

## Template for comments

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Name	Clause/ Subclause	Paragraph #/ Figure/ Table/	Type of comment <sup>1</sup> (ge, te, ed)	Comments	Proposed change	Response from JC or WG/Plan of Action
Staci Eisner	3.X Definitions		te	The word “solely” in the definition of “Synthesized cannabinoids” is confusing/misleading as it implies the compound in question is derived solely from lab/industrial facility rather than from a botanical source, when in fact a synthesized cannabinoid may be derived from either a plant or a lab/manufacturing facility (otherwise it would be an artificial cannabinoid).	Delete “solely”: <b>synthesized cannabinoids:</b> compounds <del>solely</del> -synthesized in the laboratory or industrial plant.	Remove “solely” from definition
Steven Dentali	Cannabinoid definitions		te	The definition for cannabinoid excludes endo- and artificial cannabinoids as subcategories because they don't meet the structural aspects defined there.	<b>cannabinoids:</b> Typically C <sub>21</sub> or C <sub>22</sub> (for the carboxylated derivatives) terpenophenolic compounds, their carboxylic acids, analogs and transformation products that bind to cannabinoid receptors, and endo- and artificial compounds that do the same.	Incorporate these changes to the definition
Michael Tims	3.X Definitions		ge	How come the definitions only covered THC and not other cannabinoids?	No proposed change	At this time the definitions only reference terms used in the proposed text of the standard (sections 5.3.6 and 5.7). Other cannabinoids are not mentioned in these sections and were therefore not defined in the standard definitions section.
Mark Jost	5.7 Hemp and/or hemp derived ingredients		te	Please define what is meant by hemp derived ingredients. Does this include CBD extracted from hemp?	No proposed change	Q: Add a definition for hemp derived ingredients?
Joe Betz	3.x	cannabinoids	te	This seems an ad hoc definition	'Phytocannabinoids are a diverse group of isoprenylated resorcinyll polyketides.' These compounds are produced by several plants, including hops. Change term from "cannabinoids" to "Cannabis phytocannabinoids". The first paragraph of Nat. Prod. Rep., 2016, 33, 1357 (attached) is instructive.	Q: Change term from “cannabinoids” to “Cannabis phytocannabinoids”?  Perhaps instead change phytocannabinoids to “Cannabis phytocannabinoids” as the Cannabinoids definition is meant to be broader?

<sup>1</sup> Type of comment: ge = general te = technical ed = editorial

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Joe Betz	3.x	nature identical cannabinoids	te	Inasmuch as the three GRAS notifications are based on hempseed, and products are only GRAS if used according to the conditions of use described in the GRAS notice and the GRAS notice can only be used by the GRAS filers and companies using a similar process to produce the GRAS ingredient (which definitively does not include addition of cannabinoids (natural or artificial), suggest removing this and re-visiting later.	<del>nature identical cannabinoids: synthesized or isolated cannabinoids identical to phytocannabinoids or endocannabinoids with respect to structure and stereochemistry.</del>	Q: Remove nature identical cannabinoids definition?
Joe Betz	3.x	phytocannabinoids	te	This term is not quite complete, as per comment above.	Change from 'phytocannabinoids' to 'Cannabis phytocannabinoids'	Q: Change "phytocannabinoids" to "cannabis phytocannabinoids"?
Joe Betz	3.x	synthesized cannabinoids	te	See comment above vis 'nature identical cannabinoids'	<del>synthesized cannabinoids: compounds solely synthesized in the laboratory or industrial plant.</del>	Q: Remove synthesized cannabinoids definition?
Joe Betz	3.x	artificial cannabinoids	te	See comment above vis 'nature identical cannabinoids'	<del>artificial cannabinoids: synthesized compounds not found in nature and that act by biological mechanisms similar to phytocannabinoids or endocannabinoids, e.g. K2 and Spice.</del>	Q: Remove artificial cannabinoids definition?
Joe Betz	3.x	chemovar	ed	My personal preference is the phrase 'chemical variety' rather than 'chemovar'. Note that Lewis et al (Planta Med 2018; 84: 225–233) rule out the words 'strain' and 'cultivar' for technical reasons. I do not propose adopting the new term they coin "PhytoFacts", but a simple definition should suffice	"Chemical variety (Chemovar)- Classification based on the unique biochemical attributes of particular Cannabis plants"	Q: Change "chemovar" to "chemical variety"? *If yes, remove cultivar definition and update Hemp definition removing reference to chemovars*  Q: Update definition?
Joe Betz	3.x	cultivar	te	Merriam-Webster says: "an organism and especially one of an agricultural or horticultural variety or strain originating and persistent under cultivation"	Change definition of cultivar	If changed chemovar to chemical variety this definition can be removed. If not, Q: Update definition of cultivar?
Joe Betz	3.x	endocannabinoids	te	Why do we need this definition?	<del>neurotransmitters</del> <b>compounds</b> produced in the body that bind to cannabinoid receptors	Q: Remove endocannabinoids definition?  Q: Update endocannabinoids definition?

