Cosmetics Legislation in the USA and Canada

IKW Seminar November 22, 2019

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US Active Issues

- Proposed FDA **Cosmetics registration**
- FDA request for data on **12 SunscreensCalifornia/UV Filters**
- **Organic/Natural** Claims
- Ingredient listing/INCI names
- **Cannabidiol/CBD Oil**
- State regulations
  - Environmental
    - CARB
      - **Volatile Organic Compounds**, tonnage reduction deadlines
  - Human Health
    - OEHHA
      - **Proposition 65** latest developments
    - DTSC
      - "Green Chemistry"
      - **1,4-Dioxane** in groundwater
- **"Clean Beauty"** strategies with Retailers

US FDA

- Legislation continues to be presented that would require one or more of the following:
  - Registration of cosmetics (similar to CPNP)
  - Accountability for raw materials
  - User fees for
    - Manufacturer
    - Distributor
- Third time around for the introduction of legislation
- Likelihood of becoming law, short term and long term

US Sunscreen regulations Basics

Sunscreens (SPFs) are Drugs, not cosmetics.

Drug Facts

Active Ingredients	Purpose
Avobenzone 3% Homosalate 10% Octyl methoxycinnamate 7.5%	Sunscreen

Uses
- helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, **not** skin cancer or early skin aging.

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions
- apply liberally 15 minutes before sun exposure
- reapply:
  - after 40 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
- children under 6 months: Ask a doctor

Inactive ingredients

aloe extract, barium sulfate, benzyl alcohol, carbomer, dimethicone, disodium EDTA, jojoba oil, methylparaben, octadecene/MA copolymer, polyglyceryl-3 distearate, phenethyl alcohol, propylparaben, sorbitan isostearate, sorbitol, stearic acid, tocopherol (vitamin E), triethanolamine, water

Other information
- protect this product from excessive heat and direct sun

Questions or comments?

Call toll free 1-800-XXX-XXXX

Sunscreen Regulations

- Labelling
  - Claims
  - Warnings
- Testing
- Ingredients
- Uses/product delivery
- Good Manufacturing Practices

Sunscreen ingredients

Regulations categorizes ingredients:

- Category 1- Safe and effective
- Category 2- Forbidden
- Category 3- possibly safe and effective, more data needed

New Sunscreen ingredient data needed

FDA observed the potential for systemic exposure on

- developmental toxicity
- reproductive toxicity.
  - FDA is seeking significant testing on the Category III ingredients, including Maximal Usage Trial Study (MUsT), dermal carcinogenicity tests, systemic carcinogenicity tests, DART (fertility and early embryonic development, prenatal and postnatal development, embryofetal development in two species-rodent and non-rodent)
- Need more toxicological data on 12 ingredients

Sunscreen active ingredients

- FDA observed that these 10 ingredients had the potential for transdermal absorption and systemic exposure, chronic exposure
  - Cinoxate
  - Dioxybenzone
  - Ensulizole
  - Homosalate
  - Meradimate
  - Octinoxate
  - Octisalate
  - Octocrylene
  - Padimate O
  - Sulisobenzone

Sunscreen Active Ingredients

Ingredients for Which the Record Contains Fewer Data Gaps:

- Oxybenzone and
- Avobenzone

FDA still requesting information nonetheless.

Sunscreens USA vs Europe

REQUIREMENT	USA	EUROPE
GMP	21CFR 211	ISO 22716
SPF TESTING	21CFR 201 OTC Monograph 1. SPF Determination 2. UVA BROAD Spectrum 3. Water Resistance 40 to 80 min	ISO 1. ISO 24444 Static and Water resistant 2. ISO 24443 Broad Spectrum
SHELF LIFE Stability	1. Accelerated Stability 6- 9 months 2. Real Time through expiration Maximum expiration on label 3 yrs	1. Accelerated Stability
PET or Water Activity	Which ever is applicable	Which ever is Applicable Period After Opening symbol Date of Minimum Durability

SUNSCREENS USA vs Europe

REQUIREMENT	USA	EUROPE
OUTER	• Product descriptor (FP) • Weight claim (FP) • DRUG FACTS BOX • Distributor – name & address • Country of Origin • Lot code & Expiration	• Product descriptor • Weight claim • Ingredients • Warnings • Possible SPF ingredient • Distributor – name & address • Country of origin • PAO or Durability date • Lot Code

SUNSCREENS USA vs Europe

LABELING	USA	EUROPE
INNER	• Product descriptor (FP) • Weight claim (FP) • Active ingredients & % • Warnings • Distributor – name & address • Country of Origin • Lot code & Expiration	• Product descriptor • Weight claim • Warnings • Possible SPF ingredient • Distributor – name & address • Country of origin • PAO or Durability date • Lot Code

