

BREAST CANCER FUND, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR FOOD SAFETY,
CENTER FOR SCIENCE IN THE PUBLIC INTEREST, CONSUMER FEDERATION OF AMERICA,
EARTHJUSTICE, ENVIRONMENTAL DEFENSE FUND, IMPROVING KIDS' ENVIRONMENT, LEARNING
DISABILITIES ASSOCIATION OF AMERICA, AND NATURAL RESOURCES DEFENSE COUNCIL

April 19, 2016

Dr. Dennis Keefe
Director of the Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740

Re: Citizen petition requesting that FDA remove its prior sanction of five ortho-phthalates and ban eight ortho-phthalates.

Dear Dr. Keefe:

The undersigned submit this petition pursuant to 21 CFR 10.30 to request that the Commissioner of the Food and Drug Administration (FDA) amend its regulations regarding ortho-phthalate additives to food. If you have questions or comments, please contact Tom Neltner at tneltner@edf.org or 202-572-3263. Please copy Eve Gartner at egartner@earthjustice.org, Cristina Stella at CStella@CenterforFoodSafety.org, Laura MacCleery at lmaccleery@cspinet.org, Dr. Maricel Maffini at drmvma@gmail.com, and Erik D. Olson at eolson@nrhc.org on all responses.

A. Action Requested

We submit this citizen petition¹ pursuant to 21 CFR 10.30 to the Food and Drug Administration (FDA) requesting the agency:

- 1) Add a new section to Part 189 of Title 21 prohibiting the use of eight ortho-phthalates as food contact substances that the Consumer Products Safety Commission's (CPSC) Chronic Health Advisory Panel on Phthalates (CHAP) concluded are unsafe or the evidence indicates developmental health effects are likely. These phthalates are:

Diisobutyl phthalate;
Di-n-butyl phthalate;
Butyl benzyl phthalate;
Dicyclohexyl phthalate;
Di-n-hexyl phthalate;
Diisooctyl phthalate;

¹ Petitioners are filing this citizen petition in response to FDA's letter rejecting two portions of our Food Additive Petition FDA-6B4815 as a protection motion. We believe that the requests were properly included in FAP-6B4815 and should be considered as part of that petition.

Di(2-ethylhexyl) phthalate; and
Diisononyl phthalate.

- 2) Strike section 181.27 from Title 21 of its existing regulations. This section allows the use of five ortho-phthalates as prior-sanctioned substances. The regulation only authorizes their use "as plasticizers when migrating from food packaging material." The ortho-phthalates no longer meeting the reasonable certainty of no harm safety standard are:

Butylphthalyl butyl glycolate;
Diethyl phthalate;
Ethylphthalyl ethyl glycolate;
Di-(2-ethylhexyl) phthalate (use on foods of high water content only); and
Diisooctyl phthalate (use on foods of high water content only).

B. Statement of Grounds

See Food Additive Petition (FAP) No. 6B4815 and the agency's filing letter for that petition issued on April 12, 2016. Both documents are attached to this citizen petition.

C. Environmental Impact

See Food Additive Petition (FAP) No. 6B4815 and the agency's filing letter for that petition issued on April 12, 2016. Both documents are attached to this citizen petition.

D. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,



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