

Discussion/recommendations of testing and potency standards



ARIZONA DEPARTMENT
OF HEALTH SERVICES

Health and Wellness for all Arizonans

NOTE: The following slides are intended as a starting point for Council discussion based on [information presented](#) at the initial Council meeting on 9/26/19 and updated based subsequent meetings and recommendations by Council members.

Key Discussion Points

- What parameters should be tested for within each category?
- What is the safety level before a product must be remediated or disposed?
- What test method options should be used?

Considerations for Discussion

- Statutory intent is to detect “unsafe levels” and confirm potency
- What framework should guide setting action levels? Variable? Protective for children? For immunocompromised?
- Consider requiring existing methods OR in-house developed methods meeting method criteria of previously validated methods

Potency

Council Recommendations

PASSED 11/12/19

- All products must be tested for THC-A, Δ 9-THC, CBD-A, CBD, and any label claims.
- Total THC and CBD shall be reported as follows:
 - Total THC = (Δ 9-THC + (THC-A x 87.7%))
 - Total CBD = (CBD + (CBD-A x 87.7%))
- Potency of all products must test within 20% of label claim or be repackaged to meet actual concentration.

Council Recommendations

PASSED 11/12/19

- Potency reporting should include, at minimum:
 - for anything over 10% cannabinoid - one decimal place (i.e., 12.3%)
 - for anything under 10% but above 0.1% - two decimal places (0.01%)
 - For anything under 0.01% - three decimal places (i.e., 0.012%)
- For edibles, report potency in mg with two significant figures

Council Recommendations

PASSED 11/12/19

- Potency testing can be conducted by AHP or in-house methods that are validated by AOAC Appendix K or other federal or international standards that meet the criteria

Additional Discussion

- Note about results below the limit of detection?

Microbial Contamination

E. Coli – Council Recommendations

PASSED 10/24/19

All products must be tested for *E. coli* prior to sale.

- Products testing ≤ 100 CFU/g pass
- Products testing > 100 CFU/g must be remediated or reprocessed as applicable and retested prior to sale

Salmonella – Council Recommendations

PASSED 11/12/19

All final products must be tested for Salmonella. Samples with detectable Salmonella will fail and must be destroyed - no remediation possible.

Microbial Contamination

Aspergillus – Council Recommendations

PASSED 11/12/19

All inhaled products must either be:

- a. Tested for *Aspergillus flavus*, *fumigatus*, *niger*, *terreus* using molecular methods (PCR, qPCR, DNA microarrays, sequencing). Products ≤ 1 CFU pass and no further testing is required. If the result is > 1 CFU, the product must be tested for mycotoxins using HPLC, Elisa, or an in-house developed method that is validated by AOAC Appendix K or other federal or international standards. Products testing $\geq 20\mu\text{g}/\text{kg}$ (ppm) mycotoxins fail and cannot be remediated.

OR

- b. Tested for mycotoxins using HPLC, Elisa, or an in-house developed method that is validated by AOAC Appendix K or other federal or international standards. Products testing $\geq 20\mu\text{g}/\text{kg}$ (ppm) mycotoxins fail and cannot be remediated.

Microbial Contamination

Other Parameters – Member Recommendations

No testing for aflatoxins. These would be at least partly degraded by the heat of smoking or decarboxylation, if present. Seedless cannabis plants are not capable of supporting aflatoxin production, because they lack the high oil content necessary for *A. flavus* replication.

Other Parameters – Member Recommendations

No need to test Cannabis for “total yeast and mold”. These tests detect only a small fraction of the fungal species in the environment, and do not correlate with the presence of pathogenic species. Molds can also be a source of plant spoilage, but these processes can be monitored appropriately by testing for water activity levels, and by visual or microscopic inspection.

Microbial Contamination

Other Parameters – Member Recommendations

No need to test cannabis for *Pseudomonas aeruginosa*, *Listeria*, toxigenic *E. Coli* (e.g., H7:0157), or other bacterial pathogens besides *Salmonella*. Cannabis is not a potential delivery vehicle for these organisms, or for most bacterial pathogens. This does not mean that mis-handled or improperly cured cannabis could not be a vehicle for these organisms. As with any agricultural or food product, it can be a source of increased hazard if it is maintained at high water activity levels.

Microbial Contamination

Method Considerations

- Use Bacteriological Analytical Manual (FDA 2013a) and validated by AOAC Appendix J

Additional Discussion

- Any other parameters for testing?
- Any other method options for testing?

