





for use in conventional foods. FDA's regulations in 21 CFR 170.30(a)-(c) describe the criteria for eligibility for classification of a food ingredient as GRAS. The use of a food substance may be GRAS based on either scientific procedures or, for a substance used in food before 1958, through experience based on common use in food (see 21 CFR 170.30).

We know of no basis for general recognition of safety for Delta-8 THC based either on scientific procedures or common use in food prior to January 1, 1958. Based on our review of published, scientific literature, existing data and information do not provide an adequate basis to conclude that the use of Delta-8 THC in food meets the criteria for GRAS status. Some of the available data raise serious concerns about potential harm from Delta-8 THC. Our review of published scientific literature identified potential for adverse effects on the central nervous and cardiopulmonary systems. In addition, studies in animals have suggested that gestational exposure to Delta-8 THC can interfere with neurodevelopment. Therefore, based on our review, the use of Delta-8 THC in conventional food does not satisfy the criteria for GRAS status under 21 CFR 170.30.

FDA is not aware of any other exception to the food additive definition that would apply to Delta-8 THC for use as an ingredient in a conventional food. Therefore, Delta-8 THC added to a conventional food is a food additive under section 201(s) of the FD&C Act and is subject to the



You must immediately cease marketing edible Delta-8 THC products that imitate conventional foods using advertising or packaging that is likely to be appealing to young children. The FTC also strongly urges you to review all of your marketing andad.Td(mTf-0.0003 Tc 0.0018 B4D 1yw 0 T384 4crv

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