

# Locke Lord QuickStudy: Are Your Favorite Sweets Disappearing ?From the Golden State? California Issues Ban on Common Food ?Additives

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California has become the first U.S. state to ban the use of four potentially harmful food and drink additives. On October 7, 2023, Governor Gavin Newsom signed into law California Assembly Bill 418, the California Food Safety Act, which will ban the use of brominated vegetable oil, potassium bromate, propylparaben, and red dye 3 by January 1, 2027, in the use of food products sold, manufactured, distributed, held, delivered, or offered for sale in California.<sup>[1]</sup> The first violation may lead to a fine of at most \$5,000 and subsequent violations would be subject to fines of at most \$10,000 per violation.<sup>[2]</sup> [Over 3,500 food products could fall under this ban.](#) This has potential ramifications for many in the food industry, particularly those who manufacture, supply, and distribute sodas, cereals, snack foods, candy and drinks.

## **Banned Additives**

The four additives banned by the new California law have been previously banned in the European Union (“E.U.”) and certain other parts of the world, but are still currently approved by the U.S. Food and Drug Administration (“FDA”) and commonly used in many products sold in the U.S. Below is a description of the additives subject to California’s ban, their common usage, and regulation.

### **Brominated Vegetable Oil**

[Brominated vegetable oil is used in some citric beverages as an emulsifier.](#) According to FDA regulation, the current acceptable amount of brominated vegetable oil is 15 parts per million.<sup>[3]</sup> Of note, many companies previously made a switch from brominated vegetable oil after it was banned in the E.U. in 2008 when it was not included in the E.U.’s list of approved food additives.<sup>[4]</sup> While brominated vegetable oil is subject to California’s ban as of the January 1, 2027 effective date, it is possible suppliers and manufactures whose products contain this additive will have to comply with a ban sooner than that. In Spring 2023, [FDA published a proposed rule](#) amending 21 C.F.R. § 180.30 to include brominated vegetable oil on the list of additives no longer permitted for use in food products. FDA intends to publish a revised regulation in December 2023 that may be officially adopted in 2024.

### **Potassium Bromate**

[Potassium bromate is an oxidizing agent that helps bread and baked goods maintain shape and texture.](#)

According to FDA regulation, the current acceptable amount of potassium bromate in wheat flour is 75 parts per million and 50 parts per million in white flour.<sup>[5]</sup>

## **Propylparaben**

Propylparaben is an antimicrobial preservative.<sup>[6]</sup> According to FDA regulation, the current acceptable amount of propylparaben is less than 0.1%.<sup>[7]</sup>

## **Red Dye 3**

Red dye 3 is a dye which allows food and beverages to be dyed red. According to FDA, the acceptable amount of this dye depends on the type of solvent used.<sup>[8]</sup> [Red dye 3 has been banned in the use of cosmetics since 1990 due to FDA's finding that it was a carcinogenic in rats.](#)

## **Potential Impact**

Cost and taste are crucial factors companies consider when formulating a recipe. California's ban thus has the potential to create millions of dollars in expenses for affected manufacturers and retailers, both based on the cost of identifying and integrating alternative ingredients as well as the cost of implementing those new ingredients in the supply chain.<sup>[9]</sup>

[With a GDP of 3.6 trillion dollars, California has the highest GDP of any state in the country.](#) Any market participant would suffer greatly if it were to maintain its current formulation and cease to sell within California. Thus, it is anticipated this ban will ultimately have a national impact.

## **Preemption**

Manufacturers are likely to challenge the law before making changes to their recipes. There is an argument to be made that California has acted outside the scope of its authority. While states have general police powers to ensure the health and safety of their citizens, Congress has delegated its power to regulate interstate commerce via food and drugs to the FDA. The FDA was established in 1906 and has been creating regulations ever since. Manufacturers would have a potentially compelling argument that California has placed an obstacle in the way of the FDA's enforcement, as California has banned four additives the FDA has labeled as safe within certain amounts. This is a slippery slope. Food is an industry where multiple manufacturers may use the same ingredients to achieve a similar goal, such as, a dye for coloring. Thus, to ban certain common additives would directly takeover the FDA's role in defining what is safe.

There is some precedent food manufacturers can look to for support. In the *Zogenix* case, the District Court of Massachusetts held that a state ban on an FDA approved drug was obstacle preemption.<sup>[10]</sup> The FDA is authorized by Congress to assure national safety standards for the public. When states ban FDA approved drugs, the states subvert FDA authority.<sup>[11]</sup> While drugs are different than food additives, food additives are still subject to an approval process similar to that of drug approval.<sup>[12]</sup> The FDA has listened to petitions in the past regarding the safety of certain additives.<sup>[13]</sup> In Governor Newsom's approval of the bill, he challenges the FDA to review and adjust the regulations for these additives, seemingly recognizing that the bill is trying to fill FDA's role.

Even though the law does not institute formal bans until 2027, a court could find that a manufacturer has standing to challenge the law as of today as companies must begin devoting resources to developing new recipes immediately.

## Conclusion

If your company or organization formulates or manufactures products containing one or more of the banned additives, it may be prudent to begin considering reformulations. Even if there are challenges to the California Food Safety Act, brominated vegetable oil may independently be subject to an FDA ban, and the other additives may very well ultimately be banned in California. The possibility also exists that other states will follow California's lead and attempt to pass legislation to ban these or other additives that are perceived to be harmful.

Locke Lord's Food and Beverage and FDA Regulatory teams are available to assist your company in evaluating the best way to proceed in light of the new California law and other forthcoming regulations and legislation concerning food additives.

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[1] 2023 CA A.B. 418.

[2] *Id.*

[3] *Id.*

[4] Council Regulation (EC) 1333/2008

[5] 21 C.F.R. §§ 137.160-205.

[6] 21 C.F.R. § 184.1670.

[7] *Id.*

[8] 21 C.F.R. § 74.303

[9] See Mary K. Muth et al., *How Much Can Product Reformulation Improve Diet Quality in Households with Children and Adolescents?*, *Nutrients* (2019).

[10] *Zogenix, Inc. v. Patrick*, No. CIV.A. 14-11689-RWZ, 2014 WL 1454696, at \*1-2 (D. Mass. Apr. 15, 2014).

[11] *Id.*

[12] See Institute of Medicine, *Enhancing the Regulatory Decision-Making Approval Process for Direct Food Ingredient Technologies* 13-110 (1999).

[13] See *Food Additive Regulations; Synthetic Flavoring Agents and Adjuvants*, 83 Fed. Reg. 50490, 50502 (Oct. 29, 2018) (codified at 21 C.F.R. §§ 172 and 177)

(Banning six additives as result of a nonprofits petition).

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