



Notice on FDA Order Pertaining to Partially Hydrogenated Oils (PHOs)



The California Department of Public Health (CDPH) has notified all local Environmental Health Services (EHS) agencies who enforce the provisions of the California Retail Food Code (CRFC), regarding the federal Food and Drug Administration (FDA) order pertaining to foods containing partially hydrogenated oils (PHOs) which takes effect **June 18, 2018**. The FDA Declaratory order is available at: [Final Determination on Partially Hydrogenated Oils](#)

The declaratory order further provides that “Since this is a Federal action, affected persons nationwide must comply with the provisions of the declaratory order. As stated in the declaratory order regarding state and local laws: “As with any Federal requirement, if a State or local law requirement makes compliance with both Federal law and State or local law impossible, or would frustrate Federal objectives, the State or local requirement would be preempted” (80 FR 34650 at 34655).”

The major compliance provisions of the Order:

- A. **Partially Hydrogenated Oils (PHO) are not generally recognized as safe (GRAS) for any use in human food.** The FDA defines ‘safe’ as: a reasonable certainty in the minds of competent scientists that the substance is not harmful under intended conditions of use (21 CFR 170.3(i)).
- B. The FDA is defining PHOs as those fats and oils that have been hydrogenated, but not to complete or near complete saturation, and with an iodine value (IV) greater than 4.
- C. Any party may seek food additive approval from the FDA for the use of PHOs with data that demonstrates no harm of the proposed use.
- D. **FDA compliance date of the Order is June 18, 2018**

The Order DOES NOT apply to:

- a. Naturally occurring trans fat (ingredients from ruminant sources)
- b. The use of conjugated linoleic acid (CLA).
- c. Partially hydrogenated methyl ester of rosin.
- d. Fully hydrogenated oils
- e. Edible oils that contain Industrially-Produced Trans Fatty Acids (IP-TFA) as an impurity

All local EHS agencies are urged to take the following action:

1. Post notification on their websites; and
2. Notify the retail food facilities covered by this order of their compliance obligations when conducting routine retail food inspections.

Local enforcement agencies shall issue a Notice of Violation to any covered facility that is not in compliance with this order after June 18, 2018 but may defer formal enforcement action pending further guidance from FDA regarding variances and other compliance issues. For more information or if you have any questions, please contact your local Environmental Health Services: <https://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/RetailFood/EHAgencyContactLinks.pdf>

FDA is expected to issue guidance for compliance and enforcement regarding this issue in the near future. As this information becomes more available, CDPH will update this notification and advise the local EHS agencies respectively.

*At the same time, the FDA is denying a food additive petition from the Grocery Manufacturers Association (GMA) requesting approval for certain limited uses of PHOs. To allow for time for reformulation, the agency is extending until June 18, 2019 the compliance date to stop manufacturing foods with these specific, limited petitioned uses of PHOs, and until **Jan. 1, 2021** for these products to work their way through distribution. CDPH recommends that retail food facilities check with their food suppliers regarding any food products containing PHOs they receive which may be considered “petitioned foods” related to the FDA order. CDPH is requesting a list of these petitioned foods and will post this list as soon as it becomes available. [Federal Register notice: Declaratory order; extension of compliance date](#)

For more information

- [Federal Register notice: Grocery Manufacturers Association; Denial of Food Additive Petition](#)
- [Federal Register notice: Declaratory order; extension of compliance date](#)
- [Final Determination on Partially Hydrogenated Oils](#)