

## Guidance: “Trace Amounts” of Toxicants in Consumable Hemp Products

### Purpose

This document provides guidance to Consumable Hemp Manufacturers on acceptance criteria and action levels for “Trace Amounts” of Toxicants in Consumable Hemp products. HHS will use these criteria when determining compliance of COAs and products submitted by Manufacturers. This guidance is provided in conjunction with previous guidance provided by HHS: [Certificate of Analysis \(COA\) Requirements for Consumable Hemp Products](#).

### Background

- “*Certificate of analysis*” or “COA” means an official document released by an accredited laboratory following an analysis of a consumable hemp product. The certificate of analysis contains all the concentrations of cannabinoids, pesticides, residual solvents, metals, harmful pathogens, toxicants, and synthetic or semisynthetic cannabinoids, including data on levels of total delta-9 tetrahydrocannabinol content concentration and whether a sample passed or failed any limits related to these analyses.
- “*Synthetic consumable hemp products*” means products containing synthetic or semisynthetic cannabinoids. Synthetic and semisynthetic cannabinoids refer to a class of cannabinoids that are created through a chemical process and are structurally similar to naturally occurring cannabinoids or cannabinoids that may occur in very small amounts naturally. Examples of synthetic consumable hemp products include, but may not be limited to, delta-8 tetrahydrocannabinol, delta-10 tetrahydrocannabinol, hexahydrocannabinol (HHC), tetrahydrocannabiphorol (THC-P), and tetrahydrocannabinol-O-acetate (THC-O).
- 641—156.3(204) Testing requirements and documentation.
  - 641-156.3b.(4) The consumable hemp product is from a batch that has been tested for, and does not contain more than trace amounts of, pesticides, residual solvents, metals, harmful pathogens, and toxicants; and
  - 641-156.3b.(5) The batch does not contain synthetic or semisynthetic cannabinoids as described in these rules.

## Analysis

The following acceptance criteria will be used to determine compliance for Trace Amounts of Toxicants:

Analyte (Toxicant)	Action Level	Guideline, Citation
Metals	See Table 1	<a href="#">FDA Q3D, Elemental Impurities Guidance</a>
Solvents	See Table 2	<a href="#">Oregon Administrative Rule (OAR) 333-00710-0410: Table 4</a>
Pesticides	See Table 3	<a href="#">APHL "Guidance for State Medical Cannabis Testing Programs" (2016)</a>
Microbiological Impurities (Pathogens)	See Table 4	<a href="#">American Herbal Pharmacopeia (USP 1111)</a>
Synthetic or Semi-Synthetic Cannabinoids	>0.0 (must indicate non-detect)	Iowa Code chapter 204, 641 IAC 156

## References

**Table 2 – Metals Acceptance Criteria**

Element	Class	Oral Concentration µg/g	Parenteral Concentration µg/g
Cd	1	0.5	0.2
Pb	1	0.5	0.5
As	1	1.5	1.5
Hg	1	3	0.3
Co	2A	5	0.5
V	2A	10	1
Ni	2A	20	2
Tl	2B	0.8	0.8
Au	2B	30	30
Pd	2B	10	1
Ir	2B	10	1
Os	2B	10	1
Rh	2B	10	1
Ru	2B	10	1
Se	2B	15	8
Ag	2B	15	1.5
Pt	2B	10	1
Li	3	55	25
Sb	3	120	9
Ba	3	140	70
Mo	3	300	150
Cu	3	300	30
Sn	3	600	60
Cr	3	1100	110

**Table 2 – Solvents Acceptance Criteria**

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-dimethylacetamide	127-19-5	1090
Cumene	98-82-8	70	N,N-dimethylformamide	68-12-2	880
Cyclohexane	110-82-7	3880	Pentane	109-66-0	5000
Dichloromethane	75-09-2	600	Propane	74-98-6	5000*
2,2-dimethylbutane	75-83-2	290†	Pyridine	110-86-1	200
2,3-dimethylbutane	79-29-8	290†	Sulfolane	126-33-0	160
1,2-dimethylbenzene	95-47-6	See Xylenes	Tetrahydrofuran	109-99-9	720
1,3-dimethylbenzene	108-38-3	See Xylenes	Toluene	108-88-3	890
1,4-dimethylbenzene	106-42-3	See Xylenes	Xylenes‡	1330-20-7	2170
Dimethyl sulfoxide	67-68-5	5000			

