The current regulations were reviewed in entirety for content related to testing requirements.
To clarify certain issues and present considerations of a comprehensive action plan to implement pesticide and heavy metal testing, the current regulations were reviewed in entirety for content related to testing requirements. Articles 1, 2, 3, 7, and 8 had no relevant sections or changes for further consideration.

The following sections were reviewed in depth for language that would need to be added or changed to address those issues and considerations:
•Article 4: Marijuana Cultivation Facilities
•Article 5: Marijuana Product Manufacturing Facilities
•Article 6: Marijuana Testing Facilities
•306.990 Definitions

| Topic | Sections with Related Language | Notes |
|---|---|---|
| **Existing regulatory language for pesticides and heavy metals** | *3 AAC 306.465. Random sampling* | These sections of the regulations currently already address pesticide and heavy metal testing, as current tests that are either required for clearance of products (when available) or as "supplemental marijuana quality tests" that the board or director may order for cause or at random. |
| | *3 AAC 306.475. Labeling of marijuana* | |
| | *3 AAC 306.600. Applicability* | |
| | *3 AAC 306.620. Approval of testing facility* | |
| | *3 AAC 306.645. Laboratory testing of marijuana and marijuana products* | |
| | | |
| **Pass/fail criteria and analytes** | *3 AAC 306.645. Laboratory testing of marijuana and marijuana products* | Add tables for pesticide and heavy metals showing required substances, acceptable limits and product types. |
| | | |
| **Number of samples required for testing (all or random or "for cause"** | *3 AAC 306.455. Required laboratory testing*<br>*3 AAC 306.665. Supplemental marijuana quality testing*<br>*Proposed new section- 306.676 Supplemental Surveillance Screening* | These sectiosn will need to consider new "representative sample" sizes with the additional testing. |
| | *3 AAC 306.645. Laboratory testing of marijuana and marijuana products* | This section already addresses having all samples tested. |
| | | |
| **Collection and Submission of Samples** | *3 AAC 306.455. Required laboratory testing* | This section will need to consider "representative sample" sizes considering the additional testing. |
| | *3 AAC 306.465 Random Sampling* | Add in the language regarding random sampling of peticides/heavy metals. |
| | | |
| **Required Sample Sizes** | *3 AAC 306.455. Required laboratory testing* | This section will need to address increase in sample sizes for additional testing. |

| | | |
|---|---|---|
| **Financial Responsibility for Testing** | *3 AAC 306.665 Supplemental Marijuana Quality Testing* | This section already addresses financial responsibility, but it needs to be changed IF the supplemental surveillance screening is added to this section AND the financial responsibility for this testing shifts to AMCO. |
| | *306.676 Supplemental Surveillance Screening* | This section could be added to address all issues. |
| **Laboratory to Laboratory Transfer of Samples (or any language barring that from happening.** | *3 AAC 306.650. Chain of custody* | This section already covers transferring samples from one testing facilty to another and allows it under current regulations. |
| | *3 AAC 306.665. Supplemental marijuana quality testing* | This section could be changed to include language for interfacility transfers. |
| | *Proposed new section 3 AAC 306.676 Supplemental Surveillance Screening* | This section could be added to address all issues. |
| **Testing for Cause** | *3 AAC 306.465 Random Sampling* | These sections already address how the board or director can order quality testing and the licensee is financially resposible for the cost. |
| | *3 AAC 306.665 Supplemental Marijuana Quality Testing* | |
| **Elective Supplemental Quality Testing** | *3 AAC 306.660. Failed materials; retests* | Add in information about research and development options. |
| | *3 AAC 306.665 Supplemental Marijuana Quality Testing* | This may be a section that will need language added about R&D testing options prior to testing for clearence. |
| **Remediation of Failed Products** | *3 AAC 306.660. Failed materials; retests* | Add information about potential product remediation if acceptable. |
| | *3 AAC 306.66x. Remediation of Failed Products* | This section could be added to address all issues. |
| **Labeling Requirements** | *3 AAC 306.475. Labeling of marijuana* | Add specific terms for heavy metals (and to futureproof) mycotoxins. |
| | 3 AAC 306.570. Labeling of marijuana products | Add specific terms for heavy metals (and to futureproof) mycotoxins. |

**Regulatory Language Changes Required in 3 AAC 306**

*for Additional Contaminant Screening of Marijuana and Marijuana Products*

The current regulations were reviewed in entirety for content related to testing requirements.
To clarify certain issues and present considerations of a comprehensive action plan to implement pesticide and heavy metal testing, the current regulations were reviewed in entirety for content related to testing requirements. Articles 1, 2, 3, 7, and 8 had no relevant sections or changes for further consideration.

