

Re: Outline for 2019 USDA Interim Final Rule (IFR) Comment—*Rough Draft*

Author: Melissa Torres
 Founder, Heart *plus* Grit, LLC.
melissa@heartplusgrit.com

Introduction:

The single most impressive fact about hemp is that the plant generates close to zero waste. From flower to roots, hemp is a crop affording versatility to promote positive disruptions across multiple market channels. According to New Frontier Data, in consensus with other market researchers within the hemp industry, industry growth is expected to occur across the market channels outlined below in Figure 1 & Figure 2.

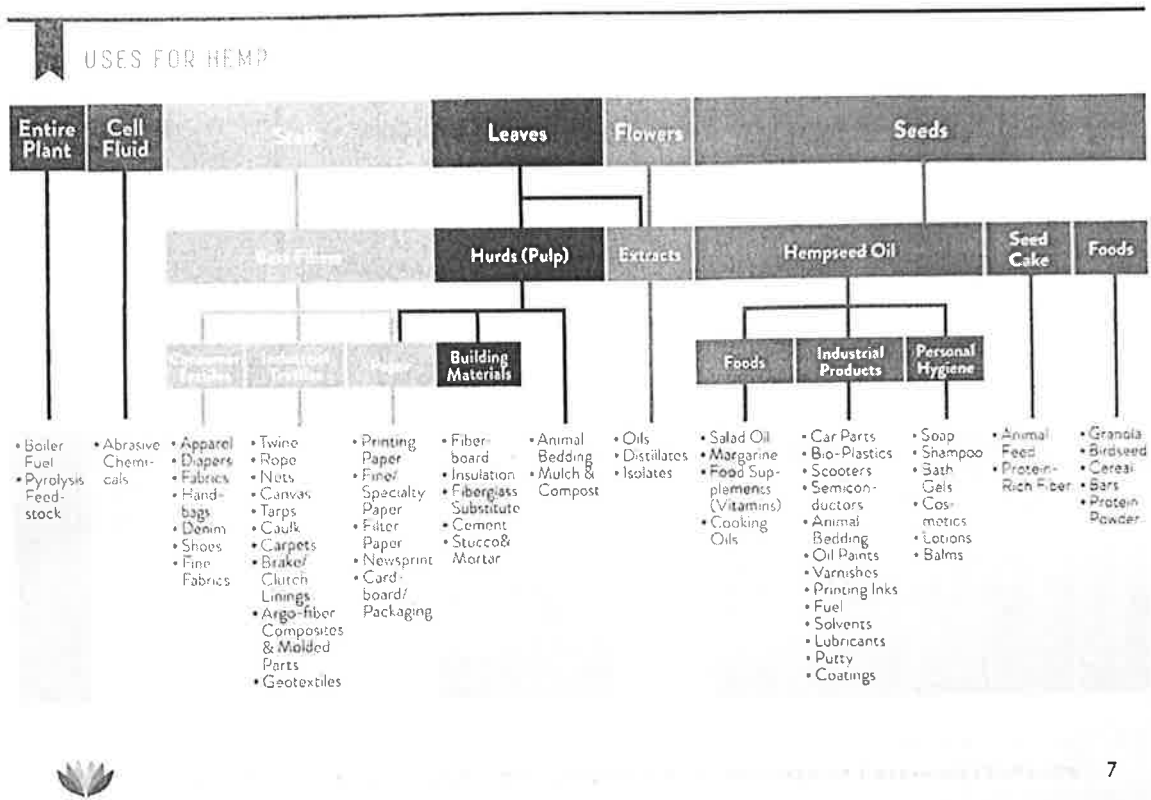


Figure 1. Uses for Hemp. Origin of figure photocopied from Hemp Business Journal’s (HBJ) market research report titled: The Global State of Hemp; 2019 Industry Outlook. (HBJ is a division of New Frontier Data)