SUNSCREENS LEGALIZATION

USA

- Fulfill GMP at manufacturer under 21CFR 211
- Manufacturer must register Facility annually
  - International facility must have a USA Agent perform registration
  - Registration identifies the company to FDA
  - FDA will perform GMP audit of facility for OTC compliance
  - FDA Audit results in an Establishment Inspection Report (EIR)
  - Any observations requiring improvement will be identified on FDA Form 483

SUNSCREEN LEGALIZATION

EUROPE

- Cosmetic File
  - Safety Assessment
  - Cosmetic Product Safety Report (CPSR)
- Product Information File
  - Responsible Person accepts Safety Assessment & CPSR
  - Confirms label acceptability
- Cosmetic Product Notification Portal Submission (CPNP)

Organic and Natural Claims

Organic and Natural Claims

- US Department of Agriculture (USDA) National Organic Program
- Foods and/or Cosmetics?
- State of California

California- Organic Products Act

- Processed and/or Frozen
- Coffee, Tea
- Juices, pulps, pastes, jams and jellies
- Beverages, alcohol, liquor
- Vegetable based dairy substitutes
- Blended food products
- Egg products
- Prepackaged meats
- Butter, curd, and whey products
- Extracts, flavorings
- Candy, chewing gum, syrups
- Dry grains, beans, and grain products
- Pasta, bread
- Milled grains and seeds
- Spices and seasonings
- Oil seeds, oils and lubricants
- Vitamins, food supplements
- Pet food and/or blended, and byproducts thereof
- **Cosmetics**

Organic Claims

- Must have at least 70% Organic content

Organic and Natural Claims

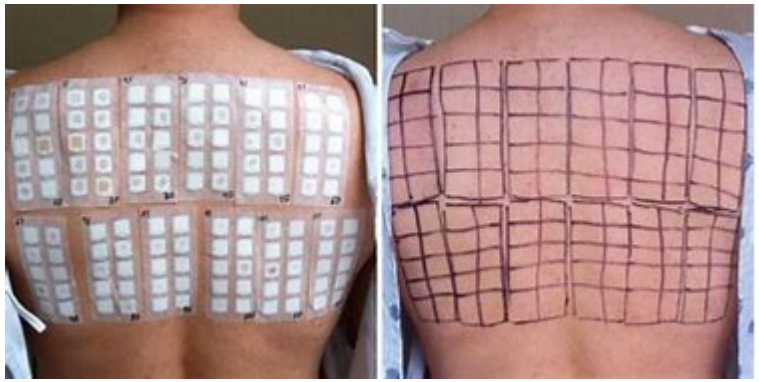
- California requires registration Every person engaged in this state in the processing or handling of processed products pursuant to Section 110460 of the Health and Safety Code, and pet food pursuant to Section 18653, and cosmetics pursuant to Section 111795 of the Health and Safety Code, including processors of alcoholic beverages, fish, and seafood, shall register with the State Public Health Officer. (annually)

Natural Claims

- Natural claims must be truthful
- “Made with” must not be deceptive
- Natural claim for entire product
- ISO 16128 is one way to provide proof, but no guarantees
- Must have rationale

Hypoallergenic Claims

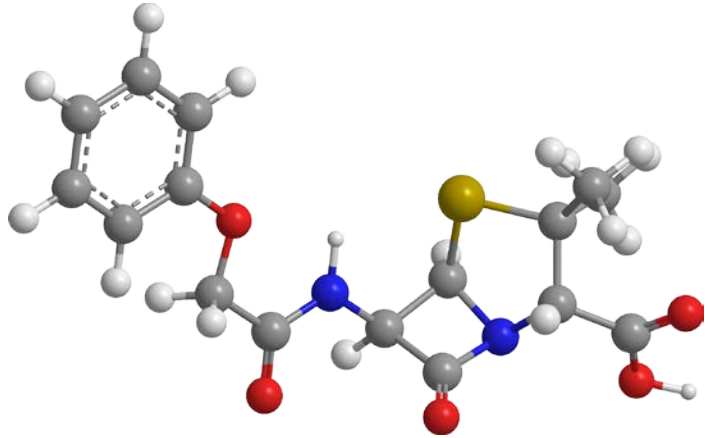
- No legal or scientific standard for Hypoallergenic claims
- hRIPT use by industry
- Typically involving a Dermatologist
- Subject to challenge
- Sensitive individuals
- “Allergy tested”



