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Four Decades of U.S. EPA Review—and Continuous Federal Registration—of Creosote

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ABSTRACT

For almost 70 years, coal tar-derived creosote has been federally registered for use as a wood preservative. During the past 40 years, the risks and benefits of creosote, like those of other major industrial wood preservatives, have been reevaluated by U.S. EPA in three successive and comprehensive review processes—Special Review, Reregistration Review, and, currently, Registration Review. These reviews have resulted in an updated and expanded scientific database for creosote, and improved nationally uniform product labeling containing risk mitigation measures for workers in creosote pressure-treatment plants. There is every reason to believe that creosote will continue to meet federal (and state) standards for registration as a pressure-treatment wood preservative.

INTRODUCTION

Creosote is a wood preservative pesticide which, like the industrial wood products that it is used to protect (primarily railway crossties, utility poles, and marine and structural piling and posts), has withstood the test of time. For almost 40 years coal tar-derived creosote, along with other “heavy-duty” wood preservatives, not only has endured but also benefitted from continual reevaluation by the United States Environmental Protection Agency (“EPA”). During much of that time, the companies that produce and/or distribute creosote within the United States have worked together under the auspices of the Creosote Council [1] to steward creosote through a succession of comprehensive scientific and regulatory reviews conducted by EPA’s Office of Pesticide Programs. To facilitate those reviews, and to ensure that creosote can continue to be used safely and effectively for pressure-treatment of wood, the Creosote Council and its members have invested millions of dollars to update, upgrade, and expand creosote’s scientific database by sponsoring EPA-specified or self-initiated product chemistry, toxicology, worker protection, and other studies. The council and its members also have proactively cooperated with EPA by voluntarily cancelling all registrations for non-pressure-treatment uses of creosote, and by developing nationally uniform, EPA-approved product labeling that requires pressure-treatment plants to utilize engineering and administrative controls along with personal protective equipment (“PPE”) to enhance wood-treatment worker safety. This paper highlights some of the major milestones in EPA’s successive reviews and continuing approval of creosote for pressure-treatment of wood.

STATUTORY BACKGROUND

EPA regulates wood preservatives as antimicrobial pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 U.S.C. §§ 136-136y. Creosote, a chemically complex bituminous coal tar distillation product, has been used in the United States since the mid-1800s to prolong the service life of railroad ties by protecting them from fungal decay and attack by insects. It was first registered under FIFRA in 1948, about a year after that statute was originally enacted. At that time the United States Department of Agriculture (“USDA”) administered FIFRA. The growing environmental movement led to President Nixon’s creation of EPA in 1970, to transfer FIFRA’s administrative authority from USDA to EPA, and to Congress’ overhaul and strengthening of FIFRA in 1972. See *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1994) (“Because of mounting public concern about the safety of pesticides and their effect on the environment . . . Congress undertook a comprehensive revision of FIFRA [that] transformed FIFRA . . . into a comprehensive regulatory statute.”).

To be lawfully distributed and sold, all pesticides, including creosote and other wood preservatives, must be registered under FIFRA. See 7 U.S.C. § 136a(a). Registration is granted only if EPA determines that a pesticide, when applied in accordance with the precautionary measures and directions for use on its EPA-approved labeling, will not cause “unreasonable adverse effects on the environment”—a phrase which FIFRA defines as “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [a] pesticide.” *Id.* §§ 136a(c)(5), 136(bb).

As EPA’s website explains, the Agency “requires extensive scientific data on the potential health and environmental effects of a pesticide before granting a registration . . .” EPA, Regulation of Pesticide Labels [2]. More specifically to obtain a FIFRA

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registration for a pesticide active ingredient, the manufacturer (or importer) must conduct and submit for EPA's review, or otherwise cite and rely upon, many types of EPA-specified studies including studies relating to the pesticide's potential risks to health and/or the environment. See 40 C.F.R. Part 158 ("Data Requirements for Pesticides").

In addition, pesticide producers must obtain EPA approval of nationally uniform product labeling which includes warnings, precautionary measures, directions for use, and other important information for safe and effective application of a pesticide. See 40 C.F.R. Part 156 ("Labeling of Pesticides"); see also 70 Fed. Reg. 12,276, 12,281 (Mar. 11, 2005) ("A pesticide label is the user's direction for using pesticides safely and effectively."). EPA's website further explains that "[p]esticide product labels provide critical information about how to safely handle and use pesticide products. . . . EPA evaluates the data and ensures that the label translates the results of those evaluations into a set of conditions, directions, and precautions that define who may use a pesticide, as well as where, how, how much, and how often it may be used." EPA, Introduction to Pesticide Labels [2]. FIFRA makes it unlawful "to use any registered pesticide in a manner inconsistent with its labeling." 7 U.S.C. § 136j(a)(2)(G).

