

suggesting that all “hemp” food and beverage products cause psychoactive effects. Rather, DEA mentions this study in response to the assertions made by some commenters that eating “hemp” foods cannot possibly cause psychoactive effects.¹³

Attached to one of the comments was another study, which was also financed by various “hemp” companies. This study, entitled “Assessment of Exposure to and Human Health Risk from THC and other cannabinoids in hemp foods,” reached similar conclusions about the reduced levels of THC in currently marketed “hemp” foods and the diminished likelihood of testing positive for THC when consuming such products.

As for the comments claiming that “hemp” foods provide essential nutrients and are safe to eat, it is not DEA’s role under the CSA to assess the nutritional value or safety of foods.¹⁴ Regardless of whether the oil from cannabis seeds contains certain nutrients,¹⁵ the CSA does not provide

¹³ In a later study, financed by various “hemp” companies, human subjects were given oil from cannabis seeds containing lower doses of THC than in the Lehman study. G. Leson, *et al.*, Evaluating the Impact of Hemp Food Consumption on Workplace Drug Tests, *Journal of Analytic Toxicology*, vol. 25 (November/December 2001). The authors of this study reported that ingestion of cannabis seed oil containing these lower doses of THC resulted in little or no positive screening for THC, depending on the amount of THC consumed and the sensitivity of the urine testing. Companies who financed this study assert that the lower THC content given to the subjects of this study is commensurate with the current methods employed by these companies for cleaning the cannabis seeds before removing the oil from them for use in food products.

¹⁴ In the context of the CSA, the public “safety” (and DEA’s role therein) is implicated by the use of controlled substances for other than a legitimate medical purpose or in any other manner not authorized by the CSA.

¹⁵ Although this rule is not a food safety measure, because DEA received so many comments regarding this issue, some members of the public may be interested in the following information. Under the Federal Food, Drug, and Cosmetic Act, a substance that is added to food is not subject to the requirement of premarket approval if its safety is generally recognized among qualified scientific experts under the conditions of its intended use. 21 U.S.C. 321(s). A substance added to a food may be considered “generally recognized as safe” (GRAS) through experience based on “common use in food,” which requires a substantial history of consumption for food use by a significant number of consumers. 21 CFR 170.3(f), (h); 21 CFR 170.30. The FDA evaluated an industry submission claiming GRAS status for certain food uses of “hempseed oil” and expressly stated that it did not believe the submission provided a sufficient basis to classify “hempseed oil” as GRAS through experience based on common use in food. See FDA Center for Food Safety & Applied Nutrition, Office of Premarket Approval, Agency Response Letter, GRAS Notice No. GRN 00035 (August 24, 2000), reproduced at www.cfsan.fda.gov/rdb/opa-g035.html. In making this determination, the FDA did not evaluate whether there would be a basis for

for DEA to exempt food products that contain THC. As explained above and in the text accompanying the interim rule, the CSA prohibits human consumption of “any quantity” of a schedule I hallucinogenic substance outside of an FDA-approved product or FDA-approved research. Other than drugs that have been approved by the FDA for prescription use, or drugs that may be lawfully sold over the counter without a prescription, DEA may not exempt controlled substances to allow them to be used for human consumption—even in the case of products that supposedly contain only “trace amounts” of a controlled substance. 21 U.S.C. 811(g). Thus, DEA may not, as some commenters proposed, pick an arbitrary cutoff line allowing a certain percentage of THC in foods and beverages. Moreover, notwithstanding the statutory prohibition, DEA believes it would be inappropriate to attempt to establish an acceptable level of schedule I hallucinogens in food products. For example, it would not be appropriate to allow food products to contain “trace amounts” of such other schedule I hallucinogens as LSD or MDMA (“ecstasy”). Finding that it is contrary to the public welfare to allow human consumption of “any quantity” of schedule I hallucinogens, Congress did not give DEA the authority to determine what constitutes a “safe amount” of such drugs in food.¹⁶

Accordingly, DEA has limited the exemptions provided in this final rule to those cannabis-derived “hemp” products that do not cause THC to enter the human body.