Hypoallergenic claim via pictogram

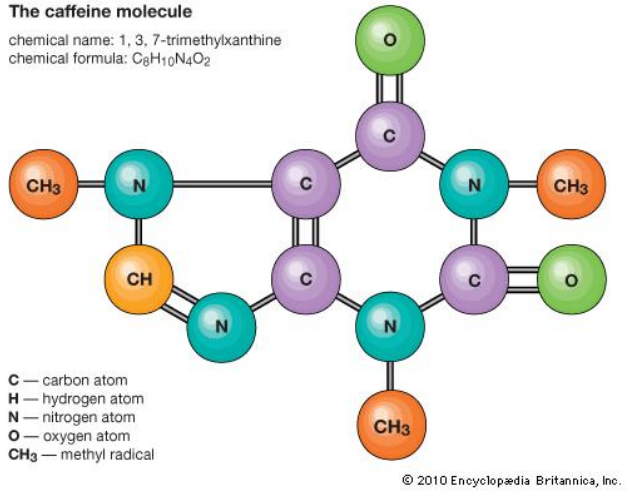
INCI Nomenclature

- USA implemented ingredient listing in 1976
- CTFA (Now PCPC) created reference with FDA blessing
- 16th Edition Dictionary, 2016 →→→ wINCI
- Currently 22,600+ INCI names, 77,000+ Trade names
- Dictionary does NOT denote ingredient safety or approval



INCI Nomenclature

- “Organic” or similar types of processing are not a part of an INCI name.
- Any different name assignment is delineated by a different chemical composition (Water, Sea Water due to vastly different composition and characteristics)



How is an INCI determined?

- INCI nomenclature Committee
- Naming is NOT random or as requested
- Modified as new science becomes available
- Compendial Standards
  - Pharmacopeia (USP, EP, BP, JP)
  - Nomenclature conventions (Chemical rules, CAS system)
  - Botanical references (Linnaean names, recognized references)
- Modified as new science and technology becomes available

INCI Nomenclature

- Foreign governments are provided with wINCI access by PCPC, ongoing
- Updated daily
- Competent Authorities reference wINCI
  - Product review for approvals
  - Shelf checks
- Cosing is provided with new INCIs from PCPC, but update on a different schedule

INCI Nomenclature

- EU multiple language dilemma
- Use of Latin names
- PCPC in constant contact with FDA
- Phase in of botanical names over several versions

INCI nomenclature: FDA's position

- Formally accepted 4th edition of INCI Dictionary
- Colorants/CI numbers are not acceptable
- Fair Packaging and Labeling Act (FPLA) specifies that ingredients must be listed by their "common or usual names"
- Avoid deceiving the consumer, must be clear

INCI Nomenclature

Example:

- Prunus Amygdalis Dulcis (Sweet Almond) Oil
- Previously Sweet Almond Oil in the US
- Previously botanical/Latin name in EU: Prunus Amygdalis Dulcis
- Name incorporates both

Cannabidiol (CBD)

Cannabidiol (CBD)

- Renewed interest in CBD Oil in Cosmetics
- States legalized Marijuana, but not all
- Much confusion about legality
- “All or nothing” approach by industry

Cannabidiol (CBD)

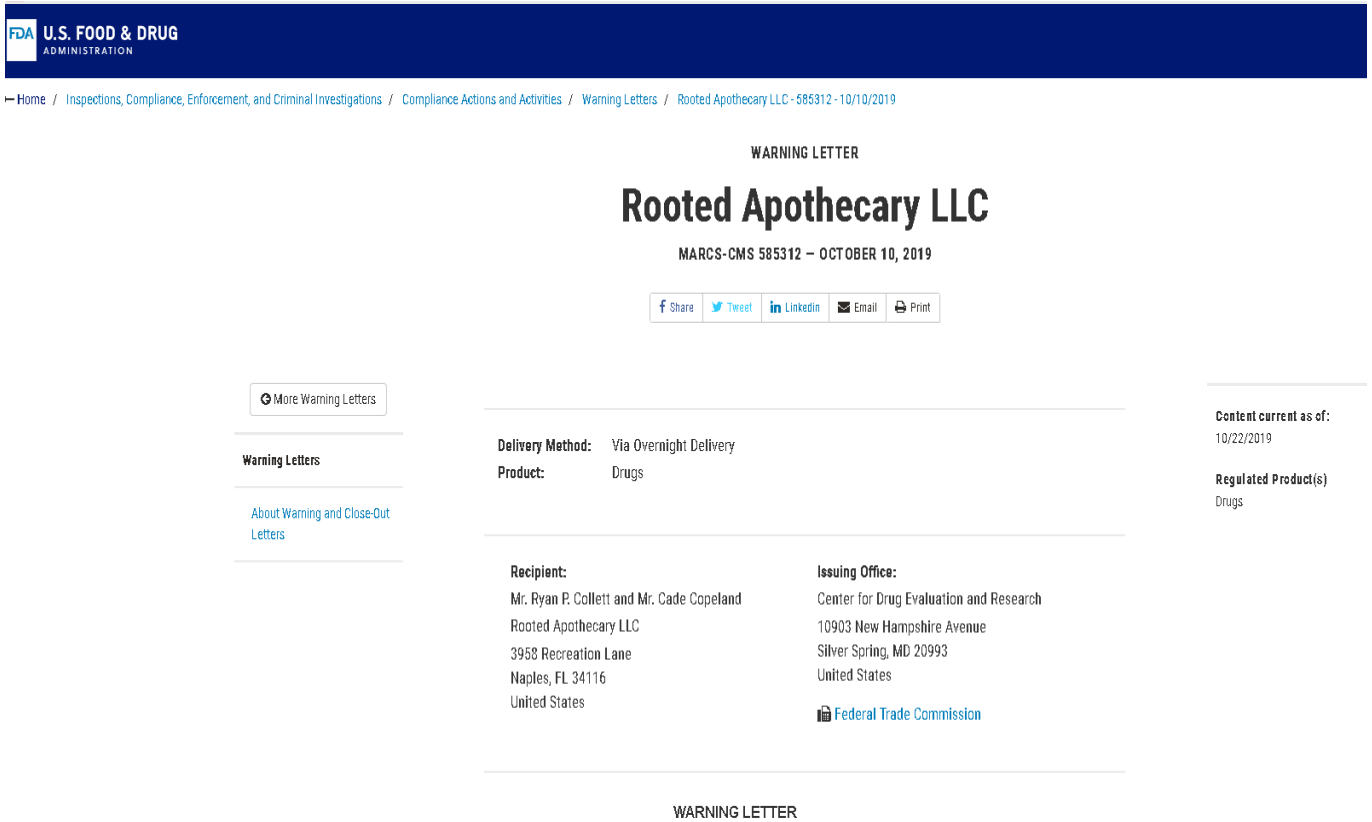
- Complicated by a formal Drug approval- establishes a precedent
- Ingredient performance
- Medical effects
- Claims and ease of regulatory issues- pick one

