FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

HEMP INDUSTRIES ASSOCIATION; ALL-ONE-GOD-FAITH, INC., dba Dr. Bronner's Magic Soaps; ATLAS CORPORATION; NATURE'S PATH FOODS USA INC.; HEMP OIL CANADA, INC.; HEMPZELS, INC.; KENEX LTD.; TIERRA MADRE, LLC; RUTH'S HEMP FOODS, INC.; ORGANIC CONSUMERS ASSOCIATION, *Petitioners,* v. DRUG ENFORCEMENT ADMINISTRATION, *Respondent.*	No. 03-71366 DEA No. Fed. Reg. DEA-205F
HEMP INDUSTRIES ASSOCIATION; ALL-ONE-GOD-FAITH, INC., dba Dr. Bronner's Magic Soaps; ATLAS CORPORATION; NATURE'S PATH FOODS USA INC.; HEMP OIL CANADA, INC.; HEMPZELS, INC.; KENEX LTD.; TIERRA MADRE, LLC; RUTH'S HEMP FOODS, INC.; ORGANIC CONSUMERS ASSOCIATION, *Petitioners,* v. DRUG ENFORCEMENT ADMINISTRATION, *Respondent.*	No. 03-71603 DEA No. Fed. Reg. DEA-206F OPINION

On Petition for Review of an Order of the
Drug Enforcement Agency

Argued and Submitted
September 17, 2003—San Francisco, California

Filed February 6, 2004

Before: Mary M. Schroeder, Chief Judge, Betty B. Fletcher,
and Alex Kozinski, Circuit Judges.

Opinion by Judge B. Fletcher

COUNSEL

Joseph E. Sandler, Sandler Reiff & Young, Washington, D.C. and Patrick Goggin, San Francisco, California, for the petitioners-appellants.

Daniel Dormont, Senior Attorney, Drug Enforcement Administration, Washington, D.C., for the respondent-appellee.

OPINION

B. FLETCHER, Circuit Judge:

Appellants manufacture, distribute, or sell comestible items containing oil or sterilized seeds from "hemp" — a species of plant within the genus *Cannabis*. They challenge two Drug Enforcement Administration ("DEA") regulations that, taken together, would ban the sale or possession of such items even if they contain only non-psychoactive trace amounts of tetrahydrocannabinols ("THC"). The DEA asserts that natural, as well as synthetic, THC is included in Schedule I of the Controlled Substances Act ("CSA"). We have previously held that the definition of "THC" in Schedule I refers only to synthetic THC, and that any THC occurring naturally within *Cannabis* is banned only if it falls within the Schedule I definition of "marijuana."[1] We reiterate that ruling here: in accor-

[1]The Act spells this as "marihuana." We employ the modern spelling here.

dance with Schedule I, the DEA's relevant rules and regulations may be enforced only insofar as they ban the presence of marijuana or synthetic THC.

I. BACKGROUND

Appellants' business activities include importing and distributing sterilized hemp seed and oil and cake derived from hemp seed, and manufacturing and selling food and cosmetic products made from hemp seed and oil.[2] On October 9, 2001, the DEA published what it labeled an "Interpretive Rule" stating that "any product that contains any amount of THC is a schedule I controlled substance . . . ." Interpretation of Listing of THC in Schedule I, 66 Fed. Reg. 51530, 51533 (Oct. 9, 2001). This rule would have banned the possession and sale of Appellants' products. On the same day, the DEA proposed

[2]We refer to hemp stalks, fiber, oil and cake made from hemp seed, and sterilized hemp seed itself—*i.e.*, those substances excluded from the definition of marijuana under 21 U.S.C. § 802(16)—as "non-psychoactive hemp." A "psychoactive" substance is one "affecting the mind or behavior." *Merriam-Webster Dictionary*.

The non-psychoactive hemp used in Appellants' products is derived from industrial hemp plants grown in Canada and in Europe, the flowers of which contain only a trace amount of the THC contained in marijuana varieties grown for psychoactive use. The hemp seed used in food products is an "achene," or small nut, that is either hulled for direct consumption or crushed for oil. It "contains 20 percent high-quality, digestible protein, which can be consumed by humans." U.S. Dept. of Agriculture, *Industrial Hemp in the United States: Status and Market Potential* 15 (Jan. 2000), *available at* http://ers.usda.gov/publications/ages001e/ages001e.pdf. Hemp seed oil "has a better profile of key nutrients, such as essential fatty acids and gamma-linolenic acid, than other oils . . . and a similar profile of other nutrients, such as sterols and tocopherols." Thompson, Berger & Allen, Univ. of Kentucky Center for Business and Economic Research, *Economic Impact of Industrial Hemp in Kentucky* 7-8 (July 1998), *available at* www.industrialhemp.net/pdf/hempstudy.pdf. Appellants list a wide range of current and planned commercial products that use hemp oil or seed, including roasted hulled seed, nutrition bars, tortilla chips, pretzels, beer, candy bars, margarine, sauces, dressings, and non-dairy versions of milk and cheese.