Heavy Metals

Member Recommendations:

Solvent	Limit (ppm)
Arsenic	≤ 0.4
Cadmium	≤ 0.4
Lead	≤ 1.0
Mercury	≤ 0.2

ADHS Note: Consider MI chromium limits, USP limits for all other elements, and differing limits for inhalables vs. other products

Solvent	Limit (ppm)	
	Inhalable	Other
Arsenic	0.2	1.5
Cadmium	0.5	0.5
Lead	0.5	0.5
Mercury	0.1	3.0
Chromium	0.6	2.0

Heavy Metals

Method Considerations

- Any FDA/USP or in-house developed method that is validated by AOAC Appendix K and can meet the method criteria from the EPA methods

Additional Discussion

- Any other parameters for testing?
- Any other method options for testing?

Pesticides, Fungicides, Herbicides, Growth Regulators

Oregon List and Limits

Table 2. Pesticide analytes and their action levels

Analyte	Chemical Abstract Services (CAS) Registry number	Action level ppm	Analyte	Chemical Abstract Services (CAS) Registry number	Action level ppm
Abamectin	71751-41-2	0.5	Imazalil	35554-44-0	0.2
Acephate	30560-19-1	0.4	Imidacloprid	138261-41-3	0.4
Acequinocyl	57960-19-7	2	Kresoxim-methyl	143390-89-0	0.4
Acetamiprid	135410-20-7	0.2	Malathion	121-75-5	0.2
Aldicarb	116-06-3	0.4	Metalaxyl	57837-19-1	0.2
Azoxystrobin	131860-33-8	0.2	Methiocarb	2032-65-7	0.2
Bifenazate	149877-41-8	0.2	Methomyl	16752-77-5	0.4
Bifenthrin	82657-04-3	0.2	Methyl parathion	298-00-0	0.2
Boscalid	188425-85-6	0.4	MGK-264	113-48-4	0.2
Carbaryl	63-25-2	0.2	Myclobutanil	88671-89-0	0.2
Carbofuran	1563-66-2	0.2	Naled	300-76-5	0.5
Chlorantraniliprole	500008-45-7	0.2	Oxamyl	23135-22-0	1
Chlorfenapyr	122453-73-0	1	Paclobutrazol	76738-62-0	0.4
Chlorpyrifos	2921-88-2	0.2	Permethrins*	52645-53-1	0.2
Clofentezine	74115-24-5	0.2	Phosmet	732-11-6	0.2
Cyfluthrin	68359-37-5	1	Piperonyl butoxide	51-03-6	2
Cypermethrin	52315-07-8	1	Prallethrin	23031-36-9	0.2
Daminozide	1596-84-5	1	Propiconazole	60207-90-1	0.4
DDVP (Dichlorvos)	62-73-7	0.1	Propoxur	114-26-1	0.2
Diazinon	333-41-5	0.2	Pyrethrins†	8003-34-7	1
Dimethoate	60-51-5	0.2	Pyridaben	96489-71-3	0.2
Ethoprophos	13194-48-4	0.2	Spinosad	168316-95-8	0.2
Etofenprox	80844-07-1	0.4	Spiromesifen	283594-90-1	0.2
Etoxazole	153233-91-1	0.2	Spirotetramat	203313-25-1	0.2
Fenoxycarb	72490-01-8	0.2	Spiroxamine	118134-30-8	0.4
Fenpyroximate	134098-61-6	0.4	Tebuconazole	80443-41-0	0.4
Fipronil	120068-37-3	0.4	Thiacloprid	111988-49-9	0.2
Fonicamid	158062-67-0	1	Thiamethoxam	153719-23-4	0.2
Fludioxonil	131341-86-1	0.4	Trifloxystrobin	141517-21-7	0.2
Hexythiazox	78587-05-0	1			

Pesticides, Fungicides, Herbicides, Growth Regulators

Member Recommendations

- Implement the Oregon list
- Implement the Colorado approved pesticide list
 - Rationale – Arizona Department of Agriculture has adapted this state's list for the Hemp program.

Method Considerations

- Utilize any AOAC or in-house developed method that is validated by AOAC Appendix K and can meet the method criteria from the EPA methods.

Additional Discussion

- Any other parameters for testing?
- Any other method options for testing?