CBD Enforcement

- Multiple companies issued enforcement by FDA

  Why?
  Physiological effects-drug action
  Labelling claims
  Composition of CBD oil

Example of Warning Letter from FDA for CBD



U.S. FOOD & DRUG ADMINISTRATION

Home / Inspections, Compliance, Enforcement, and Criminal Investigations / Compliance Actions and Activities / Warning Letters / Rooted Apothecary LLC - 585312 - 10/10/2019

WARNING LETTER

Rooted Apothecary LLC

MARCS-CMS 585312 – OCTOBER 10, 2019

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More Warning Letters

Warning Letters

About Warning and Close-Out Letters

Delivery Method: Via Overnight Delivery
Product: Drugs

Recipient:
Mr. Ryan P. Collett and Mr. Cade Copeland
Rooted Apothecary LLC
3958 Recreation Lane
Naples, FL 34116
United States

Issuing Office:
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993
United States

Federal Trade Commission

Content current as of:
10/22/2019

Regulated Product(s)
Drugs

WARNING LETTER

October 10, 2019

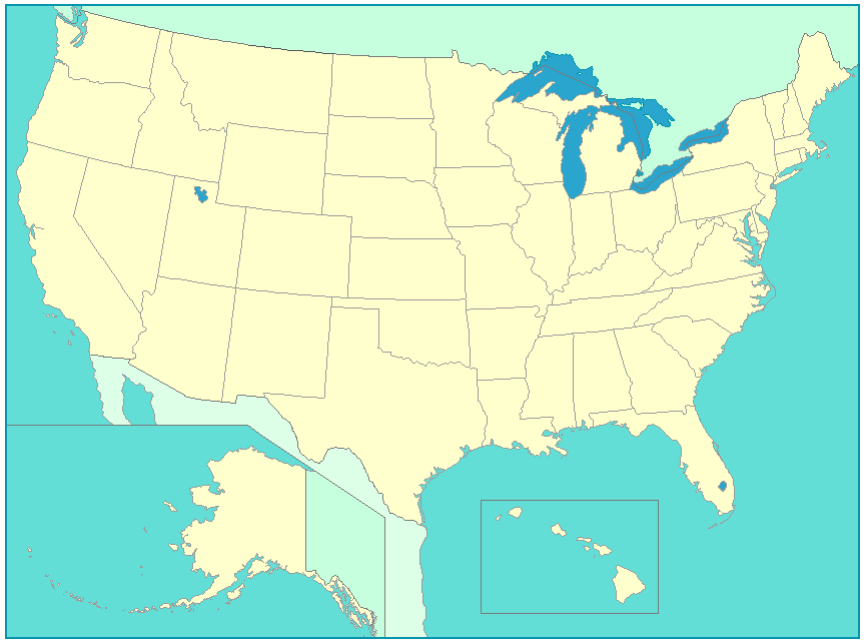
RE: 585312

Dear Mr. Collett and Mr. Copeland:

