



Feb. 22, 2024

Guidance: Hemp-Infused Soft Drink Manufacturing and Distribution in South Carolina

This guidance answers questions the South Carolina Department of Health and Environmental Control (DHEC) has received related to permitting, ingredients and labeling of hemp-infused soft drink manufacturing and distribution in South Carolina. The guidance below replaces DHEC's Jan. 22, 2024, guidance in its entirety and is limited to DHEC's regulatory authority. Additional laws may apply. DHEC will continue to update its guidance or provide additional guidance, as appropriate. This guidance is consistent with the South Carolina Department of Agriculture's (SCDA) stance on hemp-derived products being used as ingredients in human food ([Hemp Products in Human Food Quick Guide](#)).

Permitting

South Carolina Regulation 61-32¹ requires all persons who manufacture or distribute soft drinks in South Carolina to obtain and maintain a permit from DHEC. Soft drinks are defined as "any nonalcoholic, flavored carbonated beverage, including but not limited to soda or soda water, fruit flavored drink, nonalcoholic still beverage, and seltzer or club soda."

To obtain a permit for the manufacturing or distribution of hemp-infused soft drinks, manufacturers and distributors must submit an application to DHEC and meet the requirements outlined in South Carolina Regulation 61-32. Each soft drink manufacturer and distributor whose products are intended for consumption in South Carolina shall be inspected by DHEC before the issuance of a permit.²

Allowable Ingredients

"No person within South Carolina, or its jurisdiction, shall produce, provide, sell, offer, or expose for sale or have in possession with intent to sell, any soft drink that is adulterated³ or misbranded.⁴" DHEC uses federal law and scientific data to determine whether an ingredient can be approved for soft drinks.

1. Hemp ingredients that are "Generally Recognized As Safe" (GRAS)

Under sections 201(s) and 409 of the federal Food, Drug, and Cosmetic Act, any substance that is intentionally added to food is a food ingredient and is subject to premarket review and approval by the

¹ South Carolina Regulation 61-32 sets forth the minimum health standards, procedures, and practices to ensure that wholesale bottled water, soft drinks, and ice are manufactured in South Carolina in a safe and wholesome manner. It is applicable to any person who manufactures or distributes wholesale bottled water, soft drinks, or ice, sold for human consumption in South Carolina.

² S.C. Regs. R. 61-32, Section VII (A).

³ S.C. Regs. R. 61-32, Section III (B).



Food and Drug Administration (FDA), unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food ingredient. DHEC considers ingredients with GRAS notices to be safe for human consumption.

The following hemp ingredients currently have GRAS notices:

- Hulled hemp seed ([GRAS Notice GRN No. 765](#); [FDA Response Letter](#))
- Hemp seed protein powder ([GRAS Notice GRN No. 771](#); [FDA Response Letter](#))
- Hemp seed oil ([GRAS Notice GRN No. 778](#); [FDA Response Letter](#))

2. **Hemp oil/extract may also be considered an allowable ingredient if it is “full spectrum” whole-plant extract** (i.e. hemp oil from biomass) that contains the naturally occurring ratios and array of phytonutrients found in hemp.

All hemp-derived ingredients as described above must meet the federally defined Tetrahydrocannabinol (THC) level for hemp⁴ and come from a food grade facility.

NOTE: All applicants and permit holders must provide DHEC with both:

- a. A Certificate of Analysis (COA) for the applicant or permit holder’s product. DHEC will review the COA to determine if the ingredient is allowable.
- b. A South Carolina Registration Verification Certificate (RVC) or equivalent documentation evidencing inspections by a food safety regulatory authority.

Labeling

All soft drink products shall be labeled according to the requirements found in 21 CFR Part 101⁵, as amended,⁶ and will be reviewed by DHEC.

Future of South Carolina’s Food Safety Program

Pursuant to 2023 S.C. Act No. 60, on July 1, 2024, DHEC’s Food Safety Program will become a department of SCDA. All relevant powers and duties assigned to DHEC will be transferred to and devolved upon SCDA at that time.

⁴ Currently, the federally defined THC level for hemp is a delta-9 concentration of not more than a 0.3 percent on a dry weight basis.

⁵ Code of Federal Regulations

⁶ S.C. Regs. R. 6-32, Section VI.