two rules that subsequently became final on publication in the Federal Register on March 21, 2003. Clarification of Listing of THC in Schedule I, 68 Fed. Reg. 14114 (March 21, 2003). These rules ("Final Rules") are the subject of the instant appeal. DEA-205F amends the DEA's regulations at 21 C.F.R. § 1308.11(d)(27) so that the listing of THC in Schedule I includes natural as well as synthetic THC. DEA-206F exempts from control non-psychoactive hemp products that contain trace amounts of THC not intended to enter the human body. We stayed enforcement of the Final Rules pending disposition of this appeal.

Appellants challenged the putative Interpretive Rule in *Hemp Industries Assoc. v. DEA*, 333 F.3d 1082 (9th Cir. 2003) ("*Hemp I*"). During our consideration of that case, the DEA notified us that it would soon issue the Final Rules. We set aside considering the merits of *Hemp I* to await them. After their publication, we solicited briefing from both parties as to whether *Hemp I* was rendered moot by the publication of the Final Rules. Appellants in *Hemp I* argued that the case was not moot. A majority of the panel agreed. *Hemp I* was filed on June 30, 2003.

Hemp I addressed whether the putative Interpretive Rule was an interpretive rule or a legislative rule under the Administrative Procedure Act. That question turned primarily on whether the putative Interpretive Rule would "amend the DEA's own regulation on the coverage of naturally-occurring THC in Schedule I." *Hemp I*, 333 F.3d at 1088. In that context, we held that the listing of "marijuana" in Schedule I excludes

> the mature stalks of such plant, fiber produced from such stalks, *oil or cake made from the seeds of such plant*, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or

> cake, or *the sterilized seed* of such plant which is incapable of germination.

Id. (quoting 21 U.S.C. § 802(16)). We held further that the listing of THC in Schedule I, as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970, applied only to synthetically-created THC. We reasoned that "if naturally-occurring THC were covered under THC, there would be no need to have a separate category for marijuana, which obviously contains naturally-occurring THC. Yet Congress maintained marijuana as a separate category." *Hemp I*, 333 F.3d at 1089. We concluded that THC naturally-occurring within non-psychoactive hemp products did not fall under the DEA's regulation, which provided:

> The Director has investigated and designates all drugs, unless exempted by regulations in this part, containing any amount of the following substances as having a potential for abuse because of their:
>
> . . .
>
> (3) Hallucinogenic effect:
>
> . . .
>
> Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity . . . .

21 C.F.R. § 320.3(c) (1970).[3] We held that the imposition of

[3]In 1971 the title "Tetrahydrocannabinols" and a code number were added. The regulations were later transferred from 21 C.F.R. § 320.3(c) to 21 C.F.R. § 1308.11(d)(27). The Final Rules amended 21 C.F.R. § 1308.11(d)(27) to insert the words "Meaning tetrahydrocannabinols nat-

a ban on THC occurring naturally within non-psychoactive hemp products amended the DEA's own regulations, and that doing so could be accomplished, if at all, only by a legislative rule. *Hemp I*, 333 F.3d at 1091. We explicitly reserved the question of the validity of the DEA's proposed legislative rules, which have become the Final Rules, until the instant case was before us. *Id*.

II. JURISDICTION

We have jurisdiction to review Appellants' claims that the DEA's Final Rules are invalid under 21 U.S.C. § 877, and the claim of a violation of the Regulatory Flexibility Act under 5 U.S.C. § 611.

III. ANALYSIS

Appellants offer three arguments why the Final Rules may not be enforced with respect to THC naturally-occurring in non-psychoactive hemp products. First, they argue that DEA-205F is a scheduling action—placing non-psychoactive hemp in Schedule I for the first time—that fails to follow the procedures for such actions required by the Controlled Substances Act ("CSA"). Second, they argue that the adoption of DEA 206F is arbitrary and capricious in exempting non-psychoactive hemp products intended to be eaten by animals but not those intended to be eaten by humans, when humans seeking (in vain) any psychoactive effect from these substances could easily eat either. Third, they argue that in issuing DEA-205F, the DEA violated the Regulatory Flexibility Act ("RFA"). We need not reach the latter two arguments

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urally contained in a plant of the genus Cannabis (cannabis plant), as well as" immediately before "[s]ynthetic equivalents of the substances contained in the cannabis plant" in the section quoted above. In considering the propriety of the Final Rules, we necessarily consider the propriety of this amendment to § 1308.11(d)(27).

because we agree with appellants that the DEA scheduled non-psychoactive hemp without following the required procedures.