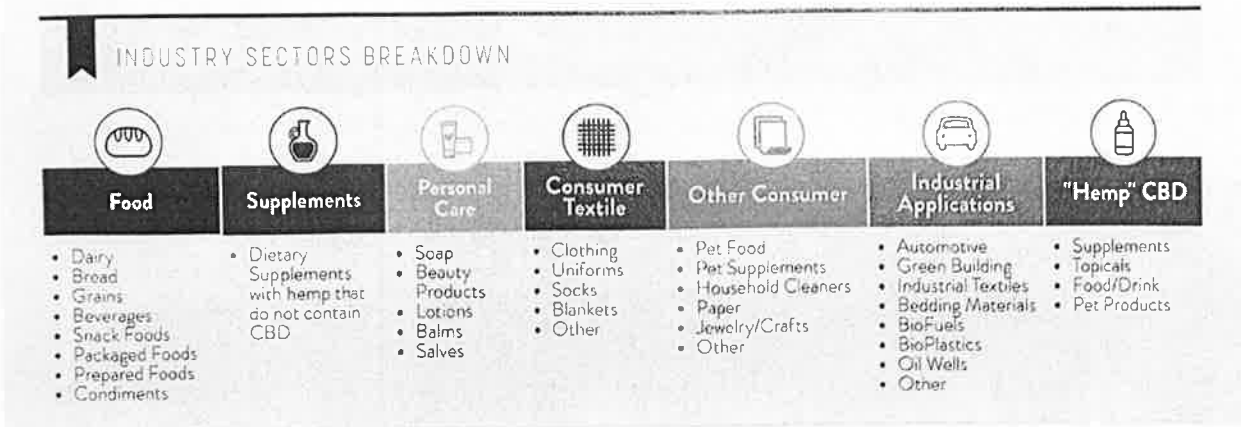


Figure 2. Uses for Hemp. Origin of figure photocopied from Hemp Business Journal’s (HBJ) market research report titled: **The Global State of Hemp; 2019 Industry Outlook.** (HBJ is a division of New Frontier Data)

Although hemp affords opportunities for industry growth throughout multiple channels, the hemp-derived CBD market is currently the highest competitive market within the industry. In 2018, the United States was reported to lead the hemp-derived CBD market world-wide (Table 1). However, the newly issued Interim Final Rule (IFR) presents not only an asphyxiation of potential growth for other market channels within the hemp industry, the rules also complicate the hemp-derived CBD market in ways that may not be necessary to the regulatory extent prescribed in the IFR.

Market Channels	Global Market Leaders
Textiles	China
Industrial Applications	Europe
Hemp Food (Non-CBD)	Canada
Hemp-derived CBD Market	USA

Table 1. 2018 Global Competitors of Hemp Industry. The United States was reported to lead in hemp-derived CBD markets throughout the world.

The task of drafting rules to regulate the production of hemp, given the versatility of the crop, could have not come easy for the USDA. The opportunity to comment on the IFR and provide feedback is recognized by many as a testament of the USDA’s efforts to evaluate

concerns and interpretations within IFR that may negatively affect the industry not just the hemp-derived CBD market, but for all potential market channels.

After analyzing the IFR, there is no question as to the central issue:

Differentiation of Hemp from:

1. *Marihuana*
2. *Marijuana*

Branching out from this central issue are all other concerns with the IFR which include required theoretical laboratory testing methods and 15-day harvest testing requirement windows—all of which are being argued in this document as unnecessary if a reasonable differentiation of hemp from both marihuana and marijuana can be established on tangible data rather theoretical “worst case scenarios” that are not being captured in the data collected within the industry.

In efforts to delineate distinctions across the three terms cross-comparative analyses were made by referencing definitions outlined within the 2018 Farm Bill (ie. 2018 Agricultural Improvement Act; amendment to Agricultural Marketing Act of 1946), The Controlled Substances Act (CSA), and the Congressional Research Service (CRS) “Defining Hemp: A Fact Sheet” publication (March 22, 2019).

The biggest hurdle with differentiating hemp from the CSA Schedule I list of plants within the cannabis genus is delta-9 tetrahydrocannabinol (delta-9 THC) psychoactive compound found in substantially higher amounts for the latter “non-hemp” cannabis plants. The recognition of the lower delta-9 THC threshold was established within the 2018 Farm Bill. Additionally, hemp-derived THC was *excluded* from being grouped with “marihuana” in section 12619 of the 2018 Farm Bill:

SEC. 12619. CONFORMING CHANGES TO CONTROLLED SUBSTANCES ACT.

