

EPA Seeks Comment on First Set of Hemp Pesticides and Begins to Develop Hemp/CBD Pesticide Policy

September 3, 2019

Environmental; Food, Drugs, and Devices

The Agricultural Improvement Act of 2018 (the 2018 Farm Bill) has created a rapidly-expanding market for hemp-derived products by legalizing the cultivation of hemp, which can be processed to make a variety of goods, including cannabidiol (“CBD”) products. Several federal agencies are involved in regulating hemp production and its derivative products. To date, much of the regulatory focus on CBD relates to FDA’s regulation of the substance in drugs, dietary supplements, cosmetics, and pet products.¹ As the industry matures, another important issue will be oversight of pesticides used to treat hemp, which EPA regulates, and the residues of those pesticides in food derived from hemp.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), EPA must register and approve pesticides, including for specific uses on specific plants. Any non-approved use, including use on crops for which the pesticide is not approved, is illegal. EPA also sets permissible residue limits (known as “tolerance levels”) for food products. Products exceeding the tolerance level are also illegal.

Currently, there are only a handful of pesticides EPA has approved for use on “industrial hemp.” On August 23, 2019, EPA proposed to approve ten existing pesticides for use on hemp and requested public comment, due on September 23, 2019.² EPA noted that the “initial applications involving hemp may be of significant interest to the public,” given the current lack of pesticides approved for that use. Industry participants should consider commenting on these applications, as EPA’s actions are likely to set a significant informal precedent. EPA’s actions are also likely to be relevant to state regulators, who may impose requirements more stringent than those that EPA sets. State regulators may also issue “special local need” pesticide registrations, allowing pesticides to be used on hemp even if EPA has not approved the particular pesticide for that use, subject to potential EPA veto.

¹ See, e.g., <https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis>.

² 84 Fed. Reg. 44,296 (Aug. 23, 2019).

More broadly, hemp and CBD industry participants seeking to get ahead of the curve should develop a strategy for FIFRA compliance, including ensuring supply chain compliance. In addition to the immediate legal consequences of violating pesticide use, or exceeding tolerance limits (which can include significant civil penalties, product seizure, and potential criminal penalties for knowing violations), there is growing public concern about the presence of pesticide residue in CBD products, with press reports highlighting the issue.³ Accordingly, industry participants face potentially significant supply-chain risk arising from pesticide use, a risk that may increase as additional pesticides are approved for use on hemp.

EPA is beginning to develop its broader hemp pesticide policy, including through its Pesticide Program Dialogue Committee, and is starting to think about how it might approach issues such as setting tolerance limits for hemp uses. Industry participants should consider participating in these ongoing processes that will establish the foundation of pesticide regulation in the hemp and CBD industry. As one EPA official recently put it, EPA “could really use feedback because this is a new agricultural commodity,” providing a unique opportunity for industry participants to work with EPA in the early stages.

FIFRA Background

EPA regulates pesticides under FIFRA, including not only typical anti-pest chemicals, but also plant regulators, defoliants, desiccants, and nitrogen stabilizers. 7 U.S.C. § 136(u). Pesticides must be EPA registered under FIFRA, and it is unlawful to sell unregistered pesticides or to use registered pesticides in a manner inconsistent with their labeling. *Id.* § 136j.

Additional restrictions apply to pesticides used on crops grown for food use. If the pesticide is used on crops that will be used for food purposes, pesticide residue is unlawful unless EPA issues either a tolerance level setting an approved residue limit, or an exemption from the requirement to establish a tolerance level. 21 U.S.C. § 346a.

States generally can impose more stringent requirements on pesticides. They also may issue a “special needs” registration, which allows for “additional uses of federally registered pesticides” to “meet special local needs.” 7 U.S.C. § 136v(c). Alternatively, EPA may veto such registrations. *Id.*

EPA Proposes to Begin Approving Pesticides for Use on Hemp

Approximately six pesticides are currently approved for use on “industrial hemp.” Under existing federal law, these are the only pesticides that may lawfully be used on hemp because of FIFRA’s prohibition on using “any registered pesticide in a manner inconsistent with its labeling.”

