

USDA Interim Final Rule on the Farm Bill

Facts, Preparation, and How You Can
Protect Your Business and Supply Chain



About Our Guest

Frank Robison is the Managing Attorney at Robison Law Group. Frank specializes in the cannabis (marijuana and hemp) industries focusing in the following areas:

- Customs Law and Import and Export Law
- Intellectual Property Commercialization and Protection
- Trademark, Brand Protection and Domain Name Law
- Hemp Law
- Tax Law

Prior to getting multiple law degrees, Frank had experience in technology and sales and also served in the Peace Corps. Frank is also fluent in Spanish. Frank is a Director at the Hemp Industry Association and a Director at the Hemp Industry Foundation.

What We'll Cover Today

- Highlights (and lowlights) of the Interim Final Rule
- How to protect yourself legally (and operationally)
- What this means to the hemp and CBD industry
- What you can do to prepare (short and long term)
- How this impacts your supply chain process and systems
- Tracking tests and documentation to ensure you are compliant
- Ensuring you meet regulatory and buyers expectations

**Disclaimer: opinions shared are not considered legal advice*

IFR: Landmark Day or Major Concern?

Congress intended to make the Whole Hemp Plant an Agriculture Commodity

- 15 day Testing Window? (4 mentions)
- Test Flower Only? (16 mentions)
- Labs Registered with DEA? (DEA, 7 mentions)
- Reports to the DEA? (**DEA, 42 mentions**)
- Banking? (2 mentions, and polemic guidance statement issued)
- Crop Insurance? (9 mentions)
- Certified Seed? (6 mentions)

Let it Grow: Destruction, Disposal and Documentation

§990.27 Non-compliant cannabis plants.

(a) ***Cannabis plants exceeding the acceptable hemp THC level constitute marijuana, a schedule I controlled substance*** under the Controlled Substances Act (CSA), 21 U.S.C. 801 et seq., and must be ***disposed of*** in accordance with the ***CSA and DEA regulations***.

- Title 21 CFR 1317.05

(b) Producers must notify USDA of their intent ***to dispose of*** non-conforming plants and ***verify disposal by submitting required documentation***.

SUMMARY:

Records are shared with the DEA.



Testing: From Hemp to CBD?

The USDA stated it would “punt” on post harvest related activities, but did it?

- “Percentage of THC on a “dry weight basis” means the percentage of THC, by weight, *in a cannabis item (plant, extract, or other derivative)*, after excluding moisture from the item.”
 - Moisture, “very small drops of water, either in the air or on a surface,” Cambridge Dictionary.
 - So where does this leave crude oil?
- The DEA and other agencies, local, state and federal, could/do take the position that crude hemp oil (over .3%) is marijuana. The USDA did nothing to alleviate this concern or massive legislative gap.
- If possible, process in close proximity to the harvested biomass to avoid crossing state lines.
- Verify traceability back to program/plan compliant hemp.

Records: What You Need to Know

(d) USDA inspectors, auditors, or their representatives shall have access to any premises where hemp plants may be held during reasonable business hours.

(e) All reports and records required to be submitted to USDA as part of participation in this program which include confidential data or business information, including but not limited to information constituting a *trade secret* or *disclosing a trade position*, financial condition, or business operations of the particular licensee or their customers, shall be received by, and at all times kept in the custody and control of, one or more employees of USDA or their representatives. Confidential data or business information may be shared with applicable Federal, State, Tribal, or local law enforcement or their designee in compliance with the Act.

Records include:

- Acquisition of hemp plants
- Production, handling and storage of hemp plants
- Disposal of hemp plants

(Keep records for 3 years)

Sampling to Test: What You Need to Know

Sample to Harvest: Work with the USDA

- Sampling is mandatory.
- Samples must be taken within 15 days prior to harvest.
- Hemp is a plant that has a target harvest date pending on many factors, many are unknown environmental.
- Lab Capacity.