(a) In General.--Section 102(16) of the Controlled Substances Act (21 U.S.C. 802(16)) is amended--

(1) by striking `` (16) The'' and inserting `` (16) (A)

Subject

to subparagraph (B), the''; and

(2) by striking ``Such term does not include the'' and inserting the following:

``(B) The term `marihuana' does not include--

``(i) hemp, as defined in section 297A of the Agricultural

Marketing Act of 1946; or
 `` (ii) the''.

(b) Tetrahydrocannabinol.--Schedule I, as set forth in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)), is amended in subsection (c) (17) by inserting after ``Tetrahydrocannabinols'' the following: ``, except for tetrahydrocannabinols in hemp (as defined under section 297A of the Agricultural Marketing Act of 1946)''.

Approved December 20, 2018.

[Reference text: Section 12619 of 2018 Farm Bill.]

Intuitively, marihuana and marijuana are considered by the general public as interchangeable words. However, legally they may be misinterpreted as slightly different from each other by respective definitions outlined for “marihuana” in the CSA and for “marijuana” in the IFR.

Term	Definition	Source
Hemp	SECTION 297A: “The term ‘hemp’ means the plant “ <i>Cannabis sativa</i> L.” and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” SECTION...	2018 Farm Bill NOTE: No more than 0.3% delta-9 THC on dry weight basis.
Marihuana	“The term ‘marihuana’ means all parts of the plant <i>Cannabis sativa</i> L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant, and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does or include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from such plant, any other compound, manufacture, salt, derivative, mixture, oil, or cake, or the sterilized seed of such plant which is incapable of germination.”	(CSA--21 U.S.C. Section. 801) NOTE: No established THC threshold.
Marijuana	“As defined in the CSA, ‘marihuana’ means all parts of the plant <i>Cannabis sativa</i> L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. The term ‘marihuana’ does not include hemp, as defined in section	2019 IFR

	<p>297A of the Agricultural Marketing Act of 1946, and does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, divative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber oil, or cake, or the sterilized seed of such plant which is incapable of germination (7 U.S.C. 1639o). <u>‘Marihuana’ means all cannabis that tests as having a concentration of level THC on a dry weight basis or higher than 0.3 percent.’</u></p>	<p><u>NOTE: The final sentence within the definitions was added and NOT found within previous definitions outlined in the CSA and 2018 Farm Bill.</u></p>
<p>Cannabis</p>	<p>“A genus of flowering plants in the family of Cannabaceae of which <i>Cannabis sativa</i> is a species, and <i>Cannabis indica</i> and <i>Cannabis ruderalis</i> are subspecies thereof. Cannabis refers to any form of the plant in <u>which the delta-9 tetrahydrocannabinol concentration on a dry weigh basis has not yet been determined.</u>”</p>	<p>2019 IFR</p>

Table 2. Definitions and References. Hemp, marihuana, and marijuana definitions by source were evaluated. Cannabis was also added in this table for further cross comparisons.

The insertion of sentences that do not appear within the CSA for “marihuana” are misleading and will most likely add further confusion to and misinterpretation by “producers” who are ultimately held liable within the IFR. The additional sentence defining “marijuana” now generates a newly defined term for a slightly different spelling that slightly circumvents the explicit directive within the 2018 Farm bill to “strike hemp” from the CSA:

In consideration of the references within Table 2 and Table 3, the CRS interpretation and definition of hemp fall in line with the views expressed in this comment. In their report, the CRS points out the distinction of hemp “in several key way: (1) statutory definitions and regulatory oversight, (2) chemical and genetic compositions, and (3) production practices and use.”