The following sections were reviewed in depth for language that would need to be added or changed to address those issues and considerations:

- *Article 4: Marijuana Cultivation Facilities*
- *Article 5: Marijuana Product Manufacturing Facilities*
- *Article 6: Marijuana Testing Facilities*
- *306.990 Definitions*

The following sections of the regulations currently already address pesticide and heavy metal testing, as current tests that are either required for clearance of products (when available) or as "supplemental marijuana quality tests" that the board or director may order for cause or at random:

- *3 AAC 306.465. Random sampling*
- *3 AAC 306.475. Labeling of marijuana*
- *3 AAC 306.600. Applicability*
- *3 AAC 306.620. Approval of testing facility*
- *3 AAC 306.645. Laboratory testing of marijuana and marijuana products*

**Some obvious requirements, such as updates and versioning, are detailed below.**

First Page: Title page

Updated xx/xx/xxxx

Second page: Marijuana Regulation Changes

Month Day, 2024

3 AAC 306.xxxx is amended to add specifics for testing contaminants (pesticides, heavy metals, and mycotoxins) prior to release of marijuana and marijuana concentrates for retail sale or use in products infused with such concentrates.

**To address the additional testing, it is more of a modification of the existing regulatory language that already exists for pesticides and heavy metals, rather than an addition to the regulations.**

**Article 6: Marijuana Testing Facilities**

***3 AAC 306.620. Approval of testing facility***

(a) A person seeking a marijuana testing facility license must first obtain the approval of the board by showing competence to perform each test the licensee will offer as an independent third-party testing facility, including tests to identify

(1) THC, THCA, CBD, CBDA and CBN potency;
(2) Harmful microbials including Escherichia coli (E. Coli), Salmonella, and Aspergillus;
(3) residual solvents;
(4) poisons or toxins;
(5) harmful chemicals;
(6) dangerous molds, mildew, or filth;
(7) pesticides;
(8) heavy metals.

**There is an error in one section already present that should be addressed.**

***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 a marijuana product. Required tests may include potency analysis, moisture content, foreign matter inspection, microbial screening, pesticide, other chemical residue, and metals screening, and residual solvents levels..... Extra "and" in the sentence before "metals screening,"

(3) testing for the listed residual solvents and metals on the listed marijuana products is required as follows: Metals should not be listed in the action limit table for residual solvents.

**The tables for heavy metals will have to be added**

***3 AAC 306.645. Laboratory testing of marijuana and marijuana products***

(b) 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 a marijuana product. Required tests may include potency analysis, moisture content, foreign matter inspection, microbial screening, pesticide, other chemical residue, and metals screening, and residual solvents levels.....

(4) testing for the listed heavy metals on (TBD: "all" or "designated") marijuana flower, shake, trim, or kief (any type of marijuana biomass) and concentrates/extracts derived from any marijuana biomass required as follows:

| Substance | Acceptable Limits Per Gram in Parts per Million (PPM) | Product to be Tested |
|---|---|---|
| Arsenic | 0.02-0.2* TBD | Marijuana biomass or concentrates/extracts derived from biomass |
| Cadmium | 0.02-0.3* TBD | |
| Lead | 0.5 | |
| Mercury | 0.1 | |
| Nickel | 0.5 | |

**The tables for pesticides will also have to be added.**

***3 AAC 306.645. Laboratory testing of marijuana and marijuana products***

(5) testing for the listed residual pesticides on (TBD: "all" or "designated") marijuana flower/shake/trim/kief (any type of marijuana biomass) and concentrates derived from any marijuana biomass required as follows:

| Substance | Acceptable Limits Per Gram in Parts per Million (PPM) | Product to be Tested |
|---|---|---|
| Abamectin B1a (sum of 2 isomers) | * TBD | |
| Acequinocyl | * TBD | |
| Azoxystrobin | * TBD | |
| Bifenazate | * TBD | |
| Bifenthrin | * TBD | |
| Boscalid | * TBD | |
| Chlorantraniliprole | * TBD | |
| Chlormequat Chloride | * TBD | |
| Clothianidin | * TBD | |
| Cyfluthrin | * TBD | |
| Cypermethrin | * TBD | |
| Daminozide | * TBD | |
| Etoxazole | * TBD | |
| Fenhexamid | * TBD | |
| Fenoxycarb | * TBD | |
| Fludioxonil | * TBD | Marijuana biomass (flower, bud, shake, trim, kief, or any form of biomass)<br><br>Concentrates derived from any biomass (all inhalable and food-based concentrates) |
| Flupyradifurone | * TBD | |
| Imazalil | * TBD | |
| Imidacloprid | * TBD | |
| Malathion | * TBD | |
| Metalaxyl | * TBD | |
| Myclobutanil | * TBD | |
| Paclobutrazol | * TBD | |
| Permethrin | * TBD | |
| (sum of 2 isomers- cis/trans) | * TBD | |
| Pentachloronitrobenzene | * TBD | |
| Piperonyl butoxide | * TBD | |
| Propiconazole | * TBD | |
| Pyraclostrobin | * TBD | |
| Pyrethrin I (sum of pyrethrin I, cinerin I, and jasmolin I) | * TBD | |
| Pyrethrin II | * TBD | |
| Spinosad (sum of 2 isomers) | * TBD | |
| Spinosyn A | * TBD | |
| Spinosyn D | * TBD | |
| Spiromesifen | * TBD | |
| Spirotetramat | * TBD | |
| Sulfoxaflor | * TBD | |
| Tebuconazole | * TBD | |