This letter is to advise you that the Food and Drug Administration (FDA or Agency) reviewed your website at the Internet address www.rootedapoth.com in July 2019 and has determined that you take orders there for various products that claim to contain cannabidiol (CBD). Your products, "Teeth/TMJ – Essential Oil + CBD Infusion" and "Ears – Essential Oil + CBD Infusion are roll-on products that you sell for topical application in adults and children. Other examples of products that you sell, which claim to contain CBD, include "Hemp Capsules, 750 mg," "Hemp Infused Body Butter," and "Hemp Oil".[1] On your website, these products are also referred to as "CBD Capsules, 750 mg," "CBD Body Butter," and "CBD Oil," respectively. We also reviewed your social media website at https://www.facebook.com/rootedapoth/, which directs consumers to your website http://www.rootedapoth.com to purchase your products. FDA has determined that your "Teeth/TMJ – Essential Oil + CBD Infusion," "Ears – Essential Oil + CBD Infusion," "Hemp Capsules, 750 mg," "Hemp Infused Body Butter," and "Hemp Oil" products are unapproved new drugs sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 355(a) and 331(d). Furthermore, these products are misbranded drugs under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1). As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the FD&C Act. You can find the FD&C Act and FDA regulations through links on FDA's home page at www.fda.gov. In addition, the Federal Trade Commission has reviewed your website for potential violations of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

As FDA stated in an announcement regarding a warning letter on July 23, 2019, "while we recognize the potential opportunities and significant interest in drug products containing cannabis and cannabis-derived compounds like CBD, protecting and promoting public health remains our top priority."[2] The Agency continues to be concerned about the proliferation of products asserting to contain CBD that are marketed for therapeutic or medical uses without having been reviewed for safety and effectiveness by the FDA as is required by law and to protect the public health. There are many unanswered questions

US State requirements



States' influence on sunscreens

- Based on environmental concerns
- Issues quickly escalated
- Proposed legislation multiplied
- Global Warming?
- Worldwide effect from a state with 1.4 million people

Hawaii's sunscreen ingredient ban

- Oxybenzone and Octinoxate containing products banned from sale
- Bleaching of coral reef
- Global warming symptom?
- Irrespective of FDA's human health responsibilities
- Another environmental issue for the industry
- Short response time vs. scientific data

California

Why California?

- Fifth largest economy in the world
- 39+ million population
- Unique environmental issues
- Long history of activism

Air Quality

California Air Resources Board (CARB)

- Federal Environmental Protection Agency (US EPA) created requirements for air quality in California
- Air quality requirements not met
- California created Air Resources Board (CARB)
- Goals

CARB

- How to measure air quality?
- How to measure improvement?
- How to determine multiple point-sources
- Cars?
- Industrial?
- Consumer products?

CALIFORNIA
AIR RESOURCES BOARD

CARB- Emissions and next steps

- Goal of reducing emissions that contribute to smog
- Calculate “tons per day” of emissions based on sales numbers and testing for VOCs in products
- Cosmetics/Personal care involved due to tonnages
- Continuing to monitor all sources of emissions, new categories

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AIR RESOURCES BOARD

Currently regulated categories (effective date 1994)

- Original effective date: October 21, 1991
- Amendments: 1993, 1996, 1997, 1998, 1999, 2000, 2001, 2005, 2007, 2009, 2010, 2011, 2013, 2015.
- Regulated in three separate pieces:
  - Antiperspirants/Deodorants
  - Consumer Products (other)
  - Aerosol Coating Products
  - Alternative Control Plan
  - Hairspray Credit Program (repealed)

CARB- Emissions and next steps

- Product formula surveys for 2013-2014-2015
- Multitude of diverse product categories surveyed
  - Charcoal Lighter fluid
  - Paint remover
  - Automobile brake cleaner
  - Scented candles
  - Insecticide
  - Floor Polish
  - Hairspray
  - Hand sanitizers

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Restrictions by product categories

Initially scrutinized large quantity Consumer Product contributors

- Antiperspirants/Deodorants
- Hairsprays
- Shaving Cream

Multiple deadlines from 1994 - present

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AIR RESOURCES BOARD

Proposed Final categories for further restrictions

CATEGORY	Existing VOC limit	Proposed VOC standard 1/1/2023	Proposed VOC standard 1/1/2027
Manual Aerosol Air Freshener	20%/30%	10%	5%
Hair Finishing Spray	55%	50%	45%
No-Rinse Shampoo	None	50%	45%
Personal Fragrance Products (≤ 20% fragrance)	75%	65%	50%
Crawling Bug Insecticide (aerosol)	15%	10%	6%
Charcoal Lighter material	0.02 lb/start	0.014 lb/start	0.014% lb/start
Sunset 2% Fragrance Exemption	2% exemption	No change	No exemption

