



Will EPA Modify FIFRA's Treated Article Exemption or Otherwise Regulate Treated Seeds and Paint Products?

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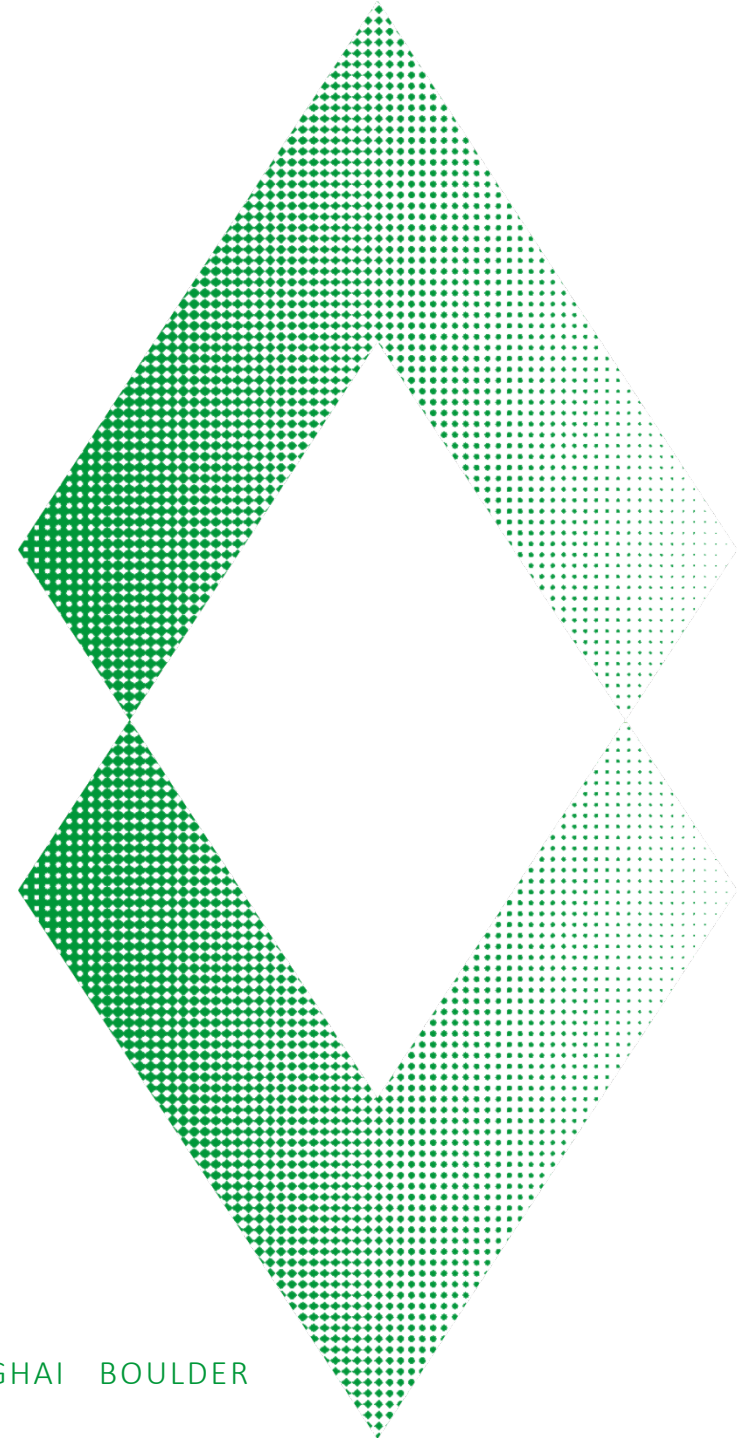
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Preliminary Word

- ◆ This presentation provides information about the law. Legal information is not the same as legal advice, which involves the application of law to an individual's specific circumstances. The interpretation and application of the law to an individual's specific circumstance depends on many factors. This presentation is not intended to provide legal advice.
- ◆ The information provided in this presentation is drawn entirely from public information. The views expressed in this presentation are the authors' alone and not those of the authors' clients.