Residual Solvents

Oregon List and Limits

Table 3. List of solvents and their action levels

Solvent	Chemical Abstract Services (CAS) Registry number	Action level (µg/g)	Solvent	Chemical Abstract Services (CAS) Registry number	Action level (µg/g)
1,2-Dimethoxyethane	110-71-4	100	Ethanol	64-17-5	5000
1,4-Dioxane	123-91-1	380	Ethyl acetate	141-78-6	5000
1-Butanol	71-36-3	5000	Ethylbenzene	100-41-4	See Xylenes
1-Pentanol	71-41-0	5000	Ethyl ether	60-29-7	5000
1-Propanol	71-23-8	5000	Ethylene glycol	107-21-1	620
2-Butanol	78-92-2	5000	Ethylene Oxide	75-21-8	50
2-Butanone	78-93-3	5000	Heptane	142-82-5	5000
2-Ethoxyethanol	110-80-5	160	n-Hexane	110-54-3	290
2-methylbutane	78-78-4	5000*	Isopropyl acetate	108-21-4	5000
2-Propanol (IPA)	67-63-0	5000	Methanol	67-56-1	3000
Acetone	67-64-1	5000	Methylpropane	75-28-5	5000*
Acetonitrile	75-05-8	410	2-Methylpentane	107-83-5	290†
Benzene	71-43-2	2	3-Methylpentane	96-14-0	290†
Butane	106-97-8	5000*	N,N-	127-19-5	1090
Cumene	98-82-8	70	dimethylacetamide		
Cyclohexane	110-82-7	3880	N,N-	68-12-2	880
Dichloromethane	75-09-2	600	dimethylformamide		
2,2-dimethylbutane	75-83-2	290†	Pentane	109-66-0	5000
2,2-dimethylbutane	79-29-8	290†	Propane	74-98-6	5000*
1,2-dimethylbenzene	95-47-6	See Xylenes	Pyridine	110-86-1	200
1,3-dimethylbenzene	108-38-3	See Xylenes	Sulfolane	126-33-0	160
1,4-dimethylbenzene	106-42-3	See Xylenes	Tetrahydrofuran	109-99-9	720
Dimethyl sulfoxide	67-68-5	5000	Toluene	108-88-3	890
			Xylenes‡	1330-20-7	2170

2019 Oregon List
45 → 24 Solvents

Residual Solvents

Member Recommendations

- Utilize Oregon's list of parameters
- At a minimum, processed finished material must be tested for residual solvents based on known cannabis extraction processes
 - Propane
 - Acetone
 - Isopropyl Acetate
 - Butanes
 - Heptanes
 - Benzene
 - Toluene
 - Hexene
 - Xylenes

Residual Solvents

Limits - Member Recommendations

- Use Oregon's safety limits
- Use United States Pharmacopeia (USP) limits
- Use limits in table

Solvent	Limit (PPM)	Solvent	Limit (PPM)
Propane	≤5000	Heptanes	≤5000
Acetone	≤1000	Benzene	≤2
Isopropyl Acetate	≤1000	Toluene	≤890
Butanes	≤5000	hexane	≤290
		Xylenes	≤1

- A failed batch may be remediated

Residual Solvents

Method Considerations

- Any EPA, AOAC, or in-house developed method that is validated by AOAC Appendix K and can meet the method criteria from the EPA methods

Additional Discussion

- Any other parameters for testing?
- Any other method options for testing?

Other Testing

Terpenes – Member Recommendation

- Any terpene claims made by a product's label, must be verified by terpene analysis
- Data must be present on certification of analysis (COA) and handed out to every patient at time of purchase

Water Activity – Member Recommendation

- Test for water activity
 - In dried flower harvest-batch sample
 - In concentrates
 - In infused products
- Limits
 - Water activity ≤ 0.65 A_w passes
 - Water activity > 0.65 A_w fails must be remediated

Rationale

Water activity vs. moisture content: While moisture content simply defines the amount of water in bud, concentrates, food and ingredients, water activity defines how the water in your food will react with microorganisms. The higher the water activity, the faster microorganisms like bacteria, yeast, and mold will be able to grow.

Filth and Foreign Material – Member Recommendation

- Use CA § 5325 for definition of “filth and foreign material” Includes but not limited to hair, insects, feces, packaging contaminants, and manufacturing waste and by-products.
- Sample passage levels:
 - Mold or foreign material – Average of $\leq 5\%$, by weight
 - Mammalian excreta – Average of $\leq 1\text{mg}$ per pound

Other Testing