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Joe Betz	3.x	hemp	te	Going to change the definition of hemp? The USDA APHIS <a href="https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/hemp">https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/hemp</a> thusly- "The term 'hemp' means the plant <i>Cannabis sativa</i> L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."	: the <i>Cannabis sativa</i> L plant with a THC concentration of not more than 0.3% on a dry weight basis that is the source of hemp plant parts. It is used to manufacture hemp ingredients and products. It is also the source material for cannabinoids and cannabinoid derivatives, other than synthesized cannabinoids. Hemp is distinguished from drug-type Cannabis chemovars which contain THC concentrations above 0.3%. Adopt USDA definition (which is also the farm bill of 2018 definition)	Q: Adopt USDA and Farm Bill definition of Hemp?
Joe Betz	3.x	identical compounds	ed	really need to define this?	delete	Q: Remove Identical Compounds definition?
Joe Betz	5.3.6	Known adulterants	te	I can easily envision a number of adulterants. The state of California prohibits 'synthetic marijuana', pesticides, toxic elements, etc.. Non-hemp Cannabis would be an expected adulterant (i.e. higher than 0.3% THC), other sources of oil (corn, soy), perhaps, other protein sources (casein, wheat, rice).	I think this one needs some more thought. For one thing, the word 'adulterant' is a term of art that can encompass accidental contamination that render the product economically deficient or hazardous.	Q: Expand the adulterants section to be more prescriptive?  Previous TG discussions concluded that we should remain consistent with the standard and not provide a list of specific adulterants unless the list would be complete. Given the nature of this ingredient that was determined to not be feasible.
Joe Betz	5.7	Hemp and/or hemp derived ingredients	te	The GRAS notices to which the Background info refers are for hempseed derived products. See <a href="https://www.fda.gov/food/cfsan-constituent-updates/fda-responds-three-gras-notices-hemp-seed-derived-ingredients-use-human-food">https://www.fda.gov/food/cfsan-constituent-updates/fda-responds-three-gras-notices-hemp-seed-derived-ingredients-use-human-food</a>	Dietary ingredients and finished products containing hemp <b>hulled hemp seed</b> , <b>hemp plant parts</b> <b>hemp seed protein powder</b> and/or hemp derived ingredients <b>hemp seed oil</b> shall have the be <b>tested for</b> THC content <b>tested and verified at</b> shall not <b>contain</b> more than 0.3% <b>THC</b> on a dry weight basis <b>using method XXX or equivalent</b> . The determination of the THC concentration must take into account the potential to convert THCA into THC.	Q: Update this section with the proposed changes focusing on the GRAS dossiers?  Q: Update this section with editorial changes – i.e. “shall have the be <b>tested for</b> THC content <b>tested and verified at</b> shall not <b>contain</b> more than 0.3% <b>THC</b> ”  Q: Specify a method within this section?

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						Previous TG discussions determined that we should not specify a method in this section.
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