

# The Evolving CBD and Hemp Market

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## At a Glance

As hemp-derived CBD products quickly flood the market, new regulatory and compliance issues emerge with this rapidly growing, multibillion-dollar industry.

The use and regulation of hemp and cannabidiol (CBD) in the United States has a long history that dates to the early colonists, who were mandated to grow hemp for the British.<sup>1</sup> Hemp has endured for centuries as a valuable cash crop, and it's projected to become a billion-dollar industry in the next few years.<sup>2</sup>

Hemp, a derivative of *cannabis sativa*, is often referred to as industrial hemp for its uses in everything from textiles — think rope and fabric — to food and jewelry. *Cannabis sativa* and *cannabis indica* are two categories of cultivars. *Cannabis sativa* are tall, thin plants with light green leaves; its flowers or buds are mainly for daytime use. In contrast, *cannabis indica* is a short bushy plant with dark green leaves; its flowers or buds are generally used for relaxing and nighttime use.<sup>3</sup> Hemp plants are taller than both *cannabis sativa* and *cannabis indica* but have the same smell and visual characteristics.<sup>4</sup>

To be considered industrial hemp, which is another cultivar of *cannabis*, the plant cannot contain more than 0.3 percent of delta-9-tetrahydrocannabinol (THC).<sup>5</sup> Each of these *cannabis* plants contains cannabinoids — hundreds of naturally occurring chemical compounds. Two of the more widely recognized chemicals are THC, the principal psychoactive component of *cannabis*, and CBD, which is often used to treat anxiety, cognition, movement disorders, and pain.<sup>6</sup> Industrial hemp and marijuana are from the same family of plants but with different characteristics, much like Gala apples and Fiji apples are both apples but with their own distinct characteristics.

When marijuana became criminalized, hemp also became illegal since both come from the same species of plant.<sup>7</sup> The Agricultural Act of 2014 allowed for the first time the lawful production of hemp in conjunction with a research program for colleges and universities in nine states. This ban remained in place until industrial hemp was removed from the Controlled Substances Act in 2018, paving the way for the Agriculture Improvement Act of 2018 to incorporate some of the proposed language of the Hemp Farming Act of 2018, which allows hemp to be grown as an agricultural crop. Quickly after the legalization of hemp, CBD and hemp products began to proliferate in the retail market.

## The current state of FDA regulations

The Agriculture Improvement Act explicitly preserved the Food and Drug Administration (FDA) authority to regulate products containing *cannabis* or *cannabis*-derived compounds under the Federal Food, Drug, and Cosmetic Act (FDCA) and the Public Health Service Act (PHSA).

In December 2018, the FDA issued three generally recognized as safe (GRAS) notices for hemp seed-derived human food ingredients: hulled hemp seed, hemp seed protein powder, and hemp seed oil.<sup>8</sup> As a result of the GRAS notices, these products can be legally marketed and used as ingredients in human foods.

The GRAS notices do not permit addition of CBD to food, and “it is a prohibited act under section 301(l) of the Federal Food, Drug, and Cosmetic Act to introduce into interstate commerce a food to which CBD or THC has been added.”<sup>9</sup> Further, the FDA has not approved *cannabis* for any use in animals, and animal food ingredients must be the subject of an approved food additive petition or GRAS for their intended use in the intended species. As a result, animal food containing CBD is considered adulterated under 21 USC 342(a)(2)(C)(i). As of now, there are no approved additive petitions, ingredient definitions, or GRAS notices for animal food substances derived from hemp.

In contrast, the FDA's position on CBD in cosmetics is different. A cosmetic is defined as an article “intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance.”<sup>10</sup> Cosmetics are not subject to premarket approval by the FDA (except as a color additive) and *cannabis* and hemp-derived ingredients are not prohibited or restricted.<sup>11</sup>

While the FDA has not formally stated that it is exercising enforcement discretion with respect to CBD products, its relative inaction in response to the overwhelming proliferation of non-compliant CBD and CBD-related products in the marketplace suggests that federal enforcement resources are being devoted to cases of egregious, high-profile product marketing



