## PRODUCT FORMULATION

# Marijuana-Infused Foods: Controlling the Uncontrolled

The regulatory and consumer-demand landscapes are changing rapidly. Here are the essentials.

#### by Rachel Zemser

eeping abreast of what's happening in the market for marijuana-infused foods (MIFs) can be daunting. The regulatory and consumer-demand landscapes are changing rapidly, and misconceptions abound.

The United States government classifies marijuana as a Schedule I controlled substance under the Controlled Substances Act. Medicinal marijuana is legal in 20 US states and the District of Columbia but is not recognized by US federal law. MIFs, which the FDA considers "adulterated" or unsafe, are the fastest-growing segment of the medicinal marijuana industry. "Medibles" – the slang term used for foods infused with tetrahydrocannabinol (THC), the active compound in marijuana – are typically sold at medical-cannabis dispensaries, in states that have legalized medicinal or recreational marijuana. Popular medibles include chocolates, brownies, hard candies, rice crisp-style treats, and beverages.

Most MIF producers say they would welcome regulation, but for now most operate underground. That's because state officials defer to the federal ban on marijuana and often do not inspect or regulate these operations. And the FDA and USDA simply won't regulate a federally illegal food product.

#### The Cannabis Plant

Cannabis comes from the female *Cannabis sativa* or *Cannabis indica* plant. The male plant does not produce usable buds, and a pollinated female produces seeds that can reduce the plant's potency. The plant's flower top is the most potent portion. Many strains are derived from *C. sativa* and *C. indica*: Some are cultivated to have higher percentages of cannabinoids (the active chemical compounds); low-cannabinoid varieties are used for their fiber and seeds, which are used to make paper and textiles, and as an edible, non-hallucinogenic protein source. Information about potency and THC extraction are discussed later in this article.

#### A Self-Regulated Industry

Testing MIFs for mold, pathogens, and THC potency is voluntary in some states where medicinal marijuana is legal, but more states have started requiring such tests; by 2016, no state with legalized medicinal marijuana is expected to lack strict testing regulations. Some states (like Colorado) are now selling MIFs recreationally and are ahead of the game on safety enforcement. Colorado is also improving its ingredient tracking systems so that if, for example, an MIF cookie causes a salmonella outbreak, the source can be traced.

If MIF producers made only non-hazardous foods that require no refrigeration, such as candy or



 Cannabis Energy Drink Mango Flavor (Netherlands) contains hemp seed extract and is THC free, with no narcotic effects.

# > Guidance for Manufacturers of Marijuana-Infused Foods

Counties in some US states have issued guidelines for safe manufacturing of edible cannabis products. These general recommendations were adapted from the City and County of San Francisco Department of Public Health:

• Do not make any edible products that require refrigeration or hot holding times, such as ice cream, yogurt, and meat products. Make only baked goods: brownies, bars, cookies, cakes, tinctures, and other non-refrigerated items.

• Prepare food in a kitchen that has a hand-washing sink, liquid soap, and paper towels. Wear gloves when handling ready-to-eat food.

• Avoid cross-contamination by preparing edible cannabis products separately from all other food products.

- Keep children and pets away from kitchen/preparation areas.
- Clean and sanitize all utensils, equipment, and food-contact surfaces.
- Label packaging with information about allergens, total weight (in ounces or grams) of cannabis, and
- a clear warning that the item is a medication and not a food. Specify the date of manufacture.
- Do not make the product look attractive to children or imitate the appearance of candy.

• Do not allow any person with a gastrointestinal illness or other communicable disease to participate in food preparation. Preparers who have cuts or sores must always wear gloves.

• Obtain state certification as a food handler, and take a state health department-approved online course. Also take other food-safety and sanitation courses recommended by your local or state health department.

rice crisp-style treats, the risk of illness would be minimal. Such products have a low water-activity level and high sugar concentration, which inhibit the growth of pathogenic bacteria and slow the growth of yeast and molds. As this industry becomes more competitive, dispensaries and independent MIF producers will want to sell higher-risk items (e.g., dairy-based products, shelf-stable low-acid beverages, and acidified foods), all of which require attention to processing time, pH levels, water activity, and thermal methods. If not manufactured properly, these products can support pathogenic growth and cause serious illness or death.

Without proper guidance from FDA, USDA, or a state health department, it is unsafe to attempt commercial-kitchen manufacturing of potentially hazardous "medible" food products that require refrigeration or control of water activity or pH.

Other overlooked necessities include finished-product testing (to ensure the absence of pathogens and other bacteria that improper storage or handling can introduce), proper allergen labeling, and final-potency information. Knowing a medible's precise potency is important for novice consumers. Although eating too many "space cakes" won't kill you, it can increase heart rate, nausea, and the risk of fainting.

#### **Pot Potency: A Primer**

Deciding how much cannabis should be in an MIF serving is difficult, given the many active ingredients and chemical compounds in the plant. Adam Mintz, president of Steep Hill Halent Laboratories (Oakland, CA), a third-party cannabis testing facility, offers this rule of thumb: "The normal adult dosage of THC for beginners is 15mg. More experienced patients can take up to 30mg. However, appropriate dosages vary among patients."