(Eff. xx/xx/2024, Register xxx; am xx/xx/2024, Register xxx; am xx/xx/2024, Register xxx; am xx/xx/2024)

**Further considerations are discussed below. Relevant changes are proposed inside the red text boxes. Text that is highlighted in yellow contains changes from current language.**

1. **Number of Samples Tested**

    a. Most states require all samples submitted for clearance to be tested.

**CHANGES:** No changes are required to make this testing mandatory for all cultivators and manufacturers to clear harvest batches, as testing of pesticides, heavy metals, and other contaminants was always part of the regulations.

***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 a marijuana product. Required tests may include potency analysis, moisture content, foreign matter inspection, microbial screening, pesticide, other chemical residue, and metals screening, and residual solvents levels.

    b. Some states do a random sampling of all samples submitted for clearance.

        i. Land & Seas is proposing that at least 25% of the samples submitted to testing facilities for METRC clearance would be selected by an automated program and designated for pesticide and heavy metal testing.

        ii. This type of sample could be called "supplemental surveillance screening."

**ADDITIONS:** Add to section ***3 AAC 306.665. Supplemental marijuana quality testing*** or add a new section ***306.676 Supplemental Surveillance Screening*** with subsections stating:

(a) For the purpose of public safety surveillance, a random selection of at least 25% of the marijuana flower and concentrates submitted in METRC for testing will be flagged to undergo a supplemental surveillance screening for pathogenic contaminants, such as pesticides, heavy metals, and/or mycotoxins or other chemical contaminants. Samples will be collected as per detailed in 3 AAC 306(a)(1-4)(i) or 306.676(x).

(b) Samples selected for supplemental surveillance screening under this section will be tested at a licensed marijuana testing facility that has been approved for the specific test(s) indicated.

(c) Samples must pass all tests prior to release of any product to retail. (Eff. xx/xx/2024, Register xxx)

2. **Financial Responsibility for Testing**

    a. Given that pesticide and heavy metal testing is very expensive to perform, this is an important consideration. For example, prices for this portion of testing alone range from $200 to $400 per sample in other states.

        i. The financial responsibility for additional testing could be assigned to all cultivators and manufacturers, as is the case with all other required testing.

Section ***3 AAC 306.665. Supplemental marijuana quality testing*** already addresses financial responsibility as follows:

(c) A marijuana testing facility that conducts laboratory testing under this section shall bill all costs directly to the marijuana cultivation facility or the marijuana product manufacturing facility that provided the samples for testing. (Eff. 2/21/2016, Register 217).

**POSSIBLE ADDITION:** Add a statement to a new section ***306.676 Supplemental Surveillance Screening*** or add a statement to other existing and related sections, i.e., "Marijuana cultivation facilities and marijuana manufacturing facilities shall bear all costs for testing under (this) subsection".....

.....*3 AAC 306.645 Laboratory testing of marijuana and marijuana products*;

.....*3 AAC 306.550. Required laboratory testing; and*

.....*3 AAC 306.465. Random sampling.*

ii. The financial responsibility for randomly-generated, supplemental surveillance screening could fall on AMCO as a part of its regular budget or out of the current overages from licensing fees.

1. In this case, cultivators and manufacturers would not have a decrease in licensing fees.

2. Licensees would not incur an increase in the cost of testing for randomly-generated, supplemental surveillance screening, as this would be covered by licensing fees.

**ADDITIONS:** Section ***3 AAC 306.665. Supplemental marijuana quality testing*** already addresses financial responsibility, but it needs to be changed IF the supplemental surveillance screening is added to this section AND the financial responsibility for this testing shifts to AMCO.

(c) A marijuana testing facility that conducts supplemental surveillance screening under this section shall bill all costs directly to the Alcohol and Marijuana Control Board. (Eff. xx/xx/2024, Register xxx).

**OTHER OPTIONS:** Add a new section with verbiage for ***306.676 Supplemental Surveillance Screening***

(a) The board may require that a percentage of samples submitted for clearance of batches undergo supplemental surveillance screening for dangerous contaminants to improve consumer safety. In this case, AMCO is financially responsible for the cost of surveillance testing.

