Have the Same Nutrition Facts Panel, Which Is Healthier?

http://sorsetech.com/wp-content/uploads/2020/02/context-influence-1500px.jpg

What Consumers Think "GRAS" Means

http://sorsetech.com/wp-content/uploads/2020/02/What-consumers-think-GRAS-Means-.pdf

ADDENDUM: QUESTIONS TO ASK

– Questions To Ask Third-Party Testing Labs

At the moment, cannabis regulations are being developed independently in different jurisdictions. Therefore, anyone producing products for human consumption should adhere to and become familiar with their local laws and testing requirements and consult legal advice when appropriate. Once familiar with the current legal landscape and the type of testing requirements for your product category, the next step is to start growing a relationship with a third-party testing laboratory. The following are a number of questions and potential answers useful in beginning the lab screening process.

Question: What analytical technique do you use for determining cannabinoid content/potency?

1. Chromatography/ Liquid chromatography with UV detection
    a. HPLC (High Performance Liquid Chromatography)
    b. UHPLC (Ultra High Performance/pressure chromatography)
2. LC-MS (Liquid Chromatography–Mass spectrometry)
3. Gas Chromatography-Mass spectrometry (GS-MS)

High performance liquid chromatography is the prominent technique for determining cannabinoid content. This technique relies on comparison of retention times to known analytical standards.

ADDENDUM: QUESTIONS TO ASK

Question: What type of products do you routinely test?

Possible answers include the general categories:

1. Cannabis derived materials:
    a. Cannabis plant material: Plant material from Cannabis spp. and its chemical varieties or "chemovars."
    b. Cannabis derivatives: Products or extracts derived from cannabis plant material.
2. Dried plant material/flower: Dried whole or milled flower plant material from Cannabis sativa and its hybrids.
3. Concentrates: A product resulting from chemical or physical processing of cannabis sativa or any of its hybrids, largely free of solvents with cannabinoid content higher than the starting material. (**https://www.aoac.org/wp-content/uploads/2020/11/SMPR202017_001.pdf**)
4. Topicals: Cannabis products such as lotions, creams and ointments that are to be applied to the skin.
5. Edibles:
    a. Solid matrix edibles, such as chocolates, confectionaries, and other solid "food" type products.
    b. Liquid edibles such as infused water, carbonated and non-carbonated soft drinks, juice, coffee, tea, etc.
6. Other non-edible products: shampoo, bath bombs, etc.

ADDENDUM: QUESTIONS TO ASK

Follow-up Question: What experience do you have testing different product types/matrices?

Answers: The answers labs give can give you an idea how well suited the lab is to analyze a specific product and analyte. Some typical responses are:

1. We only test flower and concentrates.
2. We test flower/concentrates, and edibles.
3. We test flower/concentrates, edibles and some beverages.
4. We regularly test beverages, edibles, and concentrates for common cannabinoids.

These responses can give a general idea of how easy (initially) it will be to work with a third part lab. It should be noted that a lab may only tests flower and concentrates as a result of less beverages and or edibles available nearby. That same lab may have the technical knowledge and equipment readily available. Similarly, a response like (4) shows that a lab may be more prepared to work a product into their testing workflow. This response however shows nothing else about how accurate and repeatable the results will be or how "good" of a fit a lab will be for a product.

ADDENDUM: QUESTIONS TO ASK

Follow-up Question: How are samples processed; do you process all samples the same way?

Answer: Beverages and liquid samples are analyzed for cannabinoid potency are filtered and injected to the column.

- Increased background
- Low retrieval
- Complex and viscous matrices may clog or decrease the lifespan of the column
- May lead to co-elution of analytes

A QuEChERS extraction with dispersive solid phase extraction clean-up is used with most liquid beverages, tinctures, emulsions and suspensions.

- Commonly used sample prep method for analyzing pesticides and can be applied to many polar analytes and complex matrices. (https://www.agilent.com/cs/library/eseminars/Public/QuEChERS_101_10_11_01.pdf)
- Samples are diluted in a polar solvent such as acetonitrile.

ADDENDUM: QUESTIONS TO ASK

Question: What method of extraction is the lab using?

Answers:

1. Solid phase extraction
    a. Selective
    b. Effective with variety of matrix
    c. High reproducibility
    d. High recoveries

2. Liquid-liquid extraction
    a. Labor intensive
    b. Formation of emulsion
    c. Less sensitive
    d. Considerable waste

3. No extraction/isolation, samples run straight or only diluted with solvent.

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ADDENDUM: QUESTIONS TO ASK

– Questions to Ask if You Get Inconsistent or Contradictory Results

Question: What is the limit of quantification/limit of detection?

PARAMETER	THC, THCA, CBDA, CBD	OTHER MINOR CANNABINOIDS
Limit of quantification (LOQ; %, w/w)	≤0.3	≤0.3
Analytical range (%, w/w)	≤0.3-ca. 100	≤0.3-ca. 50

Possible factors contributing to inconsistent or contradicting results:

- In the case of liquid chromatography, examples of typical variations are:
    - Influence of variations of pH in a mobile phase
    - Influence of variations in mobile phase composition
    - Different columns (different lots and/or suppliers)
    - Temperature
    - Flow rate

Follow-Up Questions:

- How frequently do you run calibration curves/verify calibration?
- What is the age of the LC-column/ stationary phase?

ADDENDUM: QUESTIONS TO ASK

- Do expected potency levels fit on the calibration curve vs extrapolating concentration?
- What analytes do you regularly test for?
- What analytes do you have verified methods for?
- What analytes do you routinely quantify?
- What reference material do you use?

-

Reference Suppliers:

- Restek
- Cerilliant
- Sigma-Aldrich
- API Standards
- Echo Pharm
- Lipomed AG
- Cayman Chemical

Helpful links:

https://www.restek.com/row/chromablography/chromablography/cbd-infused-beverages-the-recovery-dilemma/

https://www.restek.com/row/chromablography/chromablography/cannabis-potency-testing--calibration-curves/

IT'S CBD.
IT'S WATER-SOLUBLE.
IT'S SŌRSE™.

SōRSE Technology is a water-soluble emulsion technology designed for product developers to provide consumers with a better, more consistent cannabinoid experience with greater bioavailability, near-perfect dosing, shelf-stability, and safe ingredients. SōRSE's proprietary water-soluble emulsion infuses CBD and other functional ingredients into beverages, food items, topicals, and medical applications. SōRSE Technology currently powers more than 45 market-leading products in the CBD space.

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