We require clarity with respect to when you can sample, challenging test results and not having records implying the U.S. Farmers and other are growing Marijuana. .5% THC is just not enough

https://www.ams.usda.gov/rules-regulations/hemp/dea-laboratories?field_state_tid=All

Testing Regulations: The Flower

- Samples must be taken from flower material, but the rule does not specify which part of the flower material or contemplate a homogenized flower sample, equipment calibration, human experience with GS/HPLC tech, which will lead to inconsistent practices and results.
- The core market for flower is not *proactively and directly* regulated by the federal government.
- The USDA: Test the flower but the FDA hasn't gotten around to proactively regulating products that are typically made from flower and if you are off by 1,000 ppm because we are going through a process of stabilizing genetics/cultivars they may notify the DEA.

The Role of the DEA

The DEA is mentioned in the IFR approximately 45 times.

- “If a producer has produced cannabis exceeding the acceptable hemp THC level, the material must be disposed of in accordance with the CSA and DEA regulations because ***such material constitutes marijuana, a schedule I controlled substance under the CSA. Consequently, the material must be collected for destruction by a person authorized under the CSA to handle marijuana, such as a DEA-registered reverse distributor***, or a duly authorized Federal, State, or local law enforcement officer.”
- “The licensed producer must maintain information that supports, verifies, or documents information on all reports for a minimum of three years. This includes, but is not limited to, the producer’s completed criminal history report, any records of required disposal, notifications of THC test results, and the license. This new information collection proposes to create seven new forms.”
- “This information will be collected and maintained by USDA and made available in real time to Federal, state, and local law enforcement. “

Working with Registered Labs

- 21 CFR 1301 - REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES
 - 21 CFR 1301.13 “Any person who is required to be registered and who is not so registered, shall make application for registration for one of the following groups of controlled substances activities, which are deemed to be independent of each other . . . [List of Schedule I-V licenses registrations that reference Form 225.]”

What is the impact?

The IFR rules present grave challenges and extreme risks for the hemp industry as crops will likely fail to meet the total THC limit and it is far from certain that labs will have the capacity and competency to test the crops, at today’s product levels much less beyond.

Lab Registration Process

Form-225

APPLICATION FOR REGISTRATION Under the Controlled Substances Act

APPROVED OMB NO 1117-0012
FORM DEA-225 (04-12)
FORM EXPIRES: 9/30/2021

INSTRUCTIONS

Save time - apply on-line at www.deadiversion.usdoj.gov

1. To apply by mail complete this application. Keep a copy for your records.
2. Mail this form to the address provided in Section 7 or use the address provided in Section 8.
3. The "MAIL-TO ADDRESS" can be different than your "PLACE TO SEND THIS APPLICATION AND ATTACHMENTS" address.
4. If you have any questions call 800-882-9539 prior to submitting this application.

IMPORTANT: DO NOT SEND THIS APPLICATION AND ATTACHMENTS TO THE FOLLOWING ADDRESS:

DEA OFFICIAL USE:

MAIL-TO ADDRESS

Please print mailing address changes to the right of the address provided in Section 7 or use the address provided in Section 8.

SECTION 2

BUSINESS ACTIVITY

Check one business activity box only

Researcher - See page 4 for required attachments

- Analytical Lab.....fee for one year
- Researcher w/Sched I.....fee for one year
- Researcher w/Sched II - V.....fee for one year
- Canine Handler.....fee for one year
- Distributor.....fee for one year

SECTION 3

A. DRUG SCHEDULES

Check all that apply

Enter drug codes on page 2.

- List 1 (L1) - manufacturers & importers ONLY
- Schedule 2 Narcotic & Non-Narcotic
- Schedule 1
- Schedule 2 Non-Narcotic
- Check this box if you require official order forms - for Schedule 1 & 2

C. SCHEDULE AND DRUG CODES

Listed below are examples of schedules 1-5 and List 1 codes. Check all drug codes you handle as required.