In August 2019, EPA announced that it was evaluating whether to expand the registration of ten existing pesticides to allow for use on hemp. According to EPA, those requests “involve

³ See, e.g., <http://wjla.com/features/7-on-your-side/the-risk-of-contaminants-and-false-labeling-in-the-exploding-cbd-industry>; <https://www.dtnpf.com/agriculture/web/ag/crops/article/2019/06/05/epa-states-play-catch-hemp-pesticide-2>.

biological and microbial chemicals, which tend to be very low impact on the environment,” and are being evaluated on an expedited basis.⁴

EPA will need to evaluate a number of issues in determining whether and how to allow existing pesticides to be used on hemp, including:

- Efficacy regarding differing pests;
- Worker exposure issues;
- Consumer exposure issues;
- Verifying that the pesticide is safe for use on hemp; and
- Ensuring that use of the pesticide on hemp will not cause adverse environmental impacts.

Because hemp can be used for both food and non-food uses, EPA must also decide whether to approve pesticides for use on non-food-use hemp in the absence of residue and other data necessary to establish a tolerance level. Such an approval risks that hemp farmers, intentionally or otherwise, may use such a pesticide on hemp crops used for food-related purposes, and thus could expose consumers to pesticide residues for which no tolerance has been established. On the other hand, limiting approvals to pesticides with established tolerances or exemptions would lead to both additional expense and delay in approving pesticides for use on hemp, with attendant adverse effects on the hemp industry.

Separate from these federal efforts, states aiming to bolster hemp production may seek to issue “special local needs” registrations. In 2017, EPA vetoed such registrations in Nevada and California.⁵ In light of the 2018 Farm Bill and EPA’s ongoing efforts to approve pesticides for use on hemp, however, EPA is now likely to be much more receptive to such registrations.

EPA Has Not Yet Addressed Complex Issues Relating to Tolerance Levels on Hemp-Derived Products

There are currently no pesticides approved for use on hemp with either a food tolerance or an exemption from food tolerance. Accordingly, as a legal matter, pesticides cannot legally be used on hemp for use in food or animal feed products.⁶

No hemp pesticide tolerance applications are currently pending before EPA, but given the market for CBD-containing food products, such a request will almost certainly be made at some point in the relatively near future. At that point, EPA will face a number of issues in establishing tolerance limits, including:

⁴ EPA, Testimony of Alexandra Dunn (July 25, 2019).

⁵ 82 Fed. Reg. 47,773 (Oct. 13, 2017); Letter from Scott Pruitt (June 22, 2017).

⁶ The one exception relates to minimum risk pesticides, which are exempt from the requirements of FIFRA and some of which have established tolerance levels or exemptions. See 40 C.F.R. § 152.25(f).

Environmental; Food, Drugs, and Devices

- Evaluating to what extent pesticides may concentrate during the processing of hemp (e.g., into CBD products), and to what extent concentrations may vary depending on the processes used;
- Evaluating different potential exposure patterns and risks depending on the foods in which CBD or other hemp derivatives are used; and
- Working with FDA on these issues, as FDA enforces tolerance limits in food and for other uses governed by the Federal Food, Drug, and Cosmetics Act.

Generating sufficient data to obtain a tolerance is likely to take at least two years, and may present a significant barrier to using hemp derivatives like CBD in food-related applications (separate and apart from regulation of such products by FDA and the states). Companies with an interest in obtaining approval of their pesticides for food uses should seriously consider discussing the issue with the agency at an early date and beginning to gather the necessary data, as having the first EPA-approved pesticide with a tolerance limit or exemption for use on hemp will likely provide a significant competitive advantage.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Environmental and Food, Drugs, and Devices practice:

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