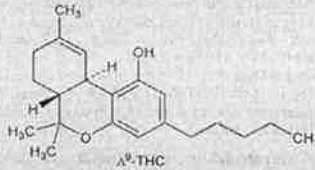
USDA 2019 IFR	Hemp Total THC vs Delta-9 THC	CRS 2019 Hemp Fact Sheet
Basis for total THC to be tested is for the genus Cannabis.	Statutory definitions	Basis for delta-9 consideration due to chemical and genetic compositions with species subspecies sativa L.
THCA and Delta-9 THC	Analytical definition	Delta-9 THC only
AMA; CSA; FFDCA <small>(FFDCA=Federal Food, Drug, and Cosmetic Act)</small>	Primary US Laws	AMA; FFDCA
USDA; DEA; FDA	Primary Federal Agencies with Regulatory Oversight	USDA; FDA
Flower	Plant part used	Fiber, seed, and flower

Table 3. Adaptation of CRS “Differences Between Hemp and Marijuana.” Abbreviated version of differences the CRS outlined in their March 22, 2019 report—“Defining Hemp: A Fact Sheet.”

The three “key” delineating factors the CRS pointed out were based on the 2018 Farm Bill’s legal definition of hemp. The role of CRS is to provide the service of federal congressional research. Yet, the IFR regulations seemed to deviate from the CRS report published after the 2018 Farm Bill was signed. Specifically, as outlined in Table 2, the IFR’s interpretation of hemp re-encapsulates hemp’s THC into CSA by rationalizing the hemp’s genetic, and not phenotypic, similarities for the cannabis genus.

The IFR goes even further to express concerns with potential decarboxylation of the inactive molecule tetrahydrocannabinolic acid (THCA). Although recognized by the IFR as not being the same molecule, the only active molecule legally defining hemp is Δ-9 THC. Figure 3 is provided to reinforce the molecular properties of THC recognized within the CRC Handbook of Chemistry and Physics. There is no mention of THCA or its potential to convert (decarboxylate) into THC.

also been identified. Isolin from cannabis resin: H. J. Vollner *et al.*, *J. Am. Chem. Soc.*, **64**, 26 (1942). Isolin and structure of Δ^9 -THC: Y. Gaoni, R. Mechoulam, *ibid.*, **86**, 1646 (1964). Isolin of Δ^9 -THC: R. L. Hively *et al.*, *ibid.*, **88**, 1832 (1966). Abs config of (-)-*trans*- Δ^9 isomer: R. Mechoulam, Y. Gaoni, *Tetrahedron Lett.*, **1967**, 1109. Stereospecific synthesis of Δ^9 - and Δ^8 -THC: R. Mechoulam *et al.*, *J. Am. Chem. Soc.*, **89**, 4552 (1967); of Δ^9 -THC: R. K. Razden *et al.*, *ibid.*, **96**, 5860 (1974); *idem*, *Experientia* **31**, 16 (1975). IR, NMR, MS data: T. Petrzilka, C. Sikemeier, *Helv. Chim. Acta* **50**, 1416, 2111 (1967). Toxicity studies: H. Rosenkranz *et al.*, *Toxicol. Appl. Pharmacol.*, **28**, 18 (1974); H. Yoshimura *et al.*, *J. Med. Chem.*, **21**, 1079 (1978). Clinical experience with Δ^9 -THC in chemotherapy induced nausea and vomiting: D. S. Postel *et al.*, *J. Am. Med. Assoc.*, **245**, 2047 (1981); as appetite stimulant in AIDS-associated anorexia: J. E. Beal *et al.*, *J. Pain Symptom Manage.*, **14**, 7 (1997). Chromatographic determin in cannabis products: L. Vollner *et al.*, *Regul. Toxicol. Pharmacol.*, **6**, 348-358 (1986). GC/MS determin in hair: M. J. Baptista *et al.*, *Forensic Sci. Int.*, **128**, 66 (2002). Review of pharmacology: W. L. Dewey, *Pharmacol. Rev.*, **38**, 151-178 (1986); of pharmacokinetics and metabolism: F. Grotenhemmen, *Clin. Pharmacokinet.*, **42**, 327-360 (2003).