(b) The board or director may require cultivators or manufacturers to submit all samples for supplemental quality testing "for cause" after receiving positive results on samples submitted for surveillance screening. In this case, the cultivator or manufacturer is financially responsible for the cost of supplemental testing for a period of time designated by the board. (Eff. xx/xx/2024, Register xxx)

**3. Loopholes to Pass Unsafe Product**

a. If cultivators and manufacturers are informed that their samples are going to be tested for pesticides and heavy metals, bad actors can present "clean" samples for testing.

b. If samples for supplemental surveillance testing are packaged separately than clearance packages, bad actors can package two products for testing-- potency samples with higher THC and "clean" samples grown separately.

**ADDITIONS:** Section ***3 AAC 306.665. Supplemental marijuana quality testing*** addresses sampling, but it could be changed IF the supplemental surveillance screening is added to this section OR a new section for **3 AAC *306.676 Supplemental Surveillance Screening*** could be created and either section could specify:

(1) Authorized personnel from the cultivation in the process of collecting representative samples for testing if the specification in subsection (i) is met.

(i) Personnel from the cultivation may collect and deliver samples to the laboratory as part of the batch clearance process if there has been no prior notification that the sample is designated to have supplemental surveillance testing.

(2) If regular surveillance screening "for cause" is mandated by the board or director after failing batches for contamination and the required samples are being collected by authorized personnel from the licensed facility, there must be no segregation of the sample for potency and supplemental quality testing so that the potency results and contaminant testing come from the same sample.

c. Cultivators who know they are failing or using pesticides that will fail, may be able to transfer product to infused product manufacturers to "off-load" contaminated product that will be further concentrated to serve as a base for edibles. For this reason, any product transferred to a manufacturer could be considered for mandatory supplemental quality testing.

**ADDITION:** ***3 AAC 306.660. Failed materials; retests***

(1) If a food-grade concentrate is mixed with a concentrate that has failed pesticide or heavy metals testing to remediate the product to pass contaminant testing, and if the concentrate will only be used for production of edible or topical products, a retest of the mixed product must still include potency, as well as the retest for contaminants.

(2) Any food-grade concentrate made from marijuana or marijuana product that has not had clearance testing must undergo supplemental quality testing.

**4. Collection and Submission of Samples**

a. Collection of samples could either be done by AMCO Enforcement agents trained in how to collect the samples without contaminating them.

b. A laboratory sampler could collect samples, but this is not financially feasible due to travel expenses.

c. The cultivators and manufacturers could be responsible for collecting their own segregated samples specifically for supplemental surveillance screening, but this could easily become a loophole for passing contaminated product to consumers, as discussed in the previous section.

**ADDITIONS:** Section ***3 AAC 306.665. Supplemental marijuana quality testing*** could be changed IF the supplemental surveillance screening is added to this section OR a new section for **3 AAC *306.676 Supplemental Surveillance Screening*** could be created and either subsection ***(3 AAC 306.xxx (x) Collection of Samples)*** could specify:

(a) Samples may be collected and presented to the laboratory by one of the following:
1. An AMCO Enforcement Officer trained in the collection of each specific type of sample;
2. Authorized personnel from the cultivation in the process of collecting representative samples for testing if the specification in subsection (a)(3)(i) is met.
    i. Personnel from the cultivation may collect and deliver samples to the laboratory as part of the batch clearance process if there has been no prior notification that the sample is designated to have supplemental surveillance testing; and
3. A trained representative of any AMCO-approved testing facility under conditions specified in (a)(4)(i)
    i. A trained agent of the testing facility approved to perform the supplemental screening may collect samples directly from the licensee under the direction of the board;
    ii. Samples received at a testing facility that is not approved to perform the supplemental screening or mandated "for cause" supplemental quality testing may be subdivided for transfer to an approved testing facility.
        A. Interlaboratory transfers must be made by laboratory personnel to maintain the chain of custody.

**ADDITION**: Alternatively, or in addition to, ***3 AAC 306.650. Chain of custody*** could be modified to include a statement allowing interlaboratory transfers.

**5. Laboratory to Laboratory Transfer of Samples**

a. For samples that are submitted for regular batch clearance to a testing facility not approved to perform supplemental tests, but the samples are designated for supplemental tests,

1. All other clearance testing (potency, microbial, terpene, and/or residual solvent testing) should be completed by the initial testing facility that accepted the samples.

2. An aliquot of the sample required for supplemental testing may be segregated and packaged by trained laboratory personnel and collected by Land & Seas on their regular courier route for transport to the lab in Wasilla for supplemental surveillance testing.