EPA's review of pesticides does not end with the granting of registrations. Instead, FIFRA long has required EPA to periodically reevaluate already-registered pesticides to ensure that they continue to meet FIFRA's "unreasonable adverse effects" standard for registration, especially in light of evolving techniques for identifying, assessing, and mitigating risks. Under FIFRA's ongoing Registration Review program, which began in 2007, EPA must reevaluate every pesticide active ingredient at least every 15 years. See 7 U.S.C. § 136a(g); 40 C.F.R. §§ 155.40-155.48. EPA's website indicates that "[t]he registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects." EPA, Why We Review Pesticides [3]. Pesticide active ingredients that were first registered prior to 1984, such as creosote, not only are subject to the Registration Review program, but were also extensively reviewed by EPA under the now completed Reregistration Program, which began in the mid-1980s. See 7 U.S.C. § 136a-1.

EPA has the authority to require a pesticide active ingredient's registrants to generate and submit "additional data . . . to maintain . . . an existing registration." 7 U.S.C. § 136a(c)(2)(B)(i). To comply with such a "data call-in," registrants can establish joint data development groups as the members of the Creosote Council did in connection with the creosote reregistration review. See *id.* § 136a(c)(2)(B)(i). If EPA has more immediate risk concerns about an already registered pesticide, it can initiate a Special Review. *Id.* § 136a(c)(8); 40 C.F.R. Part 154. EPA also can initiate formal administrative proceedings to suspend and/or cancel existing registrations if it believes that a pesticide can no longer be used without causing significant adverse effects (i.e., if the risks of use unavoidably outweigh the benefits of use). *Id.* § 136d(b) & (c).

SPECIAL REVIEW (1978-1986)

In October 1978 EPA's Office of Pesticide Programs commenced parallel "Rebuttable Presumption Against Registration" ("RPAR") reviews for three types of widely used FIFRA-registered wood preservatives—pentachlorophenol, inorganic arsenicals, and creosote. See 43 Fed. Reg. 48,154 (Oct. 18, 1978) ("Notice of Rebuttable Presumption Against Registration and Continued Registration of Pesticide Products Containing Coal Tar, Creosote, and Coal Tar Neutral Oil").¹ The RPAR review's purpose was to reexamine "both the risks and the benefits associated with the use of these pesticide chemicals." *Ibid.* "In determining whether the use of a pesticide poses risks which are greater than benefits," EPA considered "risk reduction measures short of cancellation," such as changing the directions for use on a pesticide's labeling and restricting the use of a pesticide to certified applicators. 46 Fed. Reg. 13,020, 13,022 (Feb. 19, 1981). (To avoid negative connotations, EPA subsequently changed the name of the RPAR process to "Special Review.")

The Special Review was triggered in part by EPA's concerns based on then-available studies regarding creosote-related oncogenicity and mutagenicity. See 43 Fed. Reg. at 48,155. In February 1981 EPA issued, for public and industry comment, a Preliminary Notice of Determination for all three types of wood preservatives, which at the time were labeled for both pressure-treatment and non-pressure-treatment (e.g., brush-on or spray-on) uses. As for creosote, EPA's notice asserted that there were significant risks of oncogenicity and mutagenicity to wood treatment applicators due to dermal and inhalation exposure, and, as a result, that risk reduction measures would be necessary in order to keep the risk/benefit balance pointed toward continued registration. See 46 Fed. Reg. 13,020, 13,023, 13,029 (Feb. 19, 1981).

EPA subsequently issued a final Notice of Determination, reasserting the same risk concerns and initiating risk-reduction measures, including classifying creosote and the other wood preservatives as restricted-use pesticides for use only by state-certified applicators; amending product labeling to require wood treatment workers to wear various types of personal protective

¹ Creosote, coal tar, and coal tar neutral oil originally had been separately registered as wood preservative active ingredients. By the late 1980s, EPA and registrants agreed that "coal tar creosote" or simply "creosote" should be the term used to describe the complex, multi-compound active ingredient in coal tar-derived wood preservative products. EPA and creosote registrants further agreed that based on American Wood Protection Association ("AWPA") standards, two blends of creosote, AWPA P1/P13 and AWPA P2, should be the principal FIFRA-registered creosote wood preservative products. EPA more recently has granted a registration for AWPA P3, a creosote-petroleum blend.