(-)-*trans*- Δ^9 -Form, [1972-08-3] (6a*R*,10a*R*)-6a,7,8,10a-Tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[*b*,*d*]pyran-1-ol; (-)- Δ^9 -3,4-*trans*-tetrahydrocannabinol; Δ^9 -THC; Δ^9 -THC, dronabinol; QCD-84924; Marinol. C₂₁H₃₀O₂; mol wt 314.47. C 80.21%, H 9.62%, O 10.18%. Light yellow resinous oil; hardens upon refrigeration. bp_{0.02} 200°. [α]_D²⁰ -150.5° (c = 0.53 in CHCl₃). uv max (ethanol): 283, 276 nm (log ϵ : 3.21, 3.20). pKa 10.6. Essentially insol in water. LD₅₀ (sesame oil emulsion) in male rats (mg/kg): 890 orally; 35.5 i.v.; 672 i.p. (Rosenkranz). (-)-*trans*- Δ^9 -Form, [1972-08-3] (6a*R*,10a*R*)-6a,7,8,10a-Tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[*b*,*d*]pyran-1-ol; (-)- Δ^9 -3,4-*trans*-tetrahydrocannabinol; Δ^9 -THC; Δ^9 -THC, bp_{0.02} 200°. [α]_D²⁰ -264° (c = 0.11 in CHCl₃). uv max (ethanol): 283, 276 nm (log ϵ : 3.21, 3.20). pKa 10.6. Essentially insol in water. LD₅₀ (sesame oil emulsion) in male rats (mg/kg): 890 orally; 35.5 i.v.; 672 i.p. (Yoshimura).

Figure 3. 15th Edition 15-Ec. CRC Handbook of Chemistry and Physics: Tetrahydrocannabinols (THC). The identification of THC as defined by the CRC Handbook of Chemistry and Physics classifies only the “active” compounds as Δ -9 THC and Δ -8-THC. The handbook does not include THCA, the carboxylated inactive compound naturally found in hemp and other plants within the *Cannabaceae* family.

The IFR came to the requirement of total THC testing, which means the value of both THC and THCA together, because of hemp’s taxonomy. The genus—cannabis—was the reason the IFR encapsulated hemp and its cannabinoids under DEA testing regulations of the hypothetical conversion of THCA into delta-9 THC. The “potential” described in the IFF shares little to no resemblance of tangible data generated within the hemp industry. The inverse relationship of altering hemp’s natural state into the unnatural “induced” marihuana/marijuana states is more like the case given the data that exists within the industry.

SUPPLEMENTAL DATA:

Distribution of % Δ9-THC in Hemp Flower

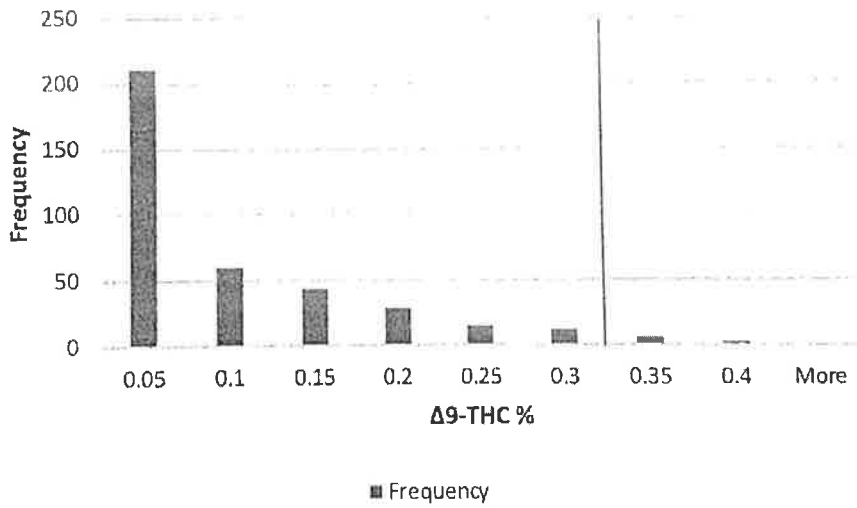


Figure 4. Clearwater Biotech ISO HPLC Δ-9 THC Distribution: Actual Yields. Histogram of Δ-9 THC results for 380 hemp samples tested by HPLC methods within an ISO accredited lab. HPLC testing demonstrated abundance of natural Δ-9 THC levels to fall well below the 0.33% Δ-9 THC threshold for actual samples within the 2018-2019 seasons.