**CHANGE:** None required, as section ***3 AAC 306.650. Chain of custody*** already permits this type of transfer.
A marijuana testing facility shall establish an adequate chain of custody and sample requirement instructions that include

(5) documenting any transfer of samples, aliquots, and extracts to another marijuana testing facility for additional testing or at the request of the marijuana cultivation facility or marijuana product manufacturing facility that provided the testing sample;

**ADDITIONS:** Section ***3 AAC 306.665. Supplemental marijuana quality testing*** could be changed IF the supplemental surveillance screening is added to this section OR a new section for **3 AAC *306.676 Supplemental Surveillance Screening*** could be created and either subsection (**3 AAC 306.xxx (x) Collection of Samples)** could specify:

(a) Samples may be collected and presented to the laboratory by one of the following.....

ii. Samples received at a testing facility that is not approved to perform the supplemental screening or mandated "for cause" supplemental quality testing may be subdivided for transfer to an approved testing facility.
A. Interlaboratory transfers must be made by laboratory personnel to maintain the chain of custody.

**6. Sample Size**

a. Regardless of the frequency of testing (whether all samples or a sub-set of randomly designated samples are going to be tested), the size of a sample submitted for a clearance package must be increased to accommodate the additional testing in order to maintain the integrity of the sample size in terms of being "representative" and adequate enough to be "defensible" statistically. Therefore, there must be an increase of the minimum allowable sample sizes for each matrix to accommodate for the supplemental testing.

i. Given that the amount of sample needed for testing flower (or any type of flower biomass) is 2.0 grams, the minimum amount of flower allowed to be submitted for testing would have to increase to 6 grams for harvest batches that are 1-3 pounds in size and no samples of less than 6 grams, regardless of harvest batch size, should be accepted by the laboratories.

**CHANGES:** ***3 AAC 306.455. Required laboratory testing***

(a) A marijuana cultivation facility shall provide samples from each harvest batch package of marijuana produced at the facility to a marijuana testing facility and may not sell or transport any marijuana, except as provided for in (c) of this section, until all laboratory testing required under 3 AAC 306.645 has been completed.

(b) To comply with (a) of this section, a marijuana cultivation facility shall

(1) collect a representative sample for testing from each harvest batch package that has been uniformly dried and cured, in an amount as set out in the following table:

| Harvest Batch Package Size (pounds) | Number of 1g sub-samples to make up required sample |
|---|---|
| 1 | 6 |
| 2 | 6 |
| 3 | 6 |
| 4 | 6 |
| 5 | 8 |
| 6 | 10 |
| 7 | 11 |
| 8 | 13 |
| 9 | 14 |
| 10 | 16 |

ii. For the same reasons as stated above, concentrates/extracts would require a minimum of an additional 1.5 grams to be submitted for METRC clearance testing.

**CHANGE:** ***3 AAC 306.550. Required laboratory testing***

(a) A marijuana product manufacturing facility shall provide a sample of each marijuana product manufactured at the facility to a licensed marijuana testing facility and may not sell or transport a marijuana product until all laboratory testing required under 3 AAC 306.645 has been completed.

(b) To comply with (a) of this section, a marijuana product manufacturing facility shall

(1) collect a random sample for testing by selecting a product from each production lot in an amount as set out in the following table:

| **Sample Type** | **Minimum amount of sample required for testing** |
|---|---|
| Solvent-based concentrates, non-solvent-based concentrates, and food-based concentrates | 2 grams |
| Infused edible products | One retail package plus the amount required by the marijuana testing facility for microbial testing |

b. Alternatively, more than the minimum increase in sample size could be submitted for a better representation of the sample for supplemental testing.

c. Food-based concentrates should likely require testing prior to clearance for infused product manufacturing.

    i. Otherwise, all end products would require testing. This is far more complicated, not as reliable, and damaging to the instruments.

    ii. Food-based concentrates should be submitted as 2.0-gram samples to complete mandatory supplemental surveillance screening prior to production of final products.

**ADDITION: AAC 306.555. Production of marijuana concentrate** could have a specific subsection about the requirements for edible concentrates; i.e., All infused edible or topical products must use marijuana extract or concentrate that has passed quality assurance testing requirements as set forth in ***3 AAC 306.645***.