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clothing and equipment; and establishing a mandatory “Consumer Awareness Program” requiring pressure-treated wood to be labeled with “Consumer Information Sheets” containing EPA-specified handling and use-site precautions. See 49 Fed. Reg. 28,666, 28,675-76 (July 13, 1984). EPA indicated that “[w]ith these modifications to the terms and conditions of registration, the Agency has determined that the use of the wood preservative products would not be expected to cause unreasonable adverse effects.” *Id.* at 28,673. To ensure compliance, EPA simultaneously issued a formal notice of intent to cancel the registrations of any wood preservative product whose producers declined to adopt the EPA-imposed risk-reduction measures.²

Wood preservative registrants, acting primarily through the now-defunct American Wood Preservers Institute and the Society of American Wood Preservers, collectively exercised their statutory right to initiate an administrative hearing to challenge the notice of intent to cancel some of the specific restrictions and requirements that EPA sought to impose. See 7 U.S.C. § 136d(b). For example, EPA’s attempt to impose a *mandatory* Consumer Awareness Program was a major point of contention. The industry’s position was that although EPA’s pesticide regulatory authority under FIFRA encompasses registration and labeling of wood preservatives, it does not extend to regulation or labeling of treated-wood products. In June 1985 an EPA Administrative Law Judge formally ruled that “[t]he Consumer Awareness Program insofar as it requires labeling of pressure-treated wood, which is not a pesticide, is not authorized by FIFRA and may not be required as a condition of . . . registration.” *In the Matter of Chapman Chem. Co., et al.*, FIFRA Docket No. 529, et al. (June 12, 1985).³

Wood preserving industry representatives and EPA ultimately entered into a detailed, written settlement agreement covering pentachlorophenol, inorganic arsenicals, and creosote. See 51 Fed. Reg. 1334 (Jan. 10, 1986) (“Amendment of notice of intent to cancel”). In addition to modifying some of EPA’s originally proposed PPE requirements, including in connection with non-pressure-treatment uses, the settlement agreement eliminated the proposed mandatory Consumer Awareness Program. See *id.* at 1337. Instead, EPA agreed to a *voluntary* industry program, utilizing Consumer Information Sheets that contained mutually agreed-upon language, as a means for downstream dissemination of use-site and precautionary information about pressure-treated wood. See *id.* at 1337-38.⁴

REREGISTRATION REVIEW (1986-2011)

Unlike the Special Review, which drew conclusions about potential “unreasonable adverse effects” primarily from then-existing studies about the risks and benefits of the major wood preservatives, EPA’s subsequent Reregistration Review program was intended to ensure that the continued FIFRA registration of hundreds of “older” pesticide active ingredients, including the major wood preservatives, is supported by comprehensive scientific databases that meet EPA’s current pesticide registration data requirements and testing protocols. Congress added a formal reregistration process to FIFRA in 1988. See 7 U.S.C. § 136a-1 (requiring reregistration of all active ingredients first registered prior to November 1984). EPA’s reregistration program, however, already was underway since the agency previously had issued “registration standards” and associated data call-ins for many active ingredients, including creosote.

The original Registration Standard for Creosote (March 1986) was accompanied by Guidance for the Reregistration of Pesticide Products Containing Coal Tar/Creosote As the Active Ingredient (October 1986). Those documents identified multiple product chemistry, toxicology, worker exposure, environmental fate, and other studies that creosote registrants would have to conduct and submit (or request EPA to waive)—as well as revised labeling that registrants would have to utilize—in order to achieve FIFRA reregistration. Coal tar creosote, which is derived entirely from high-temperature distillation of bituminous coal, is a complex and variable mixture consisting of hundreds of individual compounds. It is a unique pesticide because its somewhat differing distillate fractions (i.e., blends) are characterized by physical properties (e.g., boiling point; specific gravity; distillation range) defined in the American Wood Protection Association (“AWPA”) Book of Standards. Rather than viewing creosote as a single pesticide active ingredient, the 1986 Registration Standard and Guidance treated creosote as a combination of five distinct

² Unlike creosote’s wood preservative uses, which EPA determined should be retained, the agency determined that the risks of then-registered *non-wood preservative* uses of creosote (e.g., herbicidal, fungicidal, disinfectant, and insecticidal uses) exceeded their benefits, and as a result, cancelled virtually all of those uses. See 50 Fed. Reg. 41,943 (Oct. 16, 1985).

