From:	Jessica Alexander
To:	CED MCB AMCO (CED sponsored)
Cc:	Marijuana Licensing (CED sponsored)
Subject:	Laboratory Operational Change Plan Requiring Regulatory Changes-- Notice for Public Comment
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To whom it concerns at AMCO, the cannabis industry, and the general public:

Land & Seas Laboratory is prepared to fill the need for surveillance screening of cannabis flower and concentrates/extracts for dangerous contaminants, to include pesticides and heavy metals. As such, an *MJ15: Operational Plan Change* form was submitted for consideration at the next MCB meeting. Granting the request will require regulatory changes that should be considered by the industry and general public. PLEASE SEE THE REQUEST FROM THE MJ15 VERBATIM BELOW:

"Furthermore, we are requesting the following actions be taken or approved so that the Alaska pesticide and heavy metals testing program can begin:

1) Marijuana Control Board review of a presentation on the background and justifications for the analytes and their pass/fail criteria. This will be based on the feedback from other states (in particular Montana) and the Alaska Department of Agriculture so that there is context and relevant data on which to base these decisions.
2) Land & Seas Laboratory be granted permission to formulate a cohesive plan for a courier system to transport sub-samples from the other testing facility so that samples which have been designated for pesticide/metals testing may still be processed at the other laboratory for everything else required, while the sub-sample be set aside and transferred to Land & Seas Laboratory for pesticide and heavy metal analysis. This plan would then be submitted to MCB for final approval.
3) DEC contracting to review validations and perform on-site audits for final approval."

To balance the needs of the public for improved consumer safety against the needs of the industry for a financially feasible plan that doesn't damage its viability, Land & Seas would like to present some **other points that must be considered in making the regulatory changes requested**. We ask that members of the public and the cannabis industry not only consider these points, but present and consider additional options.

1. Number of Samples Tested
    a. Most states require all samples submitted for clearance to be tested.
    b. Some states do a random sampling of all samples submitted for clearance.
        i. Land & Seas is proposing that 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 testing."

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.
        ii. The financial responsibility for randomly-generated, supplemental surveillance testing 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 testing.
2. 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.
    c. Public and industry should present and consider other ways of bypassing the process to sale contaminated products.
3. 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.
    c. The cultivators and manufacturers could be responsible for collecting their own samples.
4. Laboratory to Laboratory Transfer of Samples
    a. For samples that are designated for pesticide and heavy metals testing that are submitted to CannTest for METRC clearance, all other testing (potency, microbial, terpene, and/or residual solvent testing) should be completed by CannTest.
    b. The portion of the sample needed for pesticide and heavy metals testing could be segregated 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.
5. 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.

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.

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

c. Food-based concentrates would 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 or supplemental surveillance testing.

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. This specifies that the cultivator or manufacturer is financially responsible for this additional testing. Under the current regulatory language, licensees may 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 test. This point would be irrelevant if all batches are tested. Alternatively, that would, in effect, cap the budget for supplemental surveillance testing if not every sample was tested and the AMCO overage was budgeted to pay for testing.

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.

8. R&D Testing for Contaminants

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.

9. Remediation of Failed Products
    a. Some states do not allow remediation of failed product.
    b. Many states allow remediation of failed products for pesticides and heavy metals.
        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 product could be marked for R&D or go back to the laboratory without R&D for a retest. States allowing remediation and retest of flower batches 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 edible 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 be non-homogenously mixed with concentrates passing testing to be smoked.

Anyone with further technical questions or requesting reference documents may email support@landandseaslab.com. Thank you for your consideration. This is a big step to improve product safety for consumer!

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