

What Are the Registration Requirements for Handlers of "Hemp" Products Under This Final Rule?

In light of the exemptions provided under this rule, the following registration requirements should be considered:

Who must obtain a registration—Persons who wish to manufacture or distribute any THC-containing product or plant material that is not exempted from control under this rule must apply for the corresponding registration to handle a schedule I controlled substance. Absent such registration, it is unlawful to manufacture, distribute, or dispense, import, or export any such product or plant material. 21 U.S.C. 822(b), 841(a)(1), 957(a), 960(a). The circumstances under which DEA may grant registrations to handle schedule I controlled substances are limited, as set forth in 21 U.S.C. 823.

In addition, no person may cultivate the cannabis plant for any purpose except when expressly registered with DEA to do so. This has always been the case since the enactment of the CSA. 21 U.S.C. 822(b), 823(a); 21 CFR Part 1301; see *New Hampshire Hemp Council, Inc. v. Marshall*, 203 F.3d 1 (1st Cir. 2000). Further, the CSA prohibits the importation of schedule I controlled substances except as authorized by 21 U.S.C. 952(a)(2). Similarly, the CSA prohibits the exportation of schedule I nonnarcotic controlled substances except as authorized by 21 U.S.C. 953(c).

Who need not obtain a registration—Persons who import and distribute "hemp" products and processed cannabis plant material that are exempted from control under this final rule are not subject to any of the CSA requirements, including the requirement of registration. For example, a person who imports "hemp" clothing is not considered to be importing a controlled substance and is, therefore, not subject to any of the CSA requirements. Similarly, a person who has imported into the United States processed cannabis plant material that is exempted under this rule (such as retted fiber) and converts such material into an exempted "hemp" product (such as clothing) is not considered to be manufacturing a controlled substance and, therefore, need not obtain a controlled substance manufacturing registration.

It is worth repeating here that, if a product marketed as a "hemp" product actually contains no THC (or any other controlled substance), it is noncontrolled and handlers of the product are not subject to any of the

CSA provisions, such as the registration requirement.

Comments That DEA Received in Response to the Interim Rule

Following publication of the interim rule, DEA received comments from thousands of individuals and groups. The comments were in the form of original letters, form letters, petitions, and a cookbook. Those who submitted comments included companies that manufacture and distribute various "hemp" products, associations that represent such manufacturers and distributors, domestic and Canadian government officials, and individuals. In accordance with the Administrative Procedure Act, DEA carefully considered all of the comments it received.

Most of the comments that DEA received relate to both of the rules that DEA published on October 9, 2001: (i) DEA 205 (66 FR 51535), a proposed rule, which proposed to clarify that the listing of THC includes both natural and synthetic THC and (ii) DEA 206 (66 FR 51539), an interim rule, which exempted certain THC-containing products and plant materials from control. Those comments that DEA received which pertain primarily to the interim rule are addressed here. Those comments which pertain primarily to the proposed rule are addressed in the final DEA 205 rule, which appears in a separate **Federal Register** document that immediately precedes this document. Both DEA 205 and DEA 206 contain a summary of the pertinent comments, along with an explanation of how DEA considered them in deciding to finalize the rules.

The number of individuals and groups that participated in the comment process far exceeded the number of different issues raised. The issues raised overlapped to a large extent as many persons submitted form letters or signed petitions written by groups which themselves submitted lengthy comments. In this document, together with the final proposed rule, DEA has addressed all the major issues raised by the commenters. Some of these issues are addressed above in the text that precedes this section. The remaining issues are addressed below.

Comments Regarding Which Products To Exempt From Control

None of the commenters objected to the basic purpose of this rule: To exempt from control certain THC-containing industrial products and animal feed mixtures made from "hemp" (portions of the cannabis plant excluded from the definition of

marijuana). To the contrary, all the commenters who expressed an opinion on this particular issue agreed with these exemptions.¹⁰ However, many commenters said that DEA should go further by also exempting "hemp" food and beverage products that contain THC. DEA declined to adopt this suggestion for the reasons provided herein.

Those commenters who requested that DEA exempt THC-containing "hemp" food and beverage products made two main claims in support of this request: (i) That "hemp" foods and beverages contain only minimal amounts of THC, which, they asserted, cannot cause any psychoactive effects; and (ii) that the oil from "hemp" seeds (sterilized cannabis seeds) provides nutritional value and is a safe food ingredient.¹¹

As to the issue of THC content, many of the comments appeared to be asking DEA simply to assume that the placement of the word "hemp" on the label of a food or beverage product automatically means that the product contains a certain low amount of THC. In fact, the existence of the word "hemp" on the label of a food container provides no definitive proof of its contents. The FDA cannot and does not evaluate the contents of every food product sold in the United States. Since there is no reliable information about the contents of all foods and beverages marketed as "hemp" products, it cannot automatically be assumed that all such products will never cause a psychoactive effect or a positive drug test for THC.

One scientific study published in 1997 examined "hemp" salad oil (containing oil from cannabis seeds) sold in "hemp shops" and health food stores in Switzerland. The authors of the study stated that all the human subjects who ate the cannabis seed oil reported THC-specific psychotropic symptoms and had urine samples positive for THC.¹² In citing this study, DEA is not

¹⁰ Some commenters were under the mistaken impression that DEA failed to exempt any products from control. These commenters asked DEA to exempt what DEA had already exempted under the interim rule. For example, several commenters objected to DEA's supposed failure to exempt "hemp" clothing and paper, even though the interim rule stated repeatedly that such products were being exempted.

¹¹ Some commenters also expressed concern about the economic impact of disallowing THC-containing "hemp" food and beverage products. This issue is addressed in the final 205 rule, in the regulatory certifications.

¹² T. Lehman, Institute of Pharmacy, University of Bern, et al., Excretion of Cannabinoids in Urine after Ingestion of Cannabis Seed Oil, *Journal of Analytical Toxicology*, vol. 21 (September 1997).