**7. Testing for Cause**

a. The current regulations under ***AAC 306.465 Random Sampling*** and ***AAC 306.665 Supplemental Marijuana Quality Testing*** already address the collection and assignment of financial responsibility for samples for which MCB or the Director of AMCO have requested additional quality testing "for cause." These sections specify that the cultivator or manufacturer is financially responsible for this additional testing. Under the current regulatory language, licensees could be asked to continue regular monitoring of batches for pesticides or heavy metals if MCB or the Director requests quality testing after failed results on a surveillance screening. This point would not be relevant if all batches are tested. Alternatively, if not all batches are tested and the division is responsible for payment of the supplemental surveillance screening program, this clause would essentially cap the cost of the program by requiring that all testing "for cause" be paid by the licensee.

b. Currently, under AAC 306.465 Random Sampling, the testing facilities are assigned responsibility for collecting samples for supplemental quality testing.

    i. This is not feasible financially for most licensees in the industry, as it would require sizable fees for transportation and collection time.

    ii. This section could be amended to state that trained Enforcement Officers or trained samplers could perform collection for supplemental marijuana quality samples. By not understanding how glass and metal exposure can contaminate samples during collection, it is important that personnel be trained.

**CHANGE:** ***AAC 306.465. Random sampling***

**(a)** The board will or the director shall from time to time require a standard or limited marijuana cultivation facility to provide samples of cannabis flower, growing medium, soil amendments, fertilizers, crop production aids, pesticides, or water for random compliance checks. The sample may be screened for pesticides and chemical residues, screened for unsafe levels of metals, and used for other laboratory tests the director finds to be in the interests of the public. **The marijuana cultivation facility shall bear all costs of testing under this subsection.**

(b) When the board or the director orders random sampling under this section, the director shall identify a licensed marijuana testing facility to perform the testing. The marijuana cultivation facility shall cooperate to facilitate the collection of samples. (Eff. 2/21/2016, Register 217)

**ADDITIONS:** ***AAC 306.465. Random sampling*** and/or ***3 AAC 306.665. Supplemental marijuana quality testing*** may include a subsection stating:

(c) Samples may be collected and presented to the laboratory by one of the following:

1. An AMCO Enforcement Officer trained in the collection of each specific type of sample;
2. Authorized personnel from the cultivation in the process of collecting representative samples for testing if the specification in subsection (a)(2)(i) is met.
    i. Personnel from the cultivation may collect and deliver samples to the laboratory as part of the batch clearance process if there has been no prior notification that the sample is designated to have supplemental surveillance testing; and
3. A trained representative of any AMCO-approved testing facility under conditions specified in (a)(3)(i-iii)
    i. A trained agent of the testing facility approved to perform the supplemental screening may collect samples directly from the licensee under the direction of the board;
    ii. Samples received at a testing facility that is <u>not</u> approved to perform the supplemental screening or mandated "for cause" supplemental quality testing may be subdivided for transfer to an approved testing facility.
        A. Interlaboratory transfers must be made by laboratory personnel to maintain the chain of custody.

**8. R&D Testing for Contaminants (Elective Supplemental Quality Testing)**

a. When consulting with laboratory personnel in other states and numerous white papers on the topic of testing cannabis and cannabis products for pesticides and heavy metals, it became clear that there will initially be many failures for contaminants that were unexpected by licensees. This results from many factors, including:

    i. Some pesticides become systemic to plants, meaning they are incorporated into the plant cells throughout the whole plant, and they transmit to the clones.

ii. Some pesticides have a longer half-life than others and need more time than expected to clear from the plant after the last use.

iii. Processing equipment (glass and nickel for instance) and low-quality cartridges are a very common sources of heavy metal contamination unknown to a cultivator or manufacturer.

b. Given that that these types of products are unsafe for public consumption, but not an intentional adulteration or contamination by licensees, MCB should consider granting "R&D" designation in METRC for licensees wishing to submit test samples for process improvement. Other states who allow this type of testing all specify that samples submitted under "R&D" may not ever clear a harvest batch. If the R&D tests pass, the harvest batch must still have all required tests performed under a regular clearance package.

i. This eliminates a loophole for licensees to submit their products under R&D always and then being able to endlessly submit portions of testing for clearance until getting the desired results.

**ADDITION:** ***AAC 306.665(x). Elective Supplemental Quality Testing***

(a) Cultivation and manufacturing facilities may submit samples for elective supplemental quality testing to an approved testing facility for the purposes of:

(1) research and development (R&D) to evaluate the facility's operational processes to ensure compliance and production of a safe product; or

(2) remediation of batches that have failed initial pesticide or metals screening.

(b) Batches and products submitted for elective supplemental quality testing must be segregated from other batches and products.

(1) Batches and products must be designated as "R&D" or "Remediation" by a clearly marked signage.

(2) Cultivation and manufacturing facilities must quarantine each R&D or Remediation batch in a separate area with signs for "R&D QUARANTINE" or "REMEDIATION QUARANTINE" clearly displayed.

(c) Elective supplemental quality testing may not clear a harvest batch for retail.

(1) Any elective tests passed must be repeated as a part of the regular clearance process with all other required tests passing per 3 AAC.645 prior to release of any harvest or production batch to retail.