Michael T. Novak

- ◆ Michael (Mike) Novak practices environmental and business law for chemical manufacturers and other clients, including agricultural, antimicrobial, and biochemical pesticide producers. His practice focuses on the regulation of pesticides and other chemicals under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the Federal Food, Drug, and Cosmetic Act (FFDCA); the Toxic Substances Control Act (TSCA); the Emergency Planning and Community Right-to-Know Act (EPCRA); and other federal and state regulatory programs.
- ◆ Mike has extensive knowledge and experience in pesticide regulatory issues associated with product registration, including the registration of biochemicals and unique technologies; petitions to cancel or deny registration; data compensation matters; adverse effects reporting; enforcement issues; import and export requirements; tolerance petitions, including the approval of inert ingredients; and the treated-article exemption. He also drafts and negotiates business contracts for pesticide clients, including distributorship, supply, sub-registration (licensing), and registration/data transfer agreements.



David B. Fischer



- ◆ David Fischer counsels clients on environmental, policy, and health and safety matters, with a concentration on the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Having served as the Deputy Assistant Administrator for EPA's Office of Chemical Safety and Pollution Prevention as well as having held senior level positions at the American Chemistry Council, David advocates for clients before the U.S. EPA and provides strategic advice to them regarding issues before Congress.
- ◆ In addition, he has experience with numerous other statutes including the Clean Air Act (CAA), Clean Water Act (CWA), Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), Safe Drinking Water Act (SDWA), Emergency Planning and Community Right-to-Know Act (EPCRA), and the Food Quality Protection Act (FQPA). David's clients include domestic and international industrial and specialty chemical manufacturers and the trade associations that represent them. Clients seek his assistance on new chemical approvals, chemical and pesticide risk evaluations, and risk management rulemaking because of his deep understanding of EPA, its internal science policy apparatus, and its many organizational pieces, responsible for all aspects of TSCA and FIFRA.



Overview of Proposed Changes to EPA's Regulation of Treated Seeds and Paint



- ◆ EPA issued an Advanced Notice of Proposed Rulemaking (ANPRM):
 - ◇ EPA seeks comment on whether to regulate certain pesticide treated seed and pesticide treated paint products
 - Currently, these products are exempt from pesticide registration under the Treated Article Exemption
- ◆ Published in the Federal Register, October 12, 2023
- ◆ Comments are due by February 9, 2024 (EPA granted the 60-day extension requests)

Overview of Proposed Changes to EPA's Regulation of Treated Seeds and Paint



- ◆ ANPRM is not a proposed rule, but...
 - ◇ It is the initiation of the rulemaking process
 - ◇ Signed by the EPA Administrator, which means he was briefed on this issue
- ◆ ANPRM is in response to a petition filed by the Center for Food Safety to regulate pesticide treated seed
 - ◇ EPA did not grant the petition but issued this ANPRM
- ◆ The ANPRM also addresses issues raised in an issue paper by the State FIFRA Issues Research and Evaluation Group (SFIREG) (August 2022)

Overview of Proposed Changes to EPA's Regulation of Treated Seeds and Paint



- ◆ Treated paints and treated seeds fall under the treated article exemption. As long as the treated article comports with the regulatory requirements for treated articles, EPA does not separately register the treated article.
- ◆ Instead, EPA assesses the use of the treating pesticide when it registers that pesticide under FIFRA, including its use to treat articles.
- ◆ EPA typically included labeling instructions on the treating pesticide label regarding both the use of the treating pesticide and the distribution, sale, and use of the treated seed product.