For more information, see our website at www.deadiversion.usdoj.gov, 21 CFR 1308, or call **1-800-882-9539**.

| | | | |
|-----------------------|--|-------------------------------|---|
| Canine Handler | must mark schedule 1 | Distributor | must mark all schedule 1, drug code 2012 |
| Exporter | must mark all schedule 1-5 | Reverse Distributor | must mark all schedule 1, drug code 2012 |
| Importer | must mark all schedule 1-5 & List 1 codes | Researcher w/Sched 1 | must mark schedule 1 |
| Manufacturer | must mark all schedule 1, 2 & List 1 codes | Researcher w/Sched 2-5 | must mark schedule 2 to be manufactured or imported as part of research |

If you bulk manufacture a substance, check the 'BULK?' column after the applicable class code.

| SCHEDULE 1 NARCOTIC & NON-NARCOTIC | CODE | BULK? | SCHEDULE 2 NARCOTIC & NON-NARCOTIC | CODE | BULK? |
|--|------|-------|-------------------------------------|------|-------|
| 3,4-Methylenedioxyamphetamine (MDA) | 7400 | | Amobarbital (Amytal, Tuinal) | 2125 | |
| 3,4-Methylenedioxyamphetamine (MDMA) | 7405 | | Amphetamine (Dexedrine, Adderall) | 1100 | |
| 4-Methyl - 2,5 - Dimethoxyamphetamine (DOM, STP) | 7395 | | Cocaine (Methyl benzoylcegonine) | 9041 | |
| 4-Methylaminorex (cis isomer) (U4Euh, McN-422) | 1590 | | Codeine (Morphine methyl ester) | 9050 | |
| Alphacetylmethadol (except LAAM) | 9603 | | Dextropropoxyphene (bulk) | 9273 | |
| Bufotenine (Mappine) | 7433 | | Diphenoxylate | 9170 | |
| Marihuana / Cannabidiol | 7360 | | Fentanyl (Duragesic) | 9801 | |
| Diethyltryptamine (DET) (| 7434 | | Hydrocodone (Dihydrocodeinone) | 9193 | |
| Difenoxin 1MG/25UG ATSO4 /DU (Motofen) | 9167 | | Hydromorphone (Diauidid) | 9150 | |
| Dimethyltryptamine (DMT) | 7435 | | Levo-Alphacetylmethadol (LAAM) | 9648 | |
| Etorphine (except HCL) | 9056 | | Levorphanol (Levo-Dromoran) | 9220 | |
| Gamma Hydroxybutyric Acid (GHB) | 2010 | | Meperidine (Demerol, Mepergan) | 9230 | |
| Heroin (Diamorphine) | 9200 | | Methadone (Dolophine, Methadose) | 9250 | |
| Ibogaine | 7260 | | Methamphetamine (Desoxyn) | 1105 | |
| Lysergic acid diethylamide (LSD) | 7315 | | Methylphenidate (Concerta, Ritalin) | 1724 | |
| Mescaline | 7381 | | Morphine (MS Contin, Roxanol) | 9300 | |
| Marihuana | 7360 | | Opium, powdered | 9639 | |
| Methaqualone (Quaalude) | 2565 | | Oxycodone (Oxycontin, Percocet) | 9143 | |
| Normorphine | 9313 | | Oxymorphone (Numorphan) | 9652 | |
| Peyote | 7415 | | Pentobarbital (bulk) (Nembutal) | 2270 | |
| Psilocybin | 7437 | | Phencyclidine (PCP) | 7471 | |
| Tetrahydrocannabinols (THC) | 7370 | | Secobarbital (Seconal, Tuinal) | 2315 | |

Latest updates

1. Comments extended?
2. USDA talking to State Agriculture
3. Industry Associations Preparing Comments

What You Can Do

1. Work with entities accustomed to working with local, state **and federal law enforcement.**
2. 2014 is still in effect until next year.
3. Submit Comments about the IFR to State Ag and USDA.
4. Evaluate Legal Action, Not the Intent of Congress, Does Not Promote Market, Appears to Pass USDA/State Ag responsibility to DEA—SUPPORT U.S. FARMERS
5. Develop Standard Operating Procedures, Methods and Processes.
6. Traceability. Know the location of your Hemp

OUR HISTORY

Dreamweaver Launched

TJ Gupta and Manish Gupta leave SAP to start a track and trace integration consulting firm, serving major enterprises including J&J, Roche and Bristol Myers Squibb.