**9. Remediation and Retest of Failed Products**

a. Some states do not allow remediation of failed products or harvest batches.

b. Many states allow remediation of failed flower or products for pesticides and heavy metals. The remediation plan is not the same for the two contaminants.

i. For flower and any type of biomass, pesticide remediation, heat, time, light (particularly UV), and ozone exposure can degrade many pesticides. These are safe ways of remediating flower product to pass testing and salvage harvest batches.

1. This flower biomass could be marked for R&D and submitted for elective supplemental quality testing, or it could be remediated and then be submitted

back to the laboratory without R&D for a single retest. States allowing remediation and retest of flower batches failing pesticides do not allow more than one retest.

ii. For concentrates failing pesticide testing, dilution into a food-grade concentrate is a reasonable strategy for safely remediating product into something that will not be inhaled.

    1. These products could be transferred to an infused product manufacturer for dilution and retest PRIOR to production of edible or topical products.

iii. Remediation of products for heavy metals includes dilution or a series of complicated chemical reactions.

    1. Because the latter involves infusing many other dangerous chemicals into a concentrate and because these chemicals are not easily removed and are not currently being tested, this strategy is not safe for products being consumed or inhaled by consumers.

    2. Dilution strategies could include mixing of a failed concentrate with a food-based concentrate that is retested and used for production of edibles once below the action level. This prevents products intended for inhalation to then get non-homogenously mixed with concentrates and then smoked.

**CHANGE:** ***3 AAC 306.660. Failed materials; retests*** could have a subsection added to it that states:

(d) If a sample from a harvest batch of marijuana or a production batch of marijuana concentrate of any kind fails pesticide testing the batch must be destroyed, as required under 3 AAC 306.740, except as permitted under subsections (1) and (2) of this subsection.

(1) If a sample from a batch of marijuana flower (or any type of biomass) fails pesticide testing, the board or the director may permit the grower to remediate the batch using procedures that would reduce the concentration of pesticides to less than the action level with such methods as:

i. Time in holding;
ii. Ozone exposure;
iii. Heat exposure; and/or
iv. UV/Light exposure.

Any batch of flower or usable biomass that has been remediated must be re-sampled and re-tested and must pass the full panel of tests applicable to the matrix being tested under 3 AAC 306.645 and supplemental quality testing for pesticides. A batch that is remediated but fails pesticide testing after being re-sampled and re-tested must be destroyed as per 3 AAC 306.740, unless:

v. The batch is remediated by mixing it with batches of flower biomass or concentrate that is under the action limit prior further dilution into a food-based concentrate for the production of infused edible or topical products. It the batch fails the subsequent mandatory retest, it must be destroyed per 3 AAC 306.740.

(2) If a manufacturing facility concentrates marijuana or usable marijuana biomass of any kind that initially passed pesticide testing under 3 AAC 306.645, or if the product was transferred to the manufacturing facility prior to compliance testing and the batch fails supplemental testing, the batch may be remediated by dilution into a food-based concentrate that would reduce the concentration of pesticides to less than the action level and it must then be used for the production of infused edible or topical products.

(e) If a sample from a harvest batch of marijuana or a production batch of marijuana concentrate of any kind fails heavy metals testing the batch must be destroyed, as required under 3 AAC 306.740, except as permitted under subsections (1) of this section.

(1) Dilution strategies could include mixing of a failed concentrate with a food-based concentrate that is retested and used for production of edibles once below the action level. This prevents products intended for inhalation to then get non-homogenously mixed with concentrates and then smoked.

**ADDITION:** Alternatively, a new section ***3 AAC 306.66x. Remediation of Failed Products*** could be added to address remediation of all types of marijuana and marijuana products, to include residual solvents.

**10. Labeling Requirements**

Regulatory language for "labeling" must also be considered. For cultivations, the section should likely say the following:

**CHANGE: 3 AAC 306.475. Labeling of marijuana**

(a) When a marijuana cultivation facility packages marijuana.....

(1) a statement listing the results of microbial testing required under 3 AAC

(2) a statement listing the results of residual solvent testing required under 3 AAC 306.645(b)(3), if applicable; and

(4) a statement listing any contaminants for which the product was tested in addition to contaminants for which 3 AAC 306.645(b) requires testing; any additional tested contaminants include

(A) molds, mildew, and filth;

(B) herbicides, pesticides, and fungicides;

(C) heavy metals; and

(D) harmful chemicals, to include mycotoxins.

(b) If a marijuana cultivation facility ships wholesale marijuana from a harvest batch that has not been tested for each contaminant listed in (e)(4) of this section, the label for that batch must include a statement identifying each contaminant listed in (e)(4) of this section for which that harvest batch has not been tested. (Eff. 2/21/2016, Register 217; am 11/8/2018, Register 228)

**For the labeling of marijuana products, to include inhalable and non-inhalable concentrates, the following should be considered:**

**3 AAC 306.570. Labeling of marijuana products**

(a) With each production lot of marijuana product sold, a marijuana product.....

