

reasons, however, DEA believes that the use of sterilized cannabis seeds in animal feed mixtures is a unique situation that warrants an exemption pursuant to section 871(b).

As stated above and in the interpretive rule, the legislative history of the 1937 Marihuana Tax Act reveals that Congress expressly contemplated allowing “hemp” animal feed. The 1937 Congress categorized such use of “hemp” as a legitimate “industrial” use. It is true that the intent of the 1937 Congress is no longer controlling since the CSA repealed the 1937 Act and declared anything containing THC to be a schedule I controlled substance. However, because neither the text nor the legislative history of the CSA addresses the legality of using sterilized cannabis seeds in animal feed, or the possibility that such seeds might contain THC, what was viewed under the 1937 Act as “legitimate industrial use” of such seeds in animal feed continued uninterrupted following the enactment of the CSA in 1970.

The historical lack of federal regulation of some THC-containing products (whether based on differences between prior law and the CSA, lack of awareness of the THC content of such product, or other considerations) does not—by itself—justify exempting such product from control under the CSA. DEA remains obligated to apply the provisions of the CSA to all controlled substances absent a statutory basis to exempt a particular substance from control. However, with respect to animal feed mixtures containing sterilized cannabis seeds, additional factors (combined with Congress’ express desire under prior legislation to allow such products) justify an exemption pursuant to section 871(b). The presence of a controlled substance in animal feed poses less potential for abuse than in a product intended for human use and does not entail the administration of THC to humans. Moreover, when sterilized cannabis seeds are mixed with other animal feed ingredients and not designed, marketed, or distributed for human use, there is minimal risk that they will be converted into a product used for human consumption. Therefore, such legitimate use in animal feed mixtures poses no significant danger to the public welfare. Accordingly, given the unique circumstances and history surrounding the use of sterilized cannabis seeds in animal feed, DEA believes that it comports with the CSA to continue to treat such activity as a legitimate industrial use—not subject to CSA control—provided the foregoing conditions are met.

How Is “Human Consumption” Defined Under This Rule?

Under this final rule, a material, compound, mixture, or preparation containing THC will be considered “used for human consumption” (and therefore not exempted from control) if it is: (i) Ingested orally or (ii) applied by any means such that THC enters the human body. A material, compound, mixture, or preparation containing THC will be considered “intended for use for human consumption” and, therefore, not exempted from control if it is: (i) Designed by the manufacturer for human consumption; (ii) marketed for human consumption; or (iii) distributed, exported, or imported with the intent that it be used for human consumption.

In any legal proceeding arising under the CSA, the burden of going forward with the evidence that a material, compound, mixture, or preparation containing THC is exempt from control pursuant to this rule shall be upon the person claiming such exemption. 21 U.S.C. 885(a)(1). In order to meet this burden with respect to a product or processed plant material that has not been expressly exempted from control by the Administrator pursuant to 21 CFR 1308.23 (as explained below under the heading “What Is the Control Status of Personal Care Products Made from ‘Hemp?’”), the person claiming the exemption must present rigorous scientific evidence, including well-documented scientific studies by experts trained and qualified to evaluate the effects of drugs on humans.

How Are “Processed Plant Material” and “Animal Feed Mixture” Defined Under This Rule?

Under this final rule, any portion of the cannabis plant excluded from the CSA definition of marijuana will be considered “processed plant material” if it has been subject to industrial processes, or mixed with other ingredients, such that it cannot readily be converted into any form that can be used for human consumption. For example, fiber that has been separated from the mature stalks by retting for use in textiles is considered processed plant material, which is exempted from control, provided it is not used, or intended for use, for human consumption. In comparison, mature stalks that have merely been cut down and collected do not fit within the definition of “processed plant material” and, therefore, are not exempted from control. As another example, if a shampoo contains oil derived from sterilized cannabis seeds, one would expect that, as part of the production of

the shampoo, the oil was subject to industrial processes and mixed with other ingredients such that, even if some THC remains in the finished product, the shampoo cannot readily be converted into a product that can be consumed by humans. Under such circumstances, the product is exempted from control under this final rule. In comparison, a personal care product that consists solely of oil derived from cannabis seeds does not meet the definition of “processed plant material” under this final rule and, therefore, is not exempted from control.

“Animal feed mixture” is defined under this final rule to mean sterilized cannabis seeds mixed with other ingredients in a formulation that is designed, marketed, and distributed for animal consumption (and not for human consumption). For example, sterilized cannabis seeds mixed with seeds from other plants and for sale in pet stores fit within the definition of “animal feed mixture” and are exempted from control under this final rule provided the feed mixture is not used, or intended for use, for human consumption. (In contrast, a container of pure sterilized cannabis seeds—mixed with no other ingredients—does not meet the definition of “animal feed mixture” under this final rule and, therefore, is not exempted from control.)

Which “Hemp” Products Are Exempted From Control Under This Rule?

It is impossible to list every potential product that might be made from portions of the cannabis plant excluded from the definition of marijuana. Therefore, DEA cannot provide an exhaustive list of “hemp” products that are exempted from control under this final rule. Nonetheless, in order to provide some guidance to the public, the following are some of the more common “hemp” products that are exempted (noncontrolled) under this final rule, provided they are not used, or intended for use, for human consumption: paper, rope, and clothing made from fiber derived from cannabis stalks, industrial solvents made with oil from cannabis seeds, and bird seed containing sterilized cannabis seed mixed with seeds from other plants (or other ingredients not derived from the cannabis plant). Personal care products (such as lotions and shampoos) made with oil from cannabis seeds are also generally exempted, as explained below.

Which “Hemp” Products Are Not Exempted From Control Under This Rule?

Other than those substances that fit within the exemption being issued in