Overview of Proposed Changes to EPA's Regulation of Treated Seeds and Paint



- ◆ Questions have been raised about clarity and enforceability as it pertains to the treated seeds.
- ◆ But if the treating pesticide or treated seed does not comport with label instructions than the treated seed is no longer exempt and the treated article is an unregistered pesticide.
- ◆ Are treated seeds being used according to label language?
- ◆ Are there EJ concerns?
- ◆ EPA is not aware that the use of treated seeds is deviating from label language.

Overview of Proposed Changes to EPA's Regulation of Treated Seeds and Paint



- ◆ Paint treated with pesticides
- ◆ Currently no label language exists on treated paints regarding the pesticide used to treat the paint
- ◆ Label language proposed for Diuron
- ◆ Should there be labelling instructions on treated paint containers?
- ◆ Are there EJ concerns?
- ◆ EPA has identified potential risks to professional painters exposed to treated paint, when sprayed. Canada is implementing risk mitigation measures.
- ◆ EPA also thinking of requiring FIFRA section 7 establishment registration of the article manufacturers.

Legal Background

- ◆ **FIFRA section 3(a)**

Except as provided by this Act, no person in any State may distribute or sell ... any pesticide that is not registered under this Act.

- ◆ **FIFRA section 3(c) – Procedure for Registration**

“no unreasonable adverse effects”

- ◆ **FIFRA section 25(b) – Exemption**

EPA may exempt from FIFRA requirements any pesticide EPA determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character unnecessary to be subject to this Act to carry out purposes of this Act.

EPA's Treated Article Exemption, 40 CFR section 152.25(a)

- ◆ Of a character not requiring regulation under FIFRA
- ◆ An article or substance treated with, or containing, a pesticide (1) to protect the article or substance itself ... (2) if the pesticide is registered for such use
- ◆ EPA registers treating pesticide or preservative by assessing use and exposure of treating pesticide and the end-use article
- ◆ EPA includes end-use article labeling instructions on the Master Label, e.g., seed bag tags, proposed label or hang tags for antimicrobial treated articles

EPA Enforcement Authority



- ◆ FIFRA section 12 – unlawful to sell or distribute an unregistered pesticide
- ◆ Not a FIFRA section 12 violation to use an unregistered pesticide or to use it contrary to its label
- ◆ EPA can enforce against sellers and distributors of treated seed and paint, *but not users*
- ◆ FIFRA section 12(a)(2)(S), unlawful to “violate any regulation issued *under section 3(a)*”

Legal Background

- ◆ **FIFRA section 3(a)**

To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this Act....

(Emphasis added.)

- ◆ EPA to determine whether to propose a FIFRA section 3(a) rule or take other regulatory or administrative action
- ◆ **FIFRA section 25(a)** authorizes EPA to “prescribe regulations to carry out the provisions of [FIFRA]”

EPA Statements on Effects

- ◆ EPA states in Treated Seed Petition Response that amending TA Exemption to require registration where there is general compliance with labeling Instructions for registered products and treated seeds “would provide little to no human health or environmental benefits.”
- ◆ “EPA has no information suggesting that users of treated seed products are distributing, selling or using the seed products contrary to labeling instructions.”
- ◆ Same for other treated articles and substances, including paint.
- ◆ Notice at pg. 70632

EPA Regulatory Authority



- ◆ FIFRA section 3(a) principal authority and requires finding that it is necessary to prevent unreasonable adverse effects
- ◆ FIFRA section 25(a) regulation to carry out provisions of FIFRA
- ◆ Label Mitigation Efforts per AI Under Reg. Review

Comments Necessary to Establish Record of Compliance

- ◆ Concerns raised by Petition and SFIREG Issue Paper
- ◆ Requesting comments from stakeholders on use/usage data, including whether contrary to registered label or seed bag tag
- ◆ Important for industry (treaters, growers, users) to demonstrate compliance through data collection and submission to counter speculative comments and establish no effects
- ◆ For treated paints, establish inhalation issues related to specific risk assessment for AI



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Thank You

Any questions?

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