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and instances of significant adverse health outcomes. The FDA has, however, issued warning letters to companies selling CBD products, claiming the labeling reflected an intent to prevent, diagnose, treat, or cure diseases such as cancer.<sup>12</sup> Some products subject to FDA enforcement were in further violation of the FDCA because the agency found that they were marketed as dietary supplements or because they involved adding CBD to food.<sup>13</sup> The FDA monitors marketing and acts selectively against companies that, in its view, market for therapeutic uses to treat serious diseases.<sup>14</sup>

### Michigan's regulations

At the state level, Michigan's hemp industry is regulated by the health section manager in the Pesticide and Plant Pest Management Division of the Michigan Department of Agriculture and Rural Development (MDARD). Marijuana, meanwhile, is regulated by the Marijuana Regulatory Agency (MRA). MDARD issues permits for growers and processors-handlers of hemp upon reviewing their respective applications. Because of the interplay — and often, confusion — with CBD and THC, the MRA and MDARD issued joint guidance to distinguish them.<sup>15</sup> Highlights include:

- Edible marijuana products containing CBD made by licensed processors may only be produced using CBD obtained from regulated sources.
- Products derived from industrial hemp, including CBD oil, fall under several different categories. Any substances that will be added to food or drink or marketed as a

dietary supplement must first be approved by the FDA for that intended use. At this time, the FDA has not approved CBD for use in food or drink or as a dietary supplement. Therefore, it's currently illegal to add CBD to food products or drinks or sell it as a dietary supplement.

- GRAS is a list of substances that the FDA considers safe to add to food. Hulled hemp seeds, hemp seed protein, and hemp seed oil are considered GRAS. CBD is currently not considered GRAS.<sup>16</sup>

Under a plan approved by the United States Department of Agriculture last fall, all growers must complete a hemp pre-harvest form at least 20 days in advance of harvest to request an appointment for an MDARD inspector to collect samples.<sup>17</sup> This ensures that hemp grown in Michigan follows acceptable hydrocarbon levels established by federal and state law. Likewise, CBD retailers are required to obtain a processor-handler permit to sell CBD products.<sup>18</sup>

### Cannabis and environmental regulations

A frequently overlooked area of hemp regulation is the impact that growing the product has on the environment. Growing cannabis can impact water quality, increase water use, lead to air pollution, and potentially degrade soils; processing facilities may impact water and air quality and potentially generate hazardous waste.<sup>19</sup> Related environmental impacts can come from increased electricity demands from indoor operations and consumption of fossil fuels when transporting cannabis products throughout the state.<sup>20</sup>

## Water supply and groundwater discharge concerns

Like most agricultural operations, cannabis growers and processors face two principal water problems: how to obtain a sufficient supply of water and what to do with process-water discharges.<sup>21</sup> These concerns apply equally to growers and processors of industrial hemp and regulated marijuana products.<sup>22</sup> In terms of water supply, growers requiring large amounts of water should be familiar with the Michigan Department of Environment, Great Lakes, and Energy (EGLE) process for evaluating and registering water withdrawals. New or increased large-quantity withdrawals—withdrawals greater than a daily average of 100,000 gallons of water per day in any consecutive 30-day period supplying a common distribution system<sup>23</sup> — must be registered with EGLE using its water withdrawal assessment tool (WWAT).<sup>24</sup> WWAT is a statutorily provided program that evaluates certain inputs<sup>25</sup> such as the location of the proposed withdrawal, the amount and rate of water to be withdrawn, and proposed withdrawal source<sup>26</sup> and determines immediately whether the proposed withdrawal is permissible.<sup>27</sup> If approved, the applicant can register their withdrawal immediately.<sup>28</sup> If denied, the applicant must submit additional information to EGLE, including an analysis of the proposed withdrawal by a professional hydrologist or hydrogeologist,<sup>29</sup> which may also entail a site-specific review<sup>30</sup> to determine whether the proposed withdrawal will result in an adverse impact.<sup>31</sup>

On the process-water discharge side, EGLE has advised all marijuana growing or processing facilities planning to discharge to the ground or groundwater must submit a groundwater discharge permit application for a Rule 2210(y)<sup>32</sup> permit due to potential pollution from fertilizers or nutrients used during the growing process.<sup>33</sup> Rule 2210(y) is a catchall provision exempting from permit requirements<sup>34</sup> any “discharge that has been determined by the department to have an insignificant potential to be injurious based on volume and constituents.”<sup>35</sup> Thus, EGLE provides 2210(y) permits as a site-specific authorization for groundwater discharge.<sup>36</sup> EGLE has indicated this “is not a guaranteed permit category, but it enables [the agency] to gather more information for assessment of the appropriate category.”<sup>37</sup> Accordingly, such a submission may transition into an individual permit application<sup>38</sup> that can require a hydrogeologic study, waste characterization, and a discharge management plan.<sup>39</sup>