- \* Limit based on similarity to pentane.
- † Limit based on similarity with n-hexane.
- ‡ Combination of: 1,2-dimethylbenzene, 1,3-dimethylbenzene, 1,4-dimethylbenzene, and ethyl benzene

**Table 3 – Pesticides Acceptance Criteria**

**Table 1: Pesticide analytes and their action levels in OR**

Analyte	Chemical Abstract Services (CAS) Registry Number	Action Level ppm
Abamectin	71751-41-2	0.5
Acephate	30560-19-1	0.4
Acequinocyl	57960-19-7	2
Acetamiprid	135410-20-7	0.2
Aldicarb	116-06-3	0.4
Azoxystrobin	131860-33-8	0.2
Bifenazate	149877-41-8	0.2
Bifenthrin	82657-04-3	0.2
Boscalid	188425-85-6	0.4
Carbaryl	63-25-2	0.2
Carbofuran	1563-66-2	0.2
Chlorantraniliprole	500008-45-7	0.2
Chlorfenapyr	122453-73-0	1
Chlorpyrifos	2921-88-2	0.2
Clofentezine	74115-24-5	0.2
Cyfluthrin	68359-37-5	1
Cypermethrin	52315-07-8	1
Daminozide	1596-84-5	1
DDVP (Dichlorvos)	62-73-7	0.1
Diazinon	333-41-5	0.2
Dimethoate	60-51-5	0.2
Ethoprophos	13194-48-4	0.2
Etofenprox	80844-07-1	0.4
Etiozole	153233-91-1	0.2
Fenoxycarb	72490-01-8	0.2
Fenpyroximate	134098-61-6	0.4
Fipronil	120068-37-3	0.4
Flonicamid	158062-67-0	1
Fludioxonil	131341-86-1	0.4
Hexythiazox	78587-05-0	1
Imazalil	35554-44-0	0.2
Imidacloprid	138261-41-3	0.4
Kresoxim-methyl	143390-89-0	0.4
Malathion	121-75-5	0.2
Metalaxyl	57837-19-1	0.2
Methiocarb	2032-65-7	0.2
Methomyl	16752-77-5	0.4
Methyl parathion	298-00-0	0.2

Analyte	Chemical Abstract Services (CAS) Registry Number	Action Level ppm
MGK-264	113-48-4	0.2
Myclobutanil	88671-89-0	0.2
Naled	300-76-5	0.5
Oxamyl	23135-22-0	1
Paclobutrazol	76738-62-0	0.4
Permethrins <sup>16</sup>	52645-53-1	0.2
Phosmet	732-11-6	0.2
Piperonyl_butoxide	51-03-6	2
Prallethrin	23031-36-9	0.2
Propiconazole	60207-90-1	0.4
Propoxur	114-26-1	0.2
Pyrethrins <sup>17</sup>	8003-34-7	1
Pyridaben	96489-71-3	0.2
Spinosad	168316-95-8	0.2
Spiromesifen	283594-90-1	0.2
Spirotetramat	203313-25-1	0.2
Spiroxamine	118134-30-8	0.4
Tebuconazole	80443-41-0	0.4
Thiacloprid	111988-49-9	0.2
Thiamethoxam	153719-23-4	0.2
Trifloxystrobin	141517-21-7	0.2

**Table 4 – Microbiological Impurities (Pathogens) Acceptance Criteria**

Microbiological Test	Consumable Products	Non-Consumable Products (Topicals, etc.)
Total aerobic microbial count	$10^3$ CFU/g Max acceptable count: 2000	$10^3$ CFU/g Max acceptable count: 2000
Total combined yeasts molds count	$10^2$ CFU/g Max acceptable count: 200	$10^2$ CFU/g Max acceptable count: 200
Shiga-Toxin Producing <i>E.coli</i>	Non-Detect	
<i>Salmonella</i>	Non-Detect	

## Conclusion

- HHS does not regulate third party accredited laboratories.
- Third-party accredited laboratories are not required to maintain methods necessary to verify or quantify all toxicants listed in these tables, but must list concentrations for those that it provides.
- A COA provided to a Manufacturer by an accredited laboratory must indicate, at a minimum, that it has been tested for:
  - Pesticides
  - Metals
  - Microbiological Impurities (Pathogens)
  - Synthetic or Semi-Synthetic Cannabinoids.
- Any COA provided to a Manufacturer by an accredited laboratory that lists results for any of the toxicants listed in these tables will be held accountable to the acceptance criteria and action levels in these tables.