ADDED SUBSTANCES IN INHALABLE MARIJUANA PRODUCTS RULE PACKAGE

ANTHONY GELTOSKY AND TJ SHEEHY

DECEMBER 17, 2020

Overview

Rulemaking process characterized by diligence and collaboration with stakeholders.

- Rulemaking initiated at June, 2020, Commission Meeting.
- Three Rules Advisory Committees held:
  1. July 24: Panel of subject matter experts (scientists, researchers, doctors);
  2. July 29: Panel of licensees and third-party stakeholders; and
  3. October 8: Panel of licensees (focus on those most directly affected by proposed rules).
- Public comment period Nov 1 – 23, 2020.
  - “Documents relied upon” in the public notice includes 30+ page white paper that reviews scholarly evidence and provides rationale for OLCC’s approach.

Need for the rules

- During 2019, a vaping induced lung injury (VALI) affected all 50 states, sickening thousands and killing 68. Oregon had 23 reported cases, 2 of which were fatal.
  - Patients manifest lipoid pneumonia and/or chemical burns in the lungs.
- VALI's cause appears to be associated with additives.
- The health effects of vaping additives is largely unknown due to novel products, complex chemistry and physiology, and federal illegality limiting research.
- OLCC's concerns regarding additives pre-dated VALI: acute and chronic health effects, limited awareness of additive ingredients, products not formulated for for inhalation, misleading statements from additive manufacturers, and consumer awareness.
- Post-VALI research is starting to show that some additives can cause harm, while it is unclear what the long and short term health effects of other additives are.

What do the rules do?

Three common-sense foundations for public health and safety:

1. Prohibits non-cannabis ingredients most likely to cause acute harm and allows OLCC to take faster action to protect the public health and safety should problematic ingredients arise.
2. Requires disclosure to OLCC and consumers in a manner that balances consumer informed choice with business trade secret considerations.
3. Creates a standard so that only products formulated for inhalation can be used in inhalable products.

What do the rules do, cont'd

1. Prohibits non-cannabis ingredients most likely to cause acute harm:
    - Vitamin E Acetate (VEA)
        - Linked by CDC to VALI cases in other states as a possible cause.
    - Squalene and Squalane
        - CDC and FDA testing of Oregon VALI cases uncovered presence of squalene in all items tested; squalane is hydrogenated oil that is derived from squalene.
        - Study by Supra Research and Development (commissioned by OLCC) compared thermal stability of squalene, squalane, and VEA – found squalene and squalane are more unstable at lower temperatures than VEA and that squalene and squalane "could be more problematic than Vitamin E Acetate."
    - Triglycerides (e.g. MCT oil)
        - Published research points to concerns of both lipoid pneumonia (inhaling oil into the lungs) and pulmonary toxicity.
    - Propylene Glycol (unless in metered dose inhaler)
        - When heated, produces formaldehyde (a known carcinogen).

What do the rules do, cont'd

2. Requires disclosure to both OLCC and consumers in a manner that balances consumer informed choice with business trade secret considerations :

- Disclosure to OLCC:
  - Additive manufacturer and mix name.
  - Full list of ingredients, including range of concentration of each ingredient. This will allow OLCC to take faster action should problematic ingredients and/or concentrations of those ingredients arise.
- Disclosure on item label:
  - Specification of "non-cannabis additive" in the product identity.
  - List of all ingredients (on exterior of label or insert) is either alphabetic order or descending order of predominance.
  - No public-facing disclosure of ingredient concentration or mix name/manufacturer.
  - These changes will make it clear to consumers the product they are consuming has non-cannabis additives and what those additives are so that they can make informed choices.

What do the rules do, cont'd

3. Standard so that only products formulated for inhalation can be used in inhalable products:

- Manufacturers will be required to state that the additive is meant for human inhalation.
- This is not a declaration of safety – merely a declaration that the mix was formulated with inhalation as an intended use of the product.
- Intended use statement distinguishes additives for inhalables from "off the shelf" culinary products, e.g. food flavorings or essential oils.
- Requirement is a *floor*, not a ceiling: additive manufacturers can add additional parameters (e.g. intended to be used in a specific ratio or within certain temperature ranges).

When do the rules become effective?

- April 1, 2021: inhalable cannabinoid products manufactured after this date must have ingredients and labels that meet new rule standards.
- July 1, 2021: Products made *prior* to April 1, 2021, may be transferred and sold until this date. On July 1, products must either be compliant with these new rules or be destroyed.

Deliberative process balancing multiple stakeholders' interests

Final rule represents the outcome of a deliberative process that accommodates business concerns without compromising public health or consumer safety.

Throughout the collaborative process, numerous changes made to the proposed rules:

- Evolved from a "precautionary ban" that would have prohibited non-cannabis additives outright to an "informed choice framework" that has a narrower list of banned ingredients and focuses on consumer-facing disclosure.
- Incorporated RAC and public comments related to testing and information disclosure to minimize costs and accommodate legitimate business concerns.
- Adjusted effective dates to provide more time for companies to comply and minimize the economic impact of rules.

Next Steps…

Addressing additives is only the first step in OLCC's deliberative process to provide greater consumer protection in the regulated marketplace.

- **Audit Testing:** OLCC will be taking steps to increase its audit testing program, to verify compliance with rules, including adulteration and labeling. This process will also provide clearer standards as to what constitutes "adulteration" of cannabis products.
- **Hardware:** Vaping hardware has the potential to introduce adulterants into cannabis products via heavy metals and off-gassing. OLCC will begin assessing the safety of these components via data gathering that will inform future decision making.

Questions?