Additional possibilities for 2031

- Anti-microbial Dry Hand Wash
- Aerosol Sunscreen
- Mouthwash/rinse
- Antiperspirants
- Many Household Products

CALIFORNIA
AIR RESOURCES BOARD

Formulation challenges

- Aerosols- first VOCs regulated in 1994
  - Antiperspirants/Deodorants
  - Shaving Creams
  - Aerosol hairsprays
- Propellants and Alcohol
- Most companies used newer, more expensive
  - HFC-152a
  - Dimethyl Ether
- Regrettable substitution?
- Challenges for International formulations

Next challenge? Greenhouse Gases

- Products using HFC-152a

- Examine available technologies
  - Compressed gas
  - New propellants
  - Technical challenges, costs, availability

- Goal to eliminate HFCs “long term”= 2035

OEHHA and Proposition 65

- Office of Environmental Health Hazard Assessment (OEHHA)
- Safe Drinking Water and Toxic Enforcement act of 1986
- “Right to Know” legislation
- Warning of Carcinogens and Reproductive Toxins
- Consumer point-of-purchase disclosure law
- Problematic for many industries
- Penalties can be costly, Enforceable by “private citizens”
- Continually updated (last update September 13, 2019)

OEHHA and Proposition 65

- List continually updated
- Science vs. legislative process
- Safe Harbor limits
  - No observable effect level evaluation
  - No significant risk level review
- Not addressed upon first listing

Proposition 65 Developments

WARNING: This product can expose you to Lead, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

BEFORE	AFTER
WARNING: This product contains chemicals known to the state of California to cause cancer and birth defects or other reproductive harm.	**WARNING:** This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer, and [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

WARNING
Cancer and Reproductive Harm
www.P65Warnings.ca.gov

Proposition 65 Chemicals

- 911 listed chemicals/groups
- Even if not intentionally added to the product
- Biggest challenges:
  - Lead
  - Diethanolamine, Cocamide DEA
  - Phthalates
- https://oehha.ca.gov/media/downloads/proposition-65//p65list091319.pdf

OEHHA
California Office of Environmental Health Hazard Assessment

Proposition 65 Scientific Approach?

- Carcinogen identification Committee
- Reproductive Toxicant Identification Committee
- Authoritative Bodies
  - US Environmental Protection Agency (EPA)
  - International Agency for Research on Cancer (WHO/IARC)
  - US FDA
  - National Institute for Occupational Safety and Health (NIOSH)
  - National Toxicology Program (NTP) of the US Department of Health

OEHHA
California Office of Environmental Health Hazard Assessment

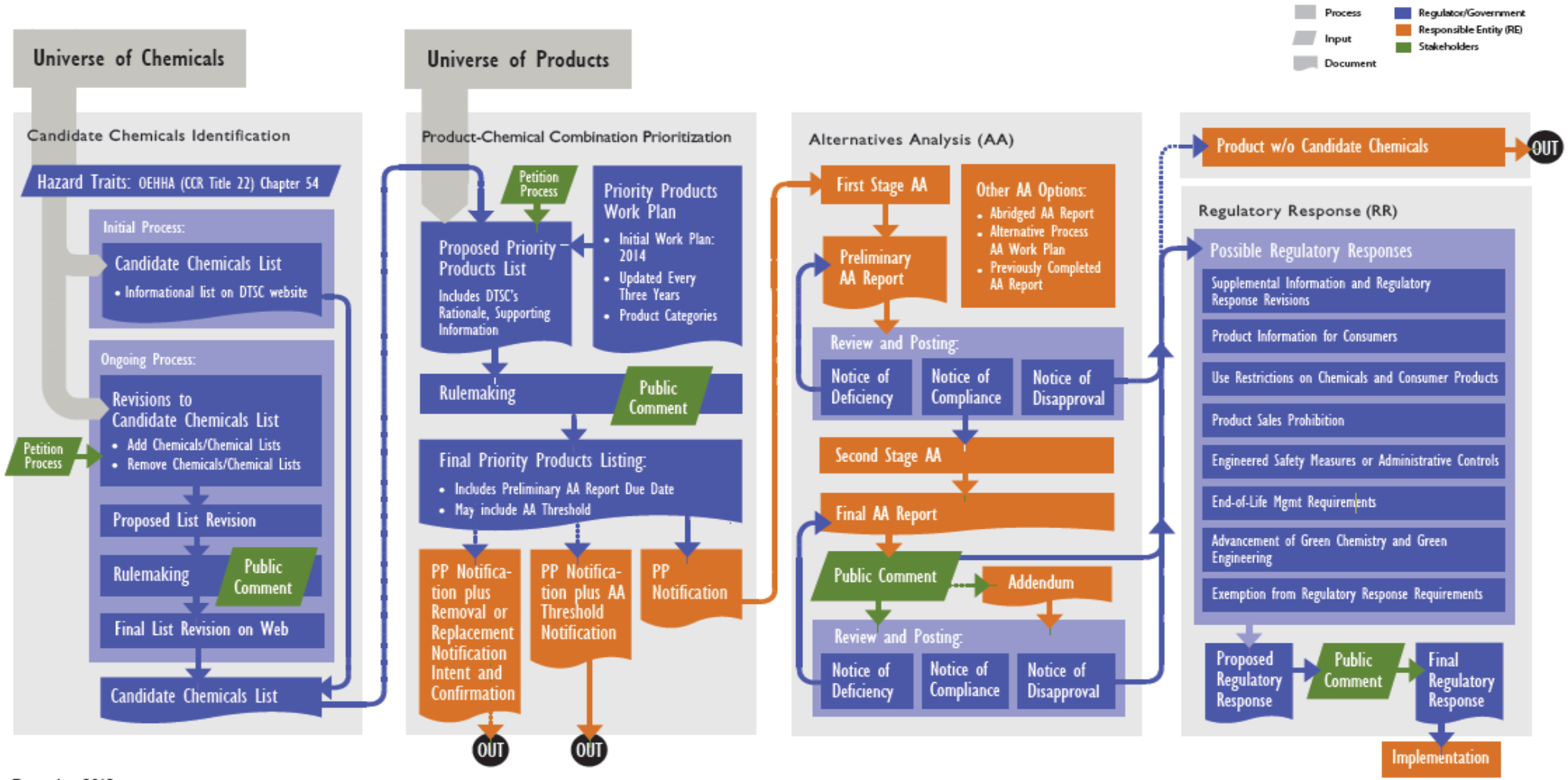
Green Chemistry- Safer Consumer Products

