CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1421

[Docket No. CPSC–2021–0014]

Notice of Availability and Request for Comment: Data Regarding Debris Penetration Hazards for Recreational Off-Highway Vehicles and Utility Task/Terrain Vehicles; Extension of Comment Period

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The U.S. Consumer Product Safety Commission (Commission or CPSC) published a notice of proposed rulemaking (NPR) in July 2022 to address debris penetration hazards for recreational off-highway vehicles (ROVs) and utility task/terrain vehicles (UTVs). On October 4, 2024, the Commission published a notice of availability and request for comment (NOA) to announce the availability of, and to seek comments on, details about incident data relevant to the NPR. The NOA invited the public to submit written comments during a 30-day comment period ending on November 4, 2024. In response to a request for an extension of the NOA comment period, the Commission is extending the comment period to December 4, 2024.

DATES: The comment period for the proposed rule published on October 4, 2024, at 89 FR 80831, is extended. Submit comments by December 4, 2024.

ADDRESSES: Submit comments, identified by Docket No. CPSC–2021–0014, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments. CPSC does not accept comments submitted by email, except as described below. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal.

Mail/Hand Delivery/Courier Written Submissions: Submit comments by mail/hand delivery/courier to: Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: *cpsc-os@cpsc.gov.*

Instructions: All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: *https://www.regulations.gov.* Do not submit electronically: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier written submissions.

Docket: To read background documents or comments received, go to: *https://www.regulations.gov,* insert Docket No. CPSC–2021–0014 in the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Han Lim, Project Manager, Office of Hazard Identification and Reduction, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987–2327; email: *hlim@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

Section 7(a) of the Consumer Product Safety Act authorizes the Commission to promulgate a mandatory consumer product safety standard that sets forth performance or labeling requirements for a consumer product, if such requirements are reasonably necessary to prevent or reduce an unreasonable risk of injury. 15 U.S.C. 2056(a). Under this statutory authority, in 2021, the Commission initiated a rulemaking to reduce the risk of injuries and deaths associated with penetration of ROVs and UTVs by debris such as fallen tree branches. The Commission published an advance notice of proposed rulemaking (ANPR) on May 11, 2021 (86 FR 25817), and an NPR on July 21, 2022 (87 FR 43688).[1]

On October 4, 2024 (89 FR 80831), the Commission published in the **Federal Register** a notice of availability and request for comment to announce the availability of, and to seek comments on, details about incident data relevant to the NPR. The NOA invited the public to submit written comments during a 30-day comment period ending on November 4, 2024.

B. Comment Period Extension

On October 8, 2024, the Outdoor Power Equipment Institute (OPEI) and the Recreational Off-Highway Vehicle Association (ROHVA) submitted a request to extend the public comment period of the NOA for an additional 30 days to December 4, 2024. In particular, OPEI and ROHVA asserted that, given the volume of the data and the format in which CPSC has provided access to the data,[2] a 30-day extension is necessary to permit OPEI, ROHVA, and other members of the public to have a meaningful opportunity to comment. The Commission has considered OPEI's and ROHVA's request to extend the comment period. Currently, the comment period is due to close on November 4, 2024. To provide the public additional time to review and comment on the data, the Commission will grant the requested 30-day extension of the comment period, until December 4, 2024.[3]

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2024–25132 Filed 10–29–24; 8:45 am]

BILLING CODE 6355–01–P

[1] On December 21, 2022, the Commission also published a notice of availability and request for comment on a report from SEA, Ltd. titled ''Study of Debris Penetration of Recreational Off-Highway Vehicle (ROV) Proof-of-Concept (POC) Floorboard Guards'' (87 FR 78037).

[2] To obtain access to the data, a request can be submitted to: *https://forms.office.com/g/Yz4tNFdhDp;* a website link to access the data will be sent to the email address provided.

[3] The Commission voted (4–1) on October 22, 2024, to publish this document.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 175, 176, 177, and 178

[Docket No. FDA–2016–F–1253]

Environmental Defense Fund, et al.; Response to Objections and Requests for a Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; response to objections and denial of public hearing requests.

SUMMARY: The Food and Drug Administration (FDA or we) received objections and requests for a public hearing submitted by the Environmental Defense Fund, Learning Disabilities Association of America, Center for Food Safety, Center for Environmental Health, Center for Science in the Public Interest, Breast Cancer Prevention Partners, Defend our Health, and Alaska Community Action on Toxics on the denial of a food additive petition (FAP

6B4815) requesting that we revoke specified regulations to no longer provide for the food contact use of 28 *ortho*-phthalates. We are overruling the objections and denying the requests for a public hearing.