Paradigm Shift

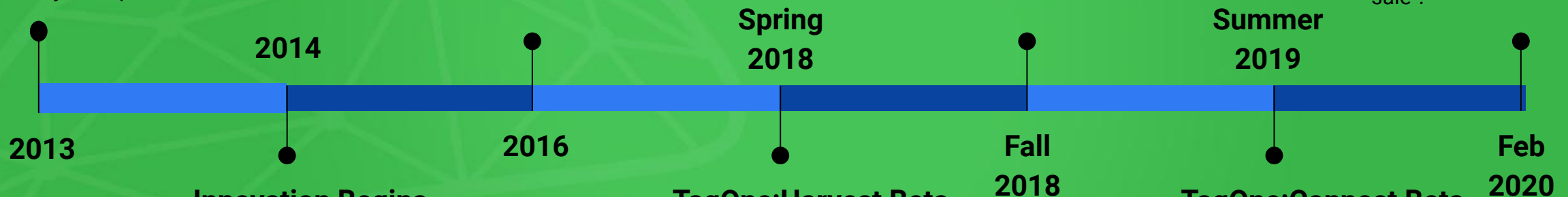
After family health issues, the team begins innovation in cloud and blockchain solutions for natural ingredients providing consumers with product source provenance.

TagOne:Enterprise Beta & Partner Pilot

Blockchain enabled cloud solution is launched and first ingredient supplier is onboarded.

Enterprise 2.0 for CBD

Framework modifications are completed to track hemp to CBD from "Seed to sale".



Innovation Begins

Recognizing that excessive investments were made on consultants, the team developed multiple technology solutions to simplify enterprise track and trace integration.

TagOne:Harvest Beta with SSCI

Collaboration with SSCI (Supplement Safety Compliance Initiative), a mobile/cloud technology was developed working with enterprises including GNC, Amazon and Walmart.