³ When EPA originally promulgated regulations implementing the 1972 FIFRA, it unequivocally took the position that pressure-treated wood is *not* a pesticide, and thus, that it was excluded from FIFRA regulation as a matter of law. See 40 C.F.R. § 162.4(c) (“Products not considered pesticides”) (listing, as an example, “lumber . . . treated to protect the material itself against any pest and for which no pesticidal claims are made as to protection of other surfaces”). In 1988, however, EPA changed its position by issuing the “treated-articles exemption.” See 40 C.F.R. § 152.25 (“Exemptions for pesticides of a character not requiring FIFRA regulation”) (emphasis added). Under the treated-articles exemption, “wood products treated to protect the wood against fungus or insect infestation” are listed as an example of “pesticides . . . determined to be of a character not requiring regulation under FIFRA” if they are treated with a pesticide (e.g., creosote) registered for use in protecting the article itself. *Id.* § 152.25(a) (emphasis added). As a practical matter, the treated-articles exemption means that wood products pressure-treated with creosote are not subject to FIFRA registration, labeling, or other requirements. As discussed below, in a 2015 Registration Review work plan, EPA expressly acknowledged that railroad ties are not subject to regulation under FIFRA.

⁴ In September 2010 the Creosote Council provided treaters with a revised and updated form of the Consumer Information Sheet for their optional use when shipping creosote-treated wood products.

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distillate fractions (defined by their boiling points). Under the Registration Standard and Guidance, each distillate fraction (or “cut”) would have to be separately studied and reregistered as an active ingredient.

Issuance of the 1986 Registration Standard and Guidance prompted formation of Creosote Council I, which was independent from other chemical/wood preserving industry associations and composed of all U.S. creosote registrants. The mission of Creosote Council I was to interact with EPA on testing, labeling, and other reregistration requirements. As a result of the Creosote Council’s efforts, EPA issued a revised reregistration Guidance document in April 1988. The 1988 Guidance document would have required toxicology and other testing of eight coal tar-derived “distillate fraction active ingredients” corresponding to specific AWP standards. The Creosote Council’s members voluntarily cancelled their existing registrations for six of those eight “creosotes,” leaving only two coal tar creosote distillate blends—AWPA P1/P13 and AWPA P2—for reregistration testing purposes.

Due to the unavoidably variable compositional nature of individual batches of AWP standard creosote, EPA’s Guidance also required registrants to utilize “composite test materials” (“CTMs”) for toxicology and other studies. The Creosote Council assembled P1/P13 and P2 CTMs in accordance with EPA-approved protocols (and in conformity with AWPA P1/P13 and P2 standards) to use for all Creosote Council generic data development. To approximate real-world usage, registrants contributed creosote to the CTMs in proportion to their market shares. Remaining quantities of the CTMs continue to be held in secured storage in stainless steel drums under a nitrogen blanket.

In conjunction with issuance of the 1988 reregistration Guidance, Creosote Council I transformed itself into Creosote Council II—a FIFRA joint data development group established under FIFRA section 3(c)(2)(B)(ii)—to conduct EPA-required studies for reregistration of creosote. See 7 U.S.C. § 136a(c)(2)(B)(ii). The ensuing multi-million dollar reregistration testing program encompassed more than 30 product chemistry, acute, subchronic, chronic toxicity, and worker exposure studies. The EPA-required reregistration data development program began in 1988 and extended through 2001. In addition, the council voluntarily sponsored and submitted to EPA cancer and non-cancer human risk assessments and a creosote ecological study in connection with newly installed creosote-treated harbor piling [4].

Throughout the reregistration process, the Creosote Council prepared and submitted written comments each time that EPA solicited stakeholder and public input (for example, comments on EPA’s publicly released preliminary risk assessments). Creosote Council technical, administrative, member, and legal representatives also met with EPA personnel on numerous occasions—sometimes accompanied by allied industry associations—to provide additional information for EPA’s consideration (for example, information on creosote’s importance to maintaining the nation’s rail system, electrical distribution grid, and other critical infrastructures).

In 2003, after all the required reregistration studies had been completed and submitted to EPA, Creosote Council II was superseded by Creosote Council III, which continued to function as a FIFRA joint data development group and also assumed the broader role of a product stewardship organization on behalf of creosote registrants and their pressure-treatment plant customers. Like its Creosote Council II predecessor, Creosote Council III was not only cooperative, but also proactive in working toward a successful conclusion of EPA’s decades-long Reregistration Review. For example, to address EPA’s risk concerns about non-pressure-treatment uses of creosote (e.g., dipping and brush-on uses; thermal-treatment use), the council’s members voluntarily requested EPA to cancel their registrations (or amend their labels) in order to eliminate those uses. Those voluntary cancellations/use terminations became effective on December 31, 2004. See 69 Fed. Reg. 55,623 (Sept. 15, 2004).