- Department of Toxic Substance Control
- Determine **Candidate Chemicals**
- Contained in **Priority Products**
- Industry provides **Alternatives Assessment**
- Determine if chemical can be eliminated

DTSC
Department of Toxic Substances Control

Regulations for Safer Consumer Products

ARTICLE 14, CHAPTER 6.5, DIVISION 20 OF THE HEALTH & SAFETY CODE
CHAPTER 55, DIVISION 4.5, TITLE 22, CALIFORNIA CODE OF REGULATIONS (CCR)
DRAFT REGULATORY FLOW CHART



December, 2013

Safer Consumer Products program

- Children's Foam-Padded Sleeping Products with TDCPP or TCEP (2017)
- Spray Polyurethane Foam Systems with unreacted Methylene Diphenyl Diisocyanates (MDI) (2018)
- Paint or Varnish Strippers with Methylene Chloride (2019)
- Expected:
  - Nail products (Toluene, Formaldehyde)
  - Hair straightening products (Formaldehyde)

CalSAFER
SAFER CONSUMER PRODUCTS INFORMATION MANAGEMENT SYSTEM

Safer Consumer Products- Candidate Chemicals

- **Candidate Chemicals** determines from Authoritative Lists ("a list of lists")
- **24 lists** generated by government and independent agencies, like:
  - California's **Proposition 65** list
  - Regulation (EC) **1272/2008 (CLP)** Carcinogens, Mutagens, Repro Toxins, Respiratory Sensitisers
  - Regulation (EC) **1907/2006 (REACH)** Candidate list of Substances of Very High Concern (SVHCs) for Endocrine Disruptors, Neurotoxicants, Carcinogens
  - Many others

CalSAFER
SAFER CONSUMER PRODUCTS INFORMATION MANAGEMENT SYSTEM

Single Use Packaging

- Hotel Amenities sized packaging now forbidden, signed into law October 9
  - Deadline: January 1, 2023 for hotels with more than 50 rooms
  - January 1, 2024 for hotels with 50 rooms or less
- Further legislation to appear on the ballot for citizens to vote for ban of
  - Polystyrene containers for Food and Beverage
  - Single-use packaging

Animal Testing Ban

- California- first state to ban animal testing
- Does not apply if required by law
- Anti-caries testing, bovine x-vivo

Ingredients with 1,4-Dioxane

- California Department of Toxic Substances Control (DTSC)
- 1,4-Dioxane in waste water above levels set by the US EPA
- Sources from industrial sites and household waste run-off
- Ethoxylated ingredients
  - Ethoxylated surfactants (ex: Sodium Laureth Sulfate)
  - Polyethylene Glycols (ex: PEG-100 Stearate)
- Comments from Industry groups
  - Personal Care Products Council
  - American Cleaning Institute

