

Proposed Regulations Project

Tab 13 (Testing Standards and Tolerances)

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Description:

This project seeks to modify testing requirements in regulation which have been identified as unachievable using available equipment and methods and to apply a tolerance value to test results in accordance with established scientific practice.

Narrative:

The board has received testimony, written and verbal, indicating that current test standards for benzene are beyond the sensitivity of available equipment and procedures. In addition, the standards for test failure do not take into account the inherent variation found in any testing regime. Regulations specify a maximum THC content of 50mg for a multi-serving product but do not allow for even a fractional amount over that limit in testing. It is worth noting that the regulations do allow a tolerance for homogeneity in individual servings of 1mg (+/- 20%) but no tolerance in the full multi-serving product. Finally, current regulations suggest that the board alone may approve the use of product which has failed a test to be used in an extraction process. Given the time between board meetings, this could be cumbersome thus, a suggested change is offered to allow the director to authorize such a re-use when a board meeting is not anticipate in the near future.

The goals for this proposed change are:

- 1) Allow a manufacturing / testing tolerance of +/- 20% for THC content of a marijuana product
- 2) Return the maximum residual benzene to 1 ppm
- 3) Allow the director to authorize the use of raw material for extraction if that material has failed certain tests.

Proposed change:

Note:

Words in **boldface and underlined** indicate language to be added

Words [CAPITALIZED AND BRACKETED] indicate language being deleted

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3 AAC 306.645. Laboratory testing of marijuana and marijuana products. (a) A marijuana testing facility shall use the general body of required laboratory tests as set out in this section for marijuana plant material, an extract or concentrate of marijuana, and an edible marijuana products. Required tests may include potency analysis, moisture content, foreign matter inspection, microbial screening,

pesticide, other chemical residue, and metals screening, and residual solvents levels. A marijuana testing facility shall establish a schedule of fees and sample size required for each test it offers.

(b) The tests required for each marijuana type or marijuana product, are as follows:

(1) potency testing is required on marijuana bud and flower, marijuana concentrate, and a marijuana product, as follows:

(A) the required cannabinoid potency test must at least determine the concentration of THC, THCA, CBD, CBDA and CBN cannabinoids; a marijuana testing facility may test and report results for any additional cannabinoid if the test is conducted in compliance with a validated method;

(B) a marijuana testing facility shall report potency test results as follows:

(i) for a potency test on marijuana and marijuana concentrate, marijuana testing facility shall list for each required cannabinoid a single percentage concentration that represents an average of all samples within the test batch; alternatively, the sum of THC and THCA may be reported as total THC; the sum of CBD and CBDA may be reported as total CBD;

(ii) for a potency test on a marijuana product, whether conducted on each individual production lot or using process validation, marijuana testing facility shall list for each cannabinoid the total number of milligrams contained within a single retail marijuana product unit for sale;

(iii) for testing whether the THC content is homogenous, the marijuana testing facility shall report the THC content of each single serving in a multi-unit package; the reported content must be within 20 percent of the manufacturer’s target; for example, in a 25 milligrams total THC package with five servings, each serving must contain between four and six milligrams of THC;

(C) the marijuana testing facility shall determine an edible marijuana product to have failed potency testing if

(i) an individually packaged edible retail marijuana product contained within a test lot is determined to have more than [50] **60** milligrams of THC within it; or

(ii) the THC content of an edible marijuana product is not homogenous;

(2) microbial testing for the listed substances on the listed marijuana products is required as follows:

Substance	Acceptable Limits Per Gram	Product to be Tested
Shiga-toxin producing Escherichia coli (STEC)- Bacteria	less than 1 colony forming unit (CFU/g)	flower; retail marijuana Products; water- and food-based concentrates
Salmonella species – bacteria	less than 1 colony forming unit (CFU/g)	
Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger - fungus	less than 1 colony forming unit (CFU/g)	

(3) testing for the listed residual solvents and metals on the listed marijuana products is required as follows:

Substance	Acceptable Limits Per Gram	Product to be Tested
Butanes	less than 800 parts per million (PPM)	solvent-based concentrates
Heptanes	less than 500 parts per million (PPM)	
Benzene	less than [.025 PARTS] 1 part per million (PPM)	
Toluene	less than 1 parts per million (PPM)	
Hexane	less than 10 parts per million (PPM)	
Total Xylenes (meta-xylenes, para-xylenes, or ortho-xylenes)	less than 1 parts per million (PPM)	

3 AAC 306.660. Failed materials, retests. (a) If a sample tested by a marijuana testing facility does not pass the required tests based on the standards set out in 3 AAC 306.645, the marijuana establishment that provided the sample shall

- (1) dispose of the entire harvest batch or production lot from which the sample was taken; and
- (2) document the disposal of the sample using the marijuana establishment’s marijuana inventory tracking system.

(b) If a sample of marijuana fails a required test, any marijuana plant trim, leaf, and other usable material from the same plants automatically fail the required test. The board **or director**, may approve a request to allow a batch of marijuana that fails a required test to be used to make a carbon dioxide or solvent-based extract. After processing, the carbon dioxide or solvent-based extract must pass all required tests.

(c) If a marijuana cultivation facility or a marijuana product manufacturing facility petitions for a retest of marijuana or a marijuana product that failed a required test, the board **or director**, may authorize a retest to validate the test results. The marijuana cultivation facility or a marijuana product manufacturing facility shall pay all costs of a retest.

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