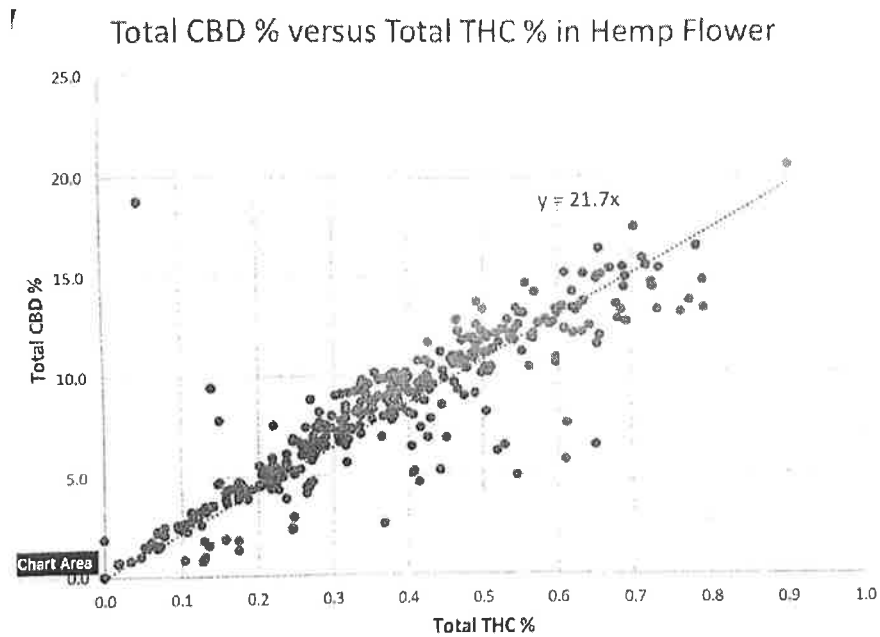


Figure 5. Clearwater Biotech ISO HPLC: Total CBD vs Total THC—Theoretical Yields. Using the calculations for proposed IFR theoretical reporting criteria (for THC), Dr. Snyder demonstrated the correlation between total CBD and THC where total THC at a 0.33% threshold would mean that current genetics would limit

the total CBD potencies to no more than approximately 8-10% total CBD if total THC levels above 0.5% are considered negligent by law.

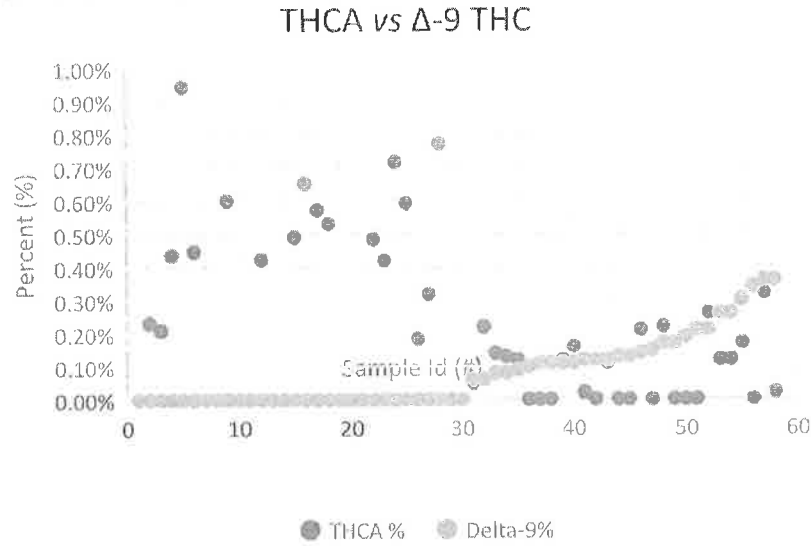


Figure 6. Oregon Preliminary Δ-9 THC vs THCA Actual Yields. Of the 57 samples collected to see if preliminary evaluation of Δ-9 THC would share a similar trend as seen for Clearwater Biotech for yields of Δ-9 THC in its natural state. All samples evaluated fell under the 0.50% limit for Δ-9 THC. Approximately half of the samples collected had Δ-9 THC levels below limits of detection. The remaining samples had higher Δ-9 THC where laboratory “drying” methods could not be eliminated as suspect of “decarboxylating” THCA into Δ-9 THC.