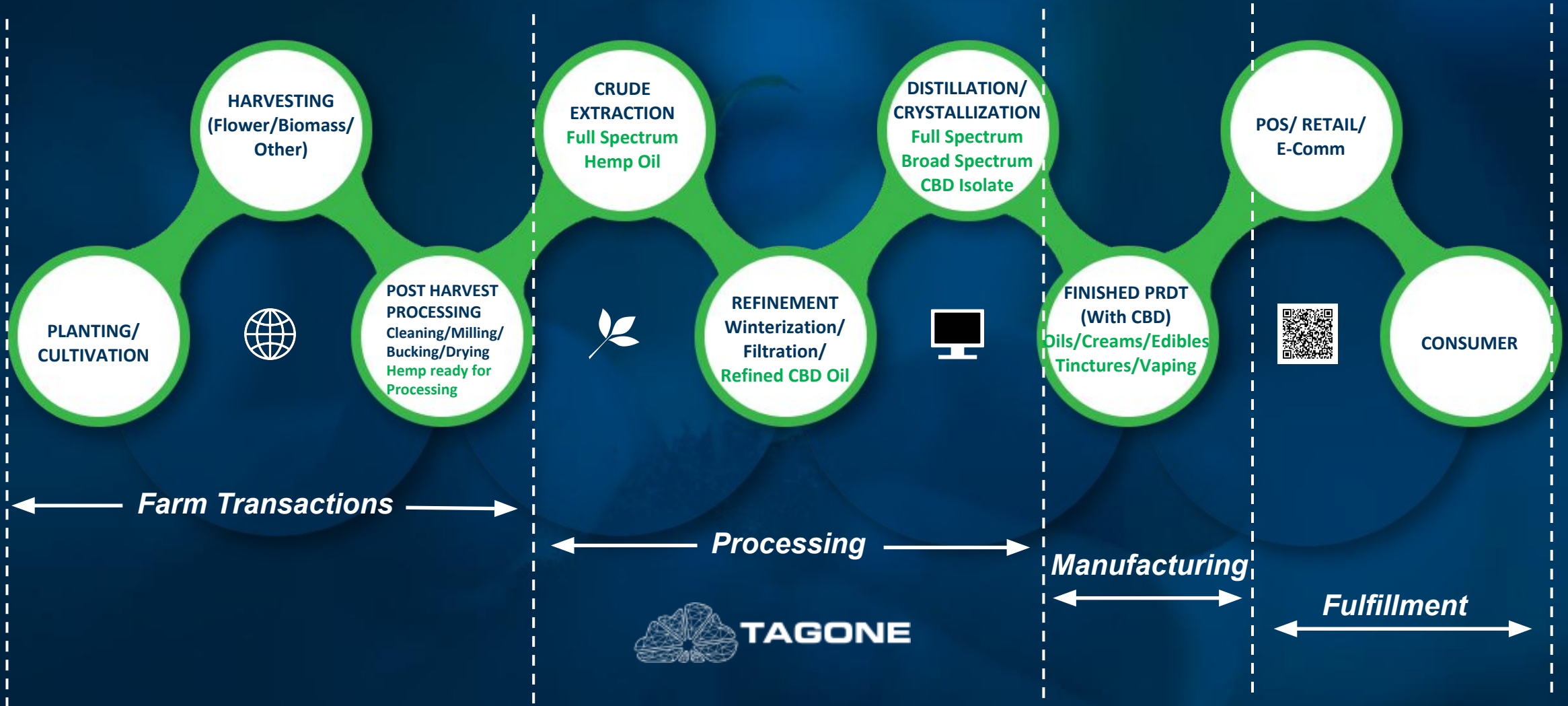
TagOne:Connect Beta

"Seed to sale" transparency is now possible with a QR code technology sharing science, source, safety and stories of brands.



Transparency in the CBD Supply Chain

Tight Supply Chain Integration is Key



Blockchain View of Product Movement

Immutable Ledger Tracks Key Data Elements from *Seed to Sale*



Cultivation

Grow (Seed or Clone)
Soil/Water/Fertilizer
Location (with photo)
Test

AND MORE

Harvest

Drying method
Biomass weight
Flower separation method & Lot#
Test

AND MORE

Extraction

Method (CO2, Ethanol, Other.)
Type (Full, Broad, Isolate, etc.)
Lot#
Test

AND MORE

Processing

Formulation Development
Delivery (Medical, Edible, Supplement, etc.)
Test
Lot # and Expiration
Distribution

AND MORE

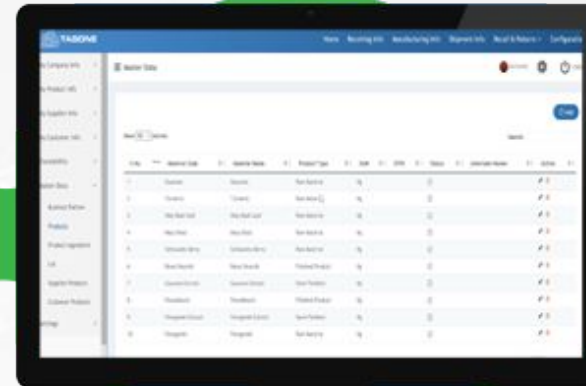
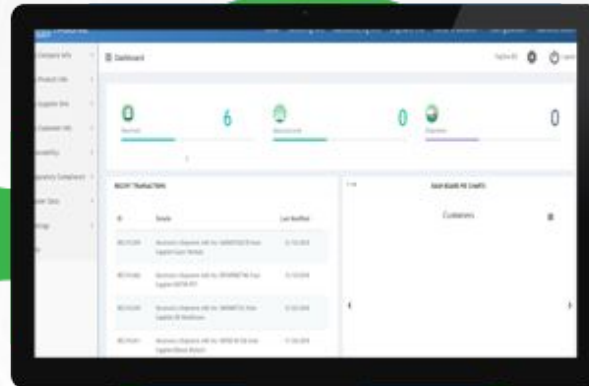
Consumer

Source
Safety (CofA)
Science (Quality)
Stories (Branding)
Lot # and Expiration

AND MORE

SIMPLIFYING COMPLEX TRANSACTIONS

The only solution capable of End to End (E2E) transparency from “Seed to Sale”



TagOne:Harvest

- Mobile application to help your farming partners capture key attributes.