Through a series of discussions, the council also reached an agreement with EPA regarding additional label-required exposure/risk mitigation measures for workers in creosote pressure-treatment plants. These included engineering controls such as mandatory installation of quick opening/closing automated cylinder doors (to replace manual bolted doors) and bridge rail systems. And to promote understanding of and compliance with administrative controls such as PPE requirements and other precautionary measures on creosote labeling, the council proposed to develop a Label Education Program that would be made available to creosote treaters for training of pressure-treatment plant workers.

These and additional label revisions were incorporated into the comprehensive Reregistration Eligibility Decision (“RED”) for Creosote, issued in November 2008. See 73 Fed. Reg. 69,646 (Nov. 19, 2008)[5]. The RED indicated that “[t]he Agency has completed its assessment of occupational and ecological risks associated with . . . creosote [and] has determined that all creosote containing products are eligible for reregistration” provided that label amendments and risk mitigation measures are implemented, and that current data gaps and confirmatory data requirements are satisfied. RED at 33.⁵ The RED further stated that “[i]f all conditions and requirements outlined in [the RED] are fully complied with, then no risks of concern would exist for the registered uses of creosote.” *Ibid.*

⁵ The RED identified two confirmatory studies: An occupational exposure study, which is underway, and a field or simulated environmental fate & ecological exposure study, which the council has requested EPA to waive based on the council’s previously conducted ecological study on newly installed harbor piling. To implement the RED, EPA in September 2011 issued a generic data call-in for these studies and product-specific data call-ins for any required end-use product-specific, product chemistry or acute toxicity data that have not been previously submitted on behalf of individual registrants.

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The RED included a list of “the uses of creosote that are eligible for reregistration.” *Ibid*. But rather than simply identifying “pressure-treatment of wood” as the creosote use eligible for reregistration, the RED purported to conflate use of creosote with use of creosote-treated wood. See RED Appendix A (“Creosote Use Patterns Eligible for Reregistration”). The Creosote Council viewed this list of “use patterns” as an improper attempt by EPA to regulate the use of creosote pressure-treated wood, which as discussed above, is excluded and/or exempt from FIFRA regulation. Following post-RED discussions with EPA on this subject, EPA and the council’s members agreed to utilize a supplemental product labeling that provides, by AWWA Commodity Specification and AWWA Use Category, a comprehensive list of wood commodities that can be pressure-treated with creosote. Distribution of the post-RED revised labeling (which included several additional post-RED wording refinements) began in August 2010. Treaters were required to comply with the new labeling by November 2010, except for the new engineering controls, which were required to be installed and implemented no later than December 31, 2013.

REGISTRATION REVIEW (2015)

All existing registered pesticides, including those that have undergone Reregistration Review, are now subject to the program’s statutory successor, Registration Review. See EPA, Registration Review Process [6]. EPA is staggering its Registration Review schedule. The Creosote Preliminary Work Plan (“PWP”) [7], issued in March 2015, provided a list of EPA’s “anticipated data needs” for registration review of creosote. This list includes the ongoing observational/confirmatory worker exposure study required by the creosote RED. Significantly, the PWP notes that reuse of creosote-treated railroad ties in residential settings (i.e., for landscaping use) “is not subject to regulation by EPA under FIFRA.” PWP at 18. Further, because “old railroad ties would likely have significantly less transferable creosote than freshly treated wood . . . the agency does not anticipate significant exposure to occur and will not conduct a residential post-application risk assessment.” *Ibid*.

This statement was repeated in the Creosote Final Work Plan (“FWP”) [8], which EPA issued in September 2015, following receipt of public comments, including from the Creosote Council [9], on the PWP. See FWP at 20. The FWP indicates that EPA will assess whether the council’s previously conducted ecological study on newly installed creosote-treated harbor piling will satisfy EPA’s anticipated need for aquatic toxicity studies.

Under EPA’s current Registration Review schedule for creosote, data call-ins will be issued in September 2016, required data will be due by September 2018, a preliminary risk assessment will be released for public comment in March 2020, a proposed registration review decision will be released for public comment in September 2020, and a final registration review decision will be issued in March 2021. See FWP at 10.

CONCLUSION

Supported by an expanding and evolving scientific database, and benefiting from registrants’ willingness to amend product labeling to incorporate additional risk mitigation measures, EPA has repeatedly concluded during the past four decades that creosote meets FIFRA’s standard for registration as a wood preservative for pressure-treatment use.

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