DATES: October 30, 2024.

FOR FURTHER INFORMATION CONTACT: Jessica Urbelis, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–5187; or Carrol Bascus, Office of Policy, Regulations and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 20, 2016 (81 FR 31877), we announced the filing of a food additive petition (FAP 6B4815) (petition) submitted by the Breast Cancer Fund (now Breast Cancer Prevention Partners), Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Clean Water Action, Consumer Federation of America, Earthjustice, Environmental Defense Fund, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council (hereinafter, petitioners).

The petition, received March 18, 2016, initially requested that we amend or revoke specified food additive regulations under parts 175, 176, 177, and 178 (21 CFR parts 175, 176, 177, and 178) to no longer provide for the food contact uses of 30 substances that the petition identified as *ortho*-phthalates. Additionally, petitioners requested that we amend regulations in part 181 (21 CFR part 181) related to prior-sanctioned uses of five *ortho*-phthalates and issue a new regulation in part 189 (21 CFR part 189) prohibiting the use of eight specific *ortho*-phthalates in food contact articles. We declined to file these portions of the submissions as a food additive petition because those requests were not within the scope of a food additive petition (81 FR 31877 at 31878).

Following our May 20, 2016, announcement that we had filed the food additive petition, the petitioners provided supplementary information on October 8, 2016, and August 24, 2017 (see FAP 6B4815 regarding *ortho*-phthalates/Responses to September 1, 2016, request from Tom Neltner, Breast Cancer Fund, et al., dated October 8, 2016, and August 24, 2017) (Supp., October 8, 2016, and Supp., August 24, 2017, respectively). In the October 8, 2016, supplement, the petitioners also requested that FDA remove two substances from the petitioner's original list of 30 substances, stating that they are not *ortho*-phthalates (Supp., October 8, 2016 at 2). Consequently, the subject of the food additive petition was limited to food additive regulations for 28 *ortho*-phthalates. In addition, regarding the certain portions of the submissions that we declined to file as a food additive petition because those requests were not within the scope of a food additive petition, on April 19, 2016, the petitioners submitted a citizen petition containing those requests (see Citizen Petition from Nancy Buermeyer, Breast Cancer Fund, et al., submitted to the Dockets Management Staff, Food and Drug Administration, dated April 19, 2016 (Comment ID FDA–2016–P–1171–0001) (citizen petition). Specifically, the citizen petition requested that we initiate rulemaking to remove the prior sanctions in part 181 for five *ortho*-phthalates and that we add a new section to part 189 prohibiting the use of eight *ortho*-phthalates (citizen petition at 1 through 2). On May 12, 2022, we denied the citizen petition.

The core premise of FAP 6B4815 was that the 28 subject *ortho*-phthalates are chemically and pharmacologically related and should therefore be treated as a class for purposes of evaluating their safety. The petitioners argued that a single purported acceptable daily intake (ADI) for one substance should be applied to the purported class of 28 *ortho*-phthalates and that the cumulative exposure to all 28 *ortho*-phthalates significantly exceeded the purported ADI for the one substance petitioners selected, thereby rendering the entire purported class unsafe for use as food additives.

In the **Federal Register** of May 20, 2022 (87 FR 31066), we announced that we were denying FAP 6B4815. In that **Federal Register** document (hereinafter, denial order), we explained that the petition did not provide sufficient information to support a finding that there is no longer a reasonable certainty of no harm for the authorized uses of the proposed class of 28 *ortho*-phthalates. As an additional matter, based on the information available to FDA, the denial order stated that we did not have a basis to conclude that dietary exposure levels from the authorized *ortho*-phthalates exceed a safe level (87 FR 31066 at 31075). The denial order advised that objections and requests for a hearing were due by June 21, 2022 (87 FR 31066). Subsequently, we received one submission from a group of eight objectors that raised several objections and requests for hearing in response to the denial order.