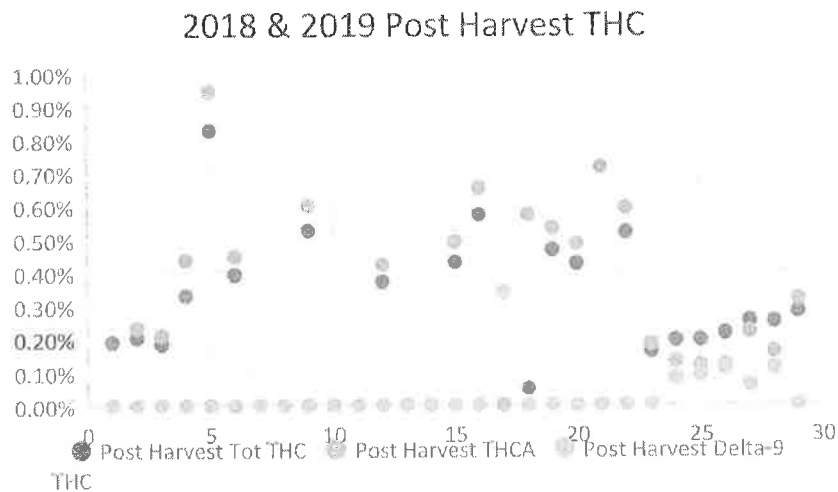


Figure 7. Post-Harvest Hemp Actual Yields. A total of 29 samples demonstrating the differences for total THC, THCA, and Δ-9 THC tested after harvesting 2018 & 2019 qualifying hemp. The same trend was seen for a subset of post-harvest samples where trends of laboratory specific increased Δ-9 THC occurred.

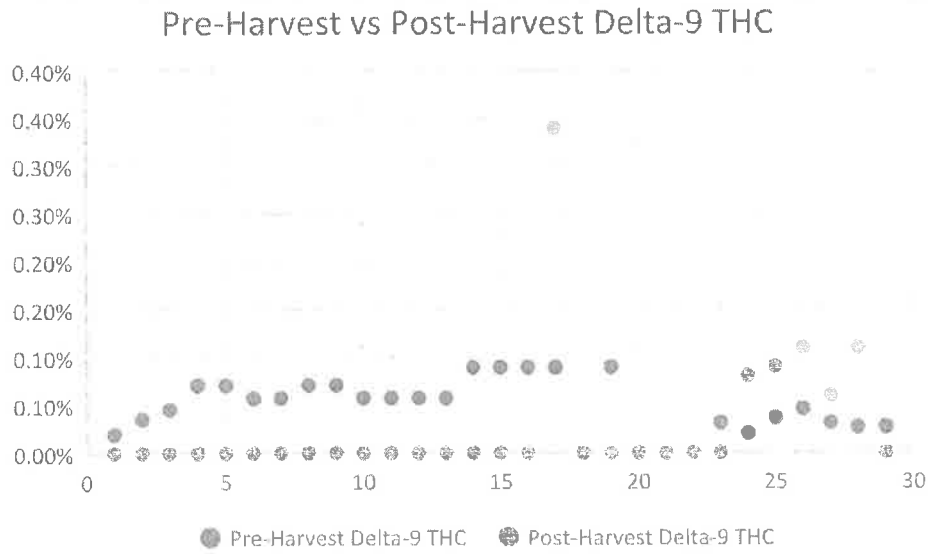


Figure 8. Pre-Harvest Post-Harvest Hemp Actual Yields. A total of 29 samples demonstrating the differences for Δ -9 THC tested before and after harvesting 2018 & 2019 qualifying hemp. The same trend was seen for a subset of post-harvest samples where trends of laboratory specific increased Δ -9 THC occurred.