TagOne:Enterprise

- Cloud, blockchain platform to track your suppliers, buyers, transactions, documentation and more!

TagOne:Connect

- iOS application allowing you to share the safety, science, source and story of your brand.

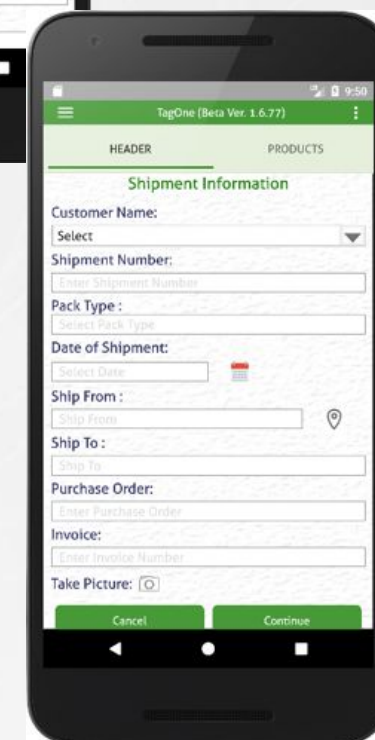
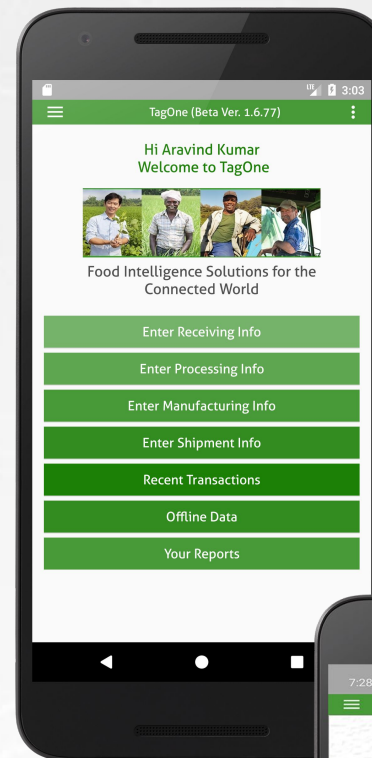
TagOne:Harvest

CAPTURING UPSTREAM DATA FROM YOUR HEMP FARM

- Detailed farm & farmer information
- Capture over 50 key attributes from Crop Management, Harvest & Post Harvesting
- Link Crop data to all your sales transactions downstream to enable E2E traceability
- Easy to fill data from drop down choices built on GFSI standards.
- Field tested in farms across the globe

Key Data Collected includes:

- Variety (seed or clone)
- Germination date
- Test data and documentation
- Water/ Soil/ Tool / Fertilizer Information
- Batch #
- Product Potency
- Yield
- and more!