[1] We review federal rules and regulations under *Chevron U.S.A, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Under *Chevron*'s two-part test, "we must decide (1) whether the statute unambiguously forbids the Agency's interpretation, and, if not, (2) whether the interpretation, for other reasons, exceeds the bounds of the permissible." *Barnhart v. Walton*, 535 U.S. 212, 218 (2002) (citing *Chevron*, 467 U.S. at 843). While at step one we "must give effect to the unambiguously expressed intent of Congress," if "the statute is silent or ambiguous with respect to the specific issue," at step two we will "sustain the Agency's interpretation if it is based on a permissible construction" of a statute. *Id.* at 217-18 (internal quotation marks omitted).

A. Procedures for Scheduling a Controlled Substance

[2] Since under the *Chevron* standard we conclude that Congress did not regulate non-psychoactive hemp in Schedule I, we must consider whether the DEA followed the appropriate procedures to schedule it as a controlled substance. The DEA concedes that it did not use the following procedures spelled out in the CSA to adopt the Final Rules.

Under 21 U.S.C. § 811(a):

> the Attorney General may by rule—
>
> (1) add to such a schedule or transfer between such schedules any drug or other substance if he—
>
> (A) finds that such drug or other substance has a potential for abuse, and

> (B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed.
>
> . . .
>
> Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of Title 5 [5 U.S.C. §§ 551 et seq.].

21 U.S.C. § 811(a) calls for formal rulemaking procedures, as described in 5 U.S.C. §§ 556 and 557. Formal rulemaking requires hearings on the record, and section 557(c) invites parties to submit proposed findings and oppose the stated bases of tentative agency decisions, and requires the agency to issue formal rulings on each finding, conclusion, or exception on the record. We will not reproduce the entirety of the Administrative Procedure Act here; it suffices to say that the DEA did not and does not claim to have followed formal rulemaking procedures.

In addition, the DEA did not comply with § 811(a)(1)(B), because the findings required by § 812(b) were not made. Section 812(b) states:

> (b) Placement on schedules; findings required.
> Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance.

> The findings required for each of the schedules are as follows:
>
> (1) SCHEDULE I.
>
> (A) The drug or other substance has a high potential for abuse.
>
> (B) The drug or other substance has no currently accepted medical use in treatment in the United States.
>
> (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

The DEA does not purport to have met the requirements for placement of non-psychoactive hemp on Schedule I, and indeed disclaims any need to show that non-psychoactive hemp "has a high potential for abuse." Instead, the DEA argues that naturally-occurring THC in those parts of the hemp plant excluded from the definition of "marijuana" have always been included under the listing for "THC," and that it had no previous need to clarify this because the intentional use of such products in foodstuffs is relatively new within the United States. The DEA urges that under *Chevron* its definition of the meaning of "THC" in the CSA should be given deference. However, no deference is required because this issue is resolved at *Chevron* step one: the statutory language on point unambiguously precludes an interpretation of the THC definition that includes non-psychoactive hemp.

B. CSA Definitions of THC and Marijuana

[3] Two CSA provisions are relevant to determining whether Appellants' hemp products were banned before the passage of the Final Rules: the definition of THC and the definition of marijuana. Both are unambiguous under *Chevron*

step one: Appellants' products do not contain the "synthetic" "substances or derivatives" that are covered by the definition of THC, and non-psychoactive hemp is explicitly excluded from the definition of marijuana.

1. Statutory Definition of THC

[4] The DEA contends that Appellants' food products may be banned as "any material compound, mixture or preparation" that "contains any quantity of" THC. *See* 21 C.F.R. § 1308.11(d). However, the definition of THC under the CSA includes only synthetic THC. 21 C.F.R. § 1308.11(d)(27) (defining banned THC as "[s]ynthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers . . . .").[4] As we noted in *Hemp I*, with a more elaborate explanation than we will provide here:

> Notably, if naturally-occurring THC were covered under THC, there would be no need to have a separate category for marijuana, which obviously contains naturally-occurring THC. Yet Congress maintained marijuana as a separate category.

Hemp I, 333 F.3d at 1089. The controlled substances listing of THC is different from the listings for DMT, mescaline, psilocybin, and psilocyn, the definitions for which are not limited to synthetic forms of the drugs. *See* 21 C.F.R. § 1308.11(d).

Therefore, DEA-205F may ban products that "contain[ ] any quantity" of THC only insofar as it does not improperly expand the definition of THC as it is used in the CSA. For the

[4]The Final Rules at issue here amend the definition of THC to include naturally-occurring THC. Because we consider here the propriety of those amendments, we quote the previous definition, which had been in effect since 1970. *See supra* note 3.

same reason, 21 U.S.C. §§ 823(f) and 841(a)(1), which disallow human consumption of Schedule I controlled substances outside of FDA-approved, DEA-registered research, do not apply to non-psychoactive hemp products: such products do not contain a "Schedule I controlled substance" as the CSA defines it.