Marijuana food products are often labeled 1x or 2x - but what the "x" means is usually not explained by the manufacturer on the packaging material. Mintz says: "1x, 2x, 5x -they all mean nothing and are purely subjective. Some makers get edibles tested once and then use that data for all future products, which is an erroneous method. Source material will never be identical, which means potency can vary from batch to batch. Testing is the only true method for understanding the mg/g of THC in an entire product."

Given the lack of clarity of terms like 1x, it's more sensible for the maker to identify the exact number of mg. Both Colorado and Washington State maintain a rigorous cap at 100mg of THC per food unit sold, but other states like California do not enforce such regulations.

What about the potency differences among plant strains? "All strains of marijuana have different levels of THC," says Mintz. "In addition, a strain that tests high for THC one time will not necessarily test high the next time."

If a maker is worried about big variations in the potency of its source material, it should do a quick test on that material before infusion; if it is already using consistent source material, it should test the fat or alcohol medium in which the marijuana has been infused and the final food product.

THC is tested via gas or liquid chromatography, using equipment that costs thousands of dollars and that requires training and a strong science background to use.

Owning such equipment and testing their own products are not feasible for most marijuana food makers, and the results would be biased anyway. MIF makers should find a local laboratory that provides THC testing services or, like Steep Hill, that offers both testing and consulting.

#### Maximizing the Extraction

Adam Gottlieb outlines the basic scientific approach to extracting THC and optimizing its digestibility. Simply put, cook the marijuana plant's leaves, seeds, and stems in oils and fats, or boil them in alcohol. Steeping or boiling those plant elements in water is not effective.

Typical media include butter, cocoa butter, or oil/water emulsions like milk. THC should not be consumed in heavy meals like pasta, as the drug will take a long



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time to enter the bloodstream and deliver its medicinal effects. Consuming the THC in small quantities of food allows it to enter the body undiluted.

Although cooking or heating does not reduce THC potency, oxidation can have that effect. The extracted material should be stored in an airtight container or freezer, to maintain potency.

As more states legalize marijuana products, companies may ask food scientists for help in developing shelf-stable snacks and beverages for this growing market.

Mintz says: "There is no perfect or best method for extracting THC and infusing it in food products, but you can't really go wrong with butter, oils, and alcohols."

However, he warns against using glycerine, which is not a good carrier for cannabinoids. Eventually, food-product developers might create a patentable process to extract THC and infuse it into food.

The patent office will grant a patent for a process, even if it is illegal to execute that process (see the Manual of Patent Examining Procedure: MPEP 706.03 (a)).

#### Hemp: A Vegan Protein Source

THC garners most of the attention in discussions about marijuana. But a separate growing industry exists for hemp, the stalk and seeds from a THC-free plant species used in textiles, foods, paper, rope, and building materials. For the past 10 years, hemp protein, derived from the plants seed and oil, has gained popularity as a vegan, allergen-free protein source.

Hemp protein has all nine essential amino acids, plus essential fatty acids like omega 3 and omega 6. Protein from hemp is about 60-70% edestin, a bioactive globular protein that, though it has a lower overall protein content than soy, is thought to be easier to digest and is not allergenic.

Nutiva, a northern Californiabased company that sells superfoods (including chia seeds, coconut oil, and other vegetarian ingredients), also sells hemp seeds, oil, protein powder, and its own line of hemp-flavored smoothies.

Another popular THC-free hemp product is Swiss Tea, a com-

pany launched in Switzerland in 1999, whose products have been sold in the US since 2011.

Hemp seeds and powders, with their nutty taste, have a variety of culinary applications, including mixing into yogurt, baking into energy bars, and adding into trail mix.

Food scientists should consider experimenting with hemp-protein powders when formulating products for the vegan and allergenfree markets.

Unfortunately, a lack of knowledge about hemp, plus the misperception that industrial hemp products are associated with cannabis, has prejudiced much of the food industry against hemp protein. Marketing teams must work creatively to reiterate the point that you cannot get high from eating hemp-protein products.

Hemp has not been cultivated as a food crop in the US since 1957, given some misguided policies that prevent farmers from growing it.

However, Section 7606 of the Agricultural Act of 2014 (signed into law by President Obama), defines industrial hemp as distinct and allows universities and state departments of agriculture in states where hemp is legal to grow it for research and pilot programs. Such research is needed to meet growing market demands.

#### A Step Ahead of the Regulations

Many states have implemented testing procedures and methods to ensure that both the source plants and finished MIF products are properly labeled and safe to eat. However, without federal government support, state regulations will remain inconsistent, and the risks of overdosing, accidently consuming an allergen-infused product, and improper food handling will persist in this niche industry.

Consumers should always remain vigilant about who makes their MIFs, and makers should model their efforts on other FDA food regulations until mandatory rules are in place.▼

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