TagOne:Enterprise

SAAS BASED PLATFORM FOR HEMP GROWERS AND CBD COMPANIES



E2E Traceability



Transaction tracking across your network +
Inventory Management



Document & Master data management



Central regulatory repository addressing Audit requirements

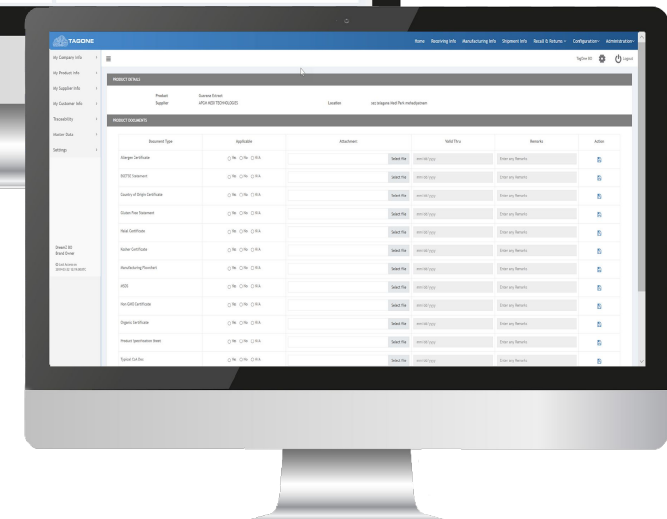
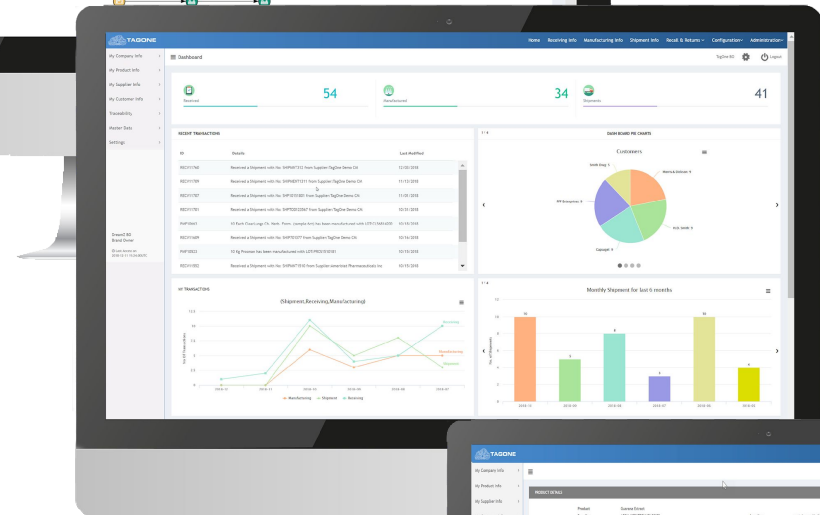
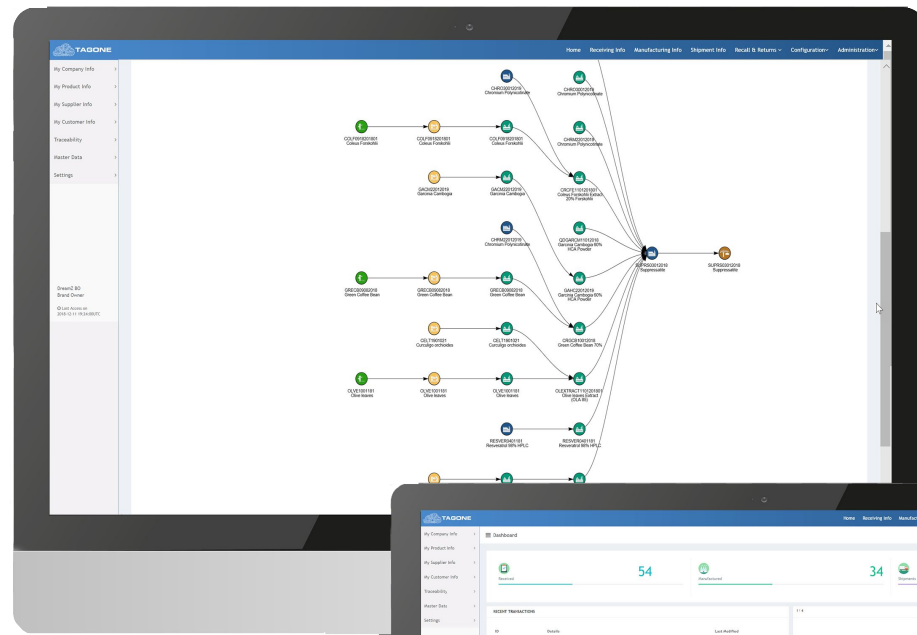


Ingredient quality management



Recalls & Returns

Every “Transformation” or “Change of Ownership”
event triggers a Blockchain posting