## Waste management and marijuana products

Regulations governing the management and disposal of waste for regulated marijuana differ from requirements for industrial hemp mainly because regulated marijuana businesses — including growers, processors, and retailers — must render marijuana products and plant waste unusable and unrecognizable before disposal.<sup>40</sup> Doing so requires incorporating

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the product or plant waste with other waste so the resulting mixture is “not less than 50 percent non-marihuana” waste.<sup>41</sup> Once rendered unusable and unrecognizable,<sup>42</sup> marijuana product and plant waste must be disposed of in a secured receptacle at a licensed municipal solid waste landfill, a registered composting facility, an anaerobic digester, or an approved in-state municipal solid waste or hazardous waste incinerator.<sup>43</sup> However, growers may dispose of marijuana plant waste as compost feed stock or in another organic method if they obtain MRA approval and do so in compliance with Part 111<sup>44</sup> of the Natural Resources and Environmental Protection Act.<sup>45</sup> Some operations, such as marijuana processors, may generate hazardous waste<sup>46</sup> by using chemicals that presents a significant risk to human health due to toxicity or flammability.<sup>47</sup> That waste must also be managed in accordance with Part 111.<sup>48</sup> Likewise, industrial hemp operations must manage hazardous or solid waste in accordance with Parts 111 and 115 of NREPA;<sup>49</sup> however, they need not follow the additional MRA requirements under Rule 211.<sup>50</sup>

## Air quality permitting concerns

Cultivating and processing cannabis produces emissions of volatile organic compounds (VOCs), which either occur naturally during plant growth or during processing due to evaporation of solvents used during the extraction process.<sup>51</sup> Processing cannabis can also produce hazardous air pollutants (HAPs).<sup>52</sup> VOCs are commonly known as an ozone precursor since they have potential to react with nitrogen oxides to form ground-level ozone,<sup>53</sup> a regulated pollutant under the Clean Air Act National Ambient Air Quality Standards.<sup>54</sup> HAPs are regulated under different programs set forth under the Clean Air Act.

In Michigan, cannabis processing facilities may need a permit called a permit to install (PTI)<sup>55</sup> to authorize construction and operation of the facility or equipment within it depending on the rate of VOC (or HAP) emissions from a particular activity. Michigan Administrative Code R 336.1201 through R 336.1209 set forth the process for obtaining a PTI. In addition, a renewable operating permit (i.e., Title V operating permit) may be required if the activity or process has the potential to emit at or above the major-source threshold for any air pollutant as

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defined in the rules.<sup>56</sup> Several types of cannabis operations may need permits, including a processing and/or indoor growing facility requiring its own power plant, emergency generators, boilers, or other equipment or a facility that extracts oils, waxes, terpenes, THC, CBD, and more from cannabis if the process uses VOCs (cold-press extraction processes may not require a PTI unless heat or solvents are used.)<sup>57</sup>

Cannabis growers and processors may want to install odor controls as part of their operations. Depending on the type of system that the owner/operator wishes to install, a PTI (e.g., a system that injects chemicals through mechanisms such as a spray, mist, or vapor, or one that creates ozone to destroy odors) could be required.<sup>58</sup> On the other hand, PTIs are generally not required if the odor-control system removes odor-causing chemicals before they leave the building.<sup>59</sup>

Since this is a relatively new industry, it is important that an owner/operator of any type of cannabis facility ensures that air permitting regulations are reviewed for applicability and keeps abreast of changes to agency guidance on the subject. If a permit is required, the next step is ensuring compliance with its requirements and managing any changes to the facility or its equipment that may affect the permit.

## Conclusion

The hemp industry is always changing, with markets from food to cosmetics emerging. The potential for a multibillion-dollar industry has created increased regulation for hemp that evolves frequently. It is important to seek out an experienced attorney practicing in this area to navigate these uncharted waters. ■



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