[5] As we did in *Hemp I*, we reject the DEA's contention that the Final Rules merely "clarify that the longstanding placement of THC in schedule I includes both natural and synthetic THC." 68 Fed. Reg. 14116 (Mar. 21, 2003). The DEA's action is not a mere clarification of its THC regulations; it improperly renders naturally-occurring non-psychoactive hemp illegal for the first time.

2. Statutory Definition of Marijuana

[6] Under 21 U.S.C. § 802(16):

> The term "marihuana" means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

The non-psychoactive hemp in Appellants' products is derived from the "mature stalks" or is "oil and cake made from the seeds" of the *Cannabis* plant, and therefore fits within the plainly stated exception to the CSA definition of marijuana.

[7] Congress was aware of the presence of trace amounts of psychoactive agents (later identified as THC) in the resin of non-psychoactive hemp when it passed the 1937 "Marihuana Tax Act," and when it adopted the Tax Act marijuana definition in the CSA. As a result, when Congress excluded from the definition of marijuana "mature stalks of such plant, fiber . . . , [and] oil or cake made from the seeds," it also made an exception to the exception, and included "resin extracted from" the excepted parts of the plant in the definition of marijuana, despite the stalks and seeds exception.[5] 21 U.S.C. § 802(16). Congress knew what it was doing, and its intent to exclude non-psychoactive hemp from regulation is entirely clear. The DEA's Final Rules are inconsistent with the unambiguous meaning of the CSA definitions of marijuana and THC, and the DEA did not use the appropriate scheduling procedures to add non-psychoactive hemp to the list of controlled substances.

[8] Although we have determined that non-psychoactive hemp is not banned under Schedule I, we need not determine in this proceeding whether under the current statute it could be listed if the agency were to undertake appropriate rulemaking. We hold only that the DEA did not follow the requisite proceedings for scheduling under 21 U.S.C. §§ 811(a) and 812(b). The Final Rules therefore may not be enforced with

[5]The DEA argues that because hemp seeds contain some THC, we should allow it to include hemp seeds and its derivatives as within the "exception to the exception" for the extraction of resin. Neither we nor the DEA are in any position to ignore the express exception for hemp seeds in the CSA, nor can we construe "resin" broadly to mean "seeds" as well. As the DEA informs us, the "exception to the exception" for resin was apparently included out of concern that the "active principle" in marijuana, later understood to be THC, might be derived from non-psychoactive hemp and so be used for psychoactive purposes. We note that Congress' policy decision is still effective in prohibiting psychoactive drugs: the DEA makes no showing that extracts from parts of hemp seeds or stalks other than resin are used or could be used for psychoactive purposes.

respect to THC that is found within the parts of *Cannabis* plants that are excluded from the CSA's definition of "marijuana" or that is not synthetic.

We find unambiguous Congress' intent with regard to the regulation of non-psychoactive hemp. Therefore, we reject the Final Rules at step one of the *Chevron* test and need not reach *Chevron* step two.[6]

IV. CONCLUSION

[9] The DEA's Final Rules purport to regulate foodstuffs containing "natural and synthetic THC." And so they can: in keeping with the definitions of drugs controlled under Schedule I of the CSA, the Final Rules can regulate foodstuffs containing natural THC if it is contained within marijuana, and can regulate synthetic THC of any kind. But they cannot regulate *naturally-occurring* THC *not* contained within or derived from marijuana—i.e., non-psychoactive hemp products—because non-psychoactive hemp is not included in Schedule I. The DEA has no authority to regulate drugs that are not scheduled, and it has not followed procedures required to schedule a substance.

[10] The DEA's definition of "THC" contravenes the unambiguously expressed intent of Congress in the CSA and cannot be upheld. DEA-205F and DEA-206F are thus scheduling actions that would place non-psychoactive hemp in Schedule I for the first time. In promulgating the Final Rules, the DEA did not follow the procedures in §§ 811(a) and 812(b) of the CSA required for scheduling. The amendments to 21 C.F.R. § 1308.11(d)(27) that make THC applicable to all parts of the *Cannabis* plant are therefore void. We grant Appellants' petition and permanently enjoin enforcement of

[6]Because our conclusion with respect to *Chevron* deference suffices to invalidate DEA-205F as applied to non-psychoactive hemp products, we need not address Appellants' Regulatory Flexibility Act arguments.

the Final Rules with respect to non-psychoactive hemp or products containing it.

PETITION GRANTED.