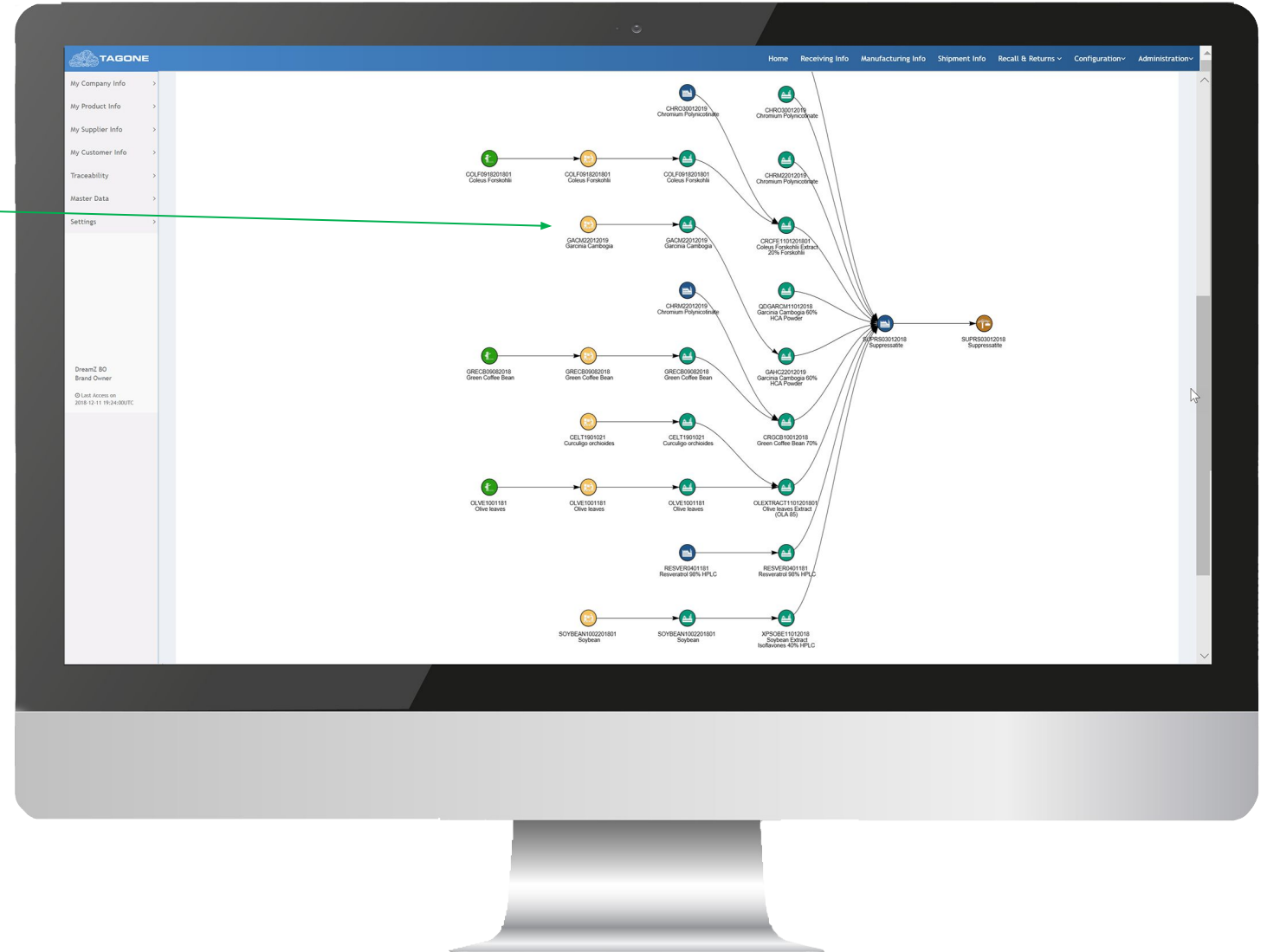


TagOne: Visual Map

TRACEABILITY REPORTING

Each node opens up based on a Blockchain query of the output and Provides:

- Supplier
- Transaction date
- Location
- Lot #





REDUCING RISK



**IMPROVING
OPERATIONAL
EFFICIENCY**



**BUILDING
CONSUMER
TRUST**

WHAT MOTIVATES TRANSPARENCY?

*A lack of transparency results in distrust
and a deep sense of insecurity*

- Dalai Lama

“Quality means doing it right when no one is looking.”

- HENRY FORD

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