(1) a cannabinoid potency profile expressed as a range of percentages that extends from the lowest percentage to highest percentage of concentration for each cannabinoid listed from every test conducted on that production lot from the same marijuana product manufacturing facility within the last three months;

(2) a statement listing the results of microbial testing required under 3 AAC 306.645(b)(2);

(3) a statement listing the results of residual solvent testing required under 3 AAC 306.645(b)(3), if applicable; and

(4) a statement listing any contaminants for which the product was tested in addition to contaminants for which 3 AAC 306.645(b) requires testing; any additional tested contaminants include

(A) molds, mildew, and filth;

(B) herbicides, pesticides, and fungicides; and

(C) heavy metals; and

(D) harmful chemicals, to include mycotoxins

If a marijuana product manufacturing facility ships wholesale marijuana product from a production lot of marijuana product that has not been tested for each contaminant listed in (d)(4) of this section, the label for that lot must include a statement identifying each contaminant listed in (d)(4) of this section for which that lot has not been tested. (Eff. 2/21/2016, Register 217)

**THE FOLLOWING ISSUES ARE NOT PART OF THE PESTICIDE/METALS TESTING, BUT ARE RECENT PROPOSALS FOR CHANGE THAT WERE FOUND IN THIS REVIEW OF THE REGULATIONS:**

**AAC 306.560. Potency limits per serving and transaction for edible marijuana products**

A marijuana product manufacturing facility may not prepare a marijuana product with potency levels exceeding the following, as tested in compliance with 3 AAC 306.645:

(1) for a single serving of a marijuana product, not more than 10 milligrams of active tetrahydrocannabinol (THC) or Delta 9; Is this changed to d8-THC plus d9-THC and is it PLUS THCA80.877 already?

(2) in a single packaged unit of a marijuana product to be eaten or swallowed, not more than 10 servings or 100 milligrams of active THC or Delta 9; the THC content must be homogenous, or evenly distributed throughout the marijuana-infused product. (Eff. 2/21/2016, Register 217; am 9/1/2021, Register 239)

**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 a marijuana product. 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 required for each test it offers, and shall perform tests using methods in compliance with guidelines prescribed by the board.

(a) 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:

the required cannabinoid potency test must at least determine the concentration of THC (d8-THC and d9-THC—wasn't this discussed and approved at the last MCB meeting???), THCA, CBD, CBDA, and CBN cannabinoids;

**3 AAC 306.645. Laboratory testing of marijuana and marijuana products**

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

(i) for a potency test on marijuana and marijuana concentrate, the marijuana testing facility shall list for each required cannabinoid a single percentage concentration, based on dry weight, that represents an average of all samples within the test batch; additionally, total THC and total CBD shall be reported;

(ii) for a potency test on a marijuana product, whether conducted on each individual production lot or using process validation, the marijuana testing facility shall list for each cannabinoid the total number of milligrams contained within a single retail marijuana product unit for sale; testing whether the THC content is homogenous, the marijuana testing facility shall report the total THC content, as defined in 3 AAC 306.990.

**3 AAC 306.645. Laboratory testing of marijuana and marijuana products**

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

SAME CONTENT IN CONDENSED LAB FORMAT

| Substance | Acceptable Limits in Colony Forming Units Per Gram | Product to be Tested |
|---|---|---|
| --*Shiga*-toxin producing *Escherichia coli* (STEC)- bacteria | <1 (CFU/g) | Marijuana; retail marijuana products; water-and food- based concentrates |
| *Salmonella* species-bacteria | <1 (CFU/g) | |
| *Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger-fungus* | <1 (CFU/g) | |

SAME CONTENT IN CONDENSED LAB FORMAT

| Substance | Acceptable Limits Per Gram in Parts per Million (PPM) | Product to be Tested |
|---|---|---|
| Butanes | <800 | Solvent-based concentrates |
| Heptanes | <500 | |
| Benzene | <1 | |
| Toluene | <1 | |
| Hexane | <10 | |
| Xylenes (Total of meta-eylenes, para-xylenes, and/or ortho- xylenes) | <1 | |

**3 AAC 306.990. Definitions**

(a) In AS 17.38 and this chapter,

(1) "THC" means tetrahydrocannabinol, the main psychoactive substance found in marijuana, which shall be a sum of the two tetrahydrocannabinol isomers-- d8-THC and d9-THC; (Did this get approved at the last meeting? If so, the wording would change to this.)

(2) "total THC" means the sum of THC (d8-THC and d9-THC) and (0.877)*(THCA). (Did this get approved at the last meeting? If so, the wording would change to this.)