



April 12, 2016

Tom Neltner
Chemicals Policy Director
Environmental Defense Fund
1875 Connecticut Ave., NW Suite 600
Washington, DC 20009

RE: Food Additive Petition (FAP) No. 6B4815

Dear Mr. Neltner:

This is in reference to your submission requesting that 1) FDA revoke and/or amend certain specified regulations in Title 21 of the Code of Federal Regulations to no longer provide for the food contact use of 30 ortho-phthalates; and 2) FDA prohibit the use of 8 specific ortho-phthalates. You have designated this submission as a food additive petition. We have designated your submission in our records system as FAP 6B4815.

We are filing the portion of your submission that requests the revocation of food additive uses of ortho-phthalates as a food additive petition. However, a portion of your submission relates to uses of 5 ortho-phthalates (diethyl phthalate, ethyl phthalyl ethyl glycolate, butyl phthalyl butyl glycolate, diisooctyl phthalate, and di(2-ethylhexyl) phthalate) that are listed in 21 CFR 181.27 as prior-sanctioned. Specifically, you request that we remove the 5 ortho-phthalates from the list of prior-sanctioned substances in 21 CFR 181.27. We are not filing as part of this food additive petition your request to revoke these prior sanctions. Section 201(s) of the Federal Food, Drug & Cosmetic Act (the Act) exempts prior-sanctioned materials from the definition of a food additive. Therefore, your request to revoke the prior-sanction for these substances is not within the scope of a food additive petition as specified under Section 409(b) of the Act (“a petition proposing the issuance of a regulation prescribing the conditions under which such [food] additive may be safety used”). You may submit a citizen petition under 21 CFR 10.30 requesting that FDA take this action.

In addition, your submission requests that FDA prohibit the food contact use of 8 specific ortho-phthalates (diisobutyl phthalate, di-n-butyl phthalate, butyl benzyl phthalate, dicyclohexyl phthalate, di-n-hexyl phthalate, di(2-ethylhexyl) phthalate, and diisononyl phthalate). Your petition requests that FDA take this action by issuing a new regulation in 21 CFR part 189. We are not filing as part of this food additive petition your request that we promulgate a regulation under 21 CFR Part 189 prohibiting the uses of these substances in food. Such a request is not within the scope of a food additive petition under Section 409(b) of the Federal Food, Drug, and Cosmetic Act (“a petition proposing the issuance of a regulation prescribing the conditions under which such [food] additive may be safely used”). You may submit a citizen petition under 21 CFR 10.30 requesting that FDA take this action.

Regarding the portion of your submission requesting the revocation of food additive uses of ortho-phthalates that we are filing as a food additive petition; the date of this letter is the filing date of your petition.¹ If we are not able to complete the scientific review within 90 days of the date of this letter, we will inform you by letter and extend the review for an additional 90 days.

Sincerely,

Francis Lin, Ph.D.
Director
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

¹ The ortho-phthalates that are the subject of FAP 6B4815 are listed in Attachment 1 to this correspondence.

Attachment 1**Ortho-phthalates that are the filing subject of FAP 6B4815**

Substance #	Identification in FAP 6B4815
1	Dimethyl phthalate (CAS Re. No. 131-11-3)
2	Diphenyl phthalate (CAS Reg. No. 84-62-8)
3	Methyl phthalyl ethyl glycolate (CAS Reg. No. 885-71-2)
4	Diethyl phthalate (CAS Reg. No. 84-66-2)
5	Diphenylguanidine phthalate (CAS Reg. No. 17573-13-6)
6	Ethyl phthalyl ethyl glycolate (CAS Reg. No. 84-72-0)
7	Diallyl phthalate (CAS Reg. No. 131-17-9)
8	Butyl benzyl phthalate (CAS Reg. No. 85-68-7)
9	Diisobutyl phthalate (CAS Reg. No. 84-69-5)
10	Di-n-butyl phthalate (CAS Reg. No. 84-74-2)
11	Butyl phthalyl butyl glycolate (CAS Reg. No. 85-70-1)
12	Dicyclohexyl phthalate (CAS Reg. No. 84-61-7)
13	Di-n-hexyl phthalate (CAS Reg. No. 84-75-3)
14	Di(butoxyethyl) phthalate (CAS Reg. No. 117-83-9)
15	Dimethylcyclohexyl phthalate (CAS Reg. No. 1322-94-7)
16	Diisooctyl phthalate (CAS Reg. No. 27554-26-3)
17	Di(2-ethylhexyl) phthalate (CAS Reg. No. 117-81-7)
18	Di-n-octyl phthalate (CAS Reg. No. 117-84-0)
19	n-butyl n-octyl phthalate (CAS Reg. No. 84-78-6)
20	Di(2-ethylhexyl) hexahydro-phthalate (CAS Reg. No. not identified)
21	Diisononyl phthalate (CAS Reg. No. 28553-12-0)
22	n-butyl n-decyl phthalate (CAS Reg. No. 89-19-0)

23	n-amyl n-decyl phthalate (CAS Reg. No. 7493-81-4)
24	n-octyl n-decyl phthalate (CAS Reg. No. 119-07-3/ 1323-73-5)
25	Di-n-decyl phthalate (CAS Reg. No. 84-77-5)
26	Diisodecyl phthalate (CAS Reg. No. 26761-40-0)
27	Dodecyl phthalate (CAS Reg. No. 21577-80-0)
28	Dihydroabietyl phthalate (CAS Reg. No. 26760-71-4)
29	Castor oil phthalate, hydrogenated (CAS Reg. No. not identified)
30	Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol (CAS Reg. No. 68650-73-7)