DTSC
Department of Toxic Substances Control

CANADA

CANADA

- Cosmetic products in the EU can fall into several categories, regulated by Health Canada
  - Cosmetics requiring notification
  - Category IV Drugs (“OTC” Drugs) requiring a Drug Identification Number (DIN)
  - Natural Health Products (NHPs) requiring a Natural Product Number (NPN)

Cosmetics in Canada

- Forbidden and restricted ingredients
- Some overlap with 1223/2009 Annexes
- Cannabis status still being clarified:
  - Medicinal uses are regulated outside of Cosmetics
  - Cosmetics with Hemp are allowable with 10µg/g THC
  - Hemp seed oil and Hemp protein allowed, however
  - Cannabinoids are not allowed, though Hemp contains CBD

The Cannabis Regulations

- October 17, 2019 proposal updated to include Cannabis Topicals category
  - 1000 mg THC per package maximum
  - Cannot contain nicotine or alcohol
  - For use only on skin, hair and nails
  - Not for use in eyes or on damaged skin
  - Non-decorative and child-resistant packaging required
  - Labeling must show standardized cannabis symbol for THC-containing products
  - Possession limit determined by dried cannabis equivalency
  - NO health claims allowed

Canada Non-prescription “DIN” Drugs

- “Monographed” Non-prescription Drugs requiring a Drug Identification Number (DIN)
- Similar to US Over-the-counter categories
  - Acne products
  - Sunscreens
  - Medicated Skin Care
  - Diaper Rash products
  - Anti-dandruff products
  - Antiseptic skin cleansers
  - Athlete’s Foot Treatments
- Need file submission and product approval prior to importation
- Assigned Samples taken from each shipment of drugs for assay
- Beta testing of system to illustrate compliance

Canada Non-Prescription Drugs
Natural Health Products (NHPs)

- System originally intended for Nutritional supplements whose effects were not well defined or regulated
- Defined by product claims/purpose and ingredient origins
- Each monographed category illustrates which ingredients match
- Ex: Includes sunscreens with physical sunblocks only

Canada Non-prescription Drug categories

Acne products

- Category 1 ingredients (Natural Health Products)
  - Salicylic acid
  - Sulfur
  - Resorcinol
  - Resorcinol monoacetate
- Category 2 ingredients (Drug Identification Number category)
  - Benzoyl Peroxide

CANADIAN SPF LEGALIZATION

- Natural Health SPF Ingredients
  - Titanium Dioxide
  - Zinc Oxide
  - Para-aminobenzoic acid
- Submit for Natural Product Number (NPN)
  - Designated Party Authorization Form
  - Finished Product Specification
  - Product License Application Form
  - Finished Product Specification Form
  - Monograph attestation Form

CANADIAN SPF LEGALIZATION

Health Canada Drug Ingredients

ACTIVE INGREDIENTS	ACTIVE INGREDIENTS
Avobenzone	SULISOBENZONE
ENSULIZOLE	DROMETRIZOLETRISILOXANE
HOMOSALATE	Enzacamene
MERADIMATE	Padomate-O
OCTINOXATE	Terephthalylidene dicamphor sulfonic acid
OCTISALATE	Cinoxate
OCTOCRYLENE	Diethanolamine methoxycinnamate
OXYBENZONE	Dioxybenzone
	Triethanolamine salicylate

CANADIAN SPF LEGALIZATION

Health Canada submission for Drug Identification Number (DIN)

Drug Master File – aligns with USA FDA requirements

- Require Canadian Licensed Importer
- Application include Canadian Importer
- Application included Drug Application Fee
- Application include tests (Drug Master File)

“Clean Beauty”

- What is it?
- Marketing claims based in theories
- One ingredient or more?
- Retailers’ standards

Clean Beauty?

- “Clean beauty is quite intense: It means a non-toxic product that is made without a long, ever-evolving list of ingredients linked to harmful health effects.” www.goop.com
- “Safe for people and the planet, *clean* means that a beauty product should have considered human and environmental health, using a nontoxic element as a baseline and plant-based ingredients for active results.” www.harpersbazaar.com
- "We use certified organic ingredients, Ecocert approved preservatives, no petrochemicals or silicones, and no potential carcinogens, endocrine disruptors or ingredients with contaminants...“ (Adam Kielbasa/The Organic Pharmacy) www.glamourmagazine.co.uk

Commonly mentioned in Clean Beauty

- Parabens (specific or category)
- Sulfates
- Phthalates (category)
- PEGs
- “Chemical” sunscreens
- Synthetic fragrances
- Triclosan
- Silicones
- BHT
- BHA

Retailers' standards

- Adopting "Clean Beauty" individual standards
- US/Canadian retail store chains all have differing standards
  - Sephora
  - Walmart
  - Walgreens Boots
  - Target
  - Whole Foods
- Standards for undesirable ingredients now can have a quick identity with consumers

www.intlcosmetics.com