Comments Regarding Testing Methods To Evaluate THC Content of Foods and Beverages

Many commenters asked the agency to indicate how it will determine whether a food or beverage product contains THC. Under federal law, it is legally sufficient to demonstrate a violation of the CSA based on the presence of any measurable amount of a prohibited controlled substance.¹⁷ Thus, the questions raised by the commenters are: “What testing methods

GRAS status through scientific procedures or whether “hempseed oil” would meet the standard for premarket approval as a food additive. *Id.*

¹⁶ To establish a violation of the CSA, the government does not have to prove that the controlled substance in question was of sufficient quantity to produce a psychoactive effect. *United States v. Nelson*, 499 F.2d 965 (8th Cir. 1974).

¹⁷ See, e.g., *United States v. Holland*, 884 F.2d 354, 357 (8th Cir. 1989), cert. denied, 493 U.S. 997 (1989); see also 21 U.S.C. 812(c), schedule I(c) (listing “any material, compound, mixture, or preparation, which contains any quantity” of hallucinogenic substances in schedule I).

will DEA utilize to determine whether a food product contains a measurable amount of THC and how sensitive are such methods?”

DEA will utilize testing assays or protocols used in standard analytical laboratories that have demonstrated valid and reliable sensitivity for the measurements of THC.¹⁸ The methodology, level of sensitivity, and degree of testing accuracy in the fields of analytical and forensic chemistry have evolved since the first discovery of THC in the 1960s. A variety of analytical equipment, testing methodologies, and protocols are described in the published scientific literature.¹⁹ Such methods may include (but are not limited to) gas chromatography, liquid chromatography, and mass spectrometry analyses. DEA has not, and will not, utilize any one method to the exclusion of others.²⁰

The lower limit of detectability of these assays can vary according to equipment, methodologies, and the form of the sample. Nonetheless, using currently available analytical methodologies and extraction procedures, it is reasonable to reproducibly and accurately detect THC at or below 1 part per million in cannabis bulk materials or products. Should more sensitive assays and analytical techniques be developed in the future, DEA will refine its testing methods accordingly.

Some companies that handle “hemp” food products have asked DEA whether the agency would test the companies’ products for THC content. It is not

¹⁸ In this context, “valid” means that the technique measures what it is designed to measure, and “reliable” means that the technique can be replicated by other laboratories.

¹⁹ See, e.g., M.V. Doig & R. Andela, *Analysis of pharmacologically active cannabinoids by GC-MS*, *Chromatographia* 52 (Supp.): S101-S102 (2000); P.D. Felgate & A.C. Dinan, *The determination of delta-9-tetrahydrocannabinol and 11-Nor-9-carboxy-delta-9-tetrahydrocannabinol in whole blood using solvent extraction combined with polar solid-phase extraction*, *Journal of Analytical Toxicology* 24:127-132 (2000); K. Ndjoko, *et al.*, *Analysis of cannabinoids by liquid chromatography-thermospray mass spectrometry and liquid chromatography-tandem mass spectrometry*, *Chromatographia* 47:72-76 (1998); B.J. Gudzinowicz & M.J. Gudzinowicz, *Analysis of drugs and metabolites by gas chromatography-mass spectrometry*, Volume 7: Natural, pyrolytic, and metabolic products of tobacco and marijuana, NY: Marcel Dekker, Inc. (1980).

²⁰ What constitutes the appropriate method of testing may vary depending on the circumstances. In any criminal prosecution, civil or administrative action, or other legal proceeding arising under the CSA, where the government must prove the presence of a controlled substance, the government may do so by the introduction of any evidence sufficient under law to prove such fact. See, e.g., *United States v. Bryce*, 208 F.3d 346, 352-354 (2d Cir. 2000).