Following receipt of FAP 6B4815 in March 2016, on June 25, 2018, we received a food additive petition (FAP 8B4820) submitted by the Flexible Vinyl Alliance (hereinafter, the abandonment petition). The abandonment petition proposed that we amend our food additive regulations in parts 175, 176, 177, and 178 to revoke the approvals of 25 plasticizer substances that the petition identified as *ortho*-phthalates for various food contact applications because such uses were permanently abandoned. In response to the abandonment petition, we issued a final rule on May 20, 2022 (87 FR 31080) amending the food additive regulations in parts 175, 176, 177, and 178 to revoke the authorization of the 25 substances that were the subject of the petition for various food contact applications (the abandonment final order). FDA issued the abandonment final order concurrently with its denial order for FAP 6B4815. On May 20, 2022, we also issued a request for information (RFI) seeking scientific data and information on current uses, use levels, dietary exposure, and safety data for *ortho*-phthalates that remain authorized for use in food contact applications (87 FR 31090). The objections and requests for hearing we received refer to the denial order, citizen petition, abandonment final order, and RFI.

Ortho-phthalates also are included on FDA's list of chemicals in the food supply that are under review (see *https://www.fda.gov/food/food-chemical-safety/list-select-chemicals-food-supply-under-fda-review*). We are committed to continuing the evaluation of all relevant scientific information and data to determine whether additional regulatory action regarding *ortho*-phthalates is warranted to ensure the safety of all authorized food contact uses of *ortho*-phthalates.

II. Objections and Requests for Hearing

Section 409(f)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(f)(1)) provides that, within 30 days after publication of an order denying a food additive petition, any person adversely affected by such order may file objections, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections.

Under our regulations at 21 CFR 171.110, objections and requests for a hearing relating to food additive regulations are governed by part 12 (21 CFR part 12). Under § 12.22(a), each

objection must: (1) be submitted on or before the 30th day after the date of publication of the final rule; (2) be separately numbered; (3) specify with particularity the provision of the regulation or proposed order objected to; (4) specifically state each objection on which a hearing is requested (failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection); and (5) include a detailed description and analysis of the factual information to be presented in support of the objection if a hearing is requested (failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection).

We received one submission, on June 21, 2022, from the Environmental Defense Fund, Learning Disabilities Association of America, Center for Food Safety, Center for Environmental Health, Center for Science in the Public Interest, Breast Cancer Prevention Partners, Defend Our Health, and Alaska Community Action on Toxics (hereinafter, objectors) (see Objections and Request for Evidentiary Public Hearing Regarding FDA's Denial of Phthalates Food Additive Petition (FAP 6B4815)), submitted by Katherine K. O' Brien, Earthjustice, dated June 21, 2022, to the Dockets Management Staff, Food and Drug Administration (Comment ID FDA–2016–F–1253–0462) (Objections). The submission raises eight specific objections to the denial and requests hearings on six objections.

III. Standards for Granting a Hearing

The criteria for granting a hearing are set out in § 12.24(b). Under that regulation, a hearing will be granted if the material submitted by an objector shows that: (1) there is a genuine and substantial factual issue for resolution at a hearing (a hearing will not be granted on issues of policy or law); (2) the factual issue can be resolved by available and specifically identified reliable evidence (a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions); (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the objector (a hearing will be denied if the data and information submitted are insufficient to justify the factual determination urged, even if accurate); (4) resolution of the factual issue in the way sought by the objector is adequate to justify the action requested (a hearing will not be granted on factual issues that are not determinative with respect to the action requested, *e.g.,* if the action would be the same even if the factual issue were resolved in the way sought); (5) the action requested is not inconsistent with any provision in the FD&C Act or any FDA regulation particularizing statutory standards (the proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved); and (6) the requirements in other applicable regulations, *e.g.,* 21 CFR 10.20, 12.21, 12.22, 314.200, 514.200, and 601.7(a), and in the document issuing the final regulation or the notice of opportunity for a hearing are met.

In general, in an administrative proceeding under section 409(f) of the FD&C Act, FDA is authorized to issue a decision without holding a part 12 hearing when a party's objections do not raise a genuine and material issue of fact that, if proved in that party's favor, would suffice to warrant the relief requested (see *Community Nutrition Inst.* v. *Young,* 773 F.2d 1356, 1364 (D.C. Cir. 1985), *cert. denied,* 475 U.S. 1123 (1986); see also *Vermont Dep't of Pub. Serv.* v. *FERC,* 817 F.2d 127, 140 (D.C. Cir. 1987)). A party seeking a hearing must meet a ''threshold burden of tendering evidence suggesting the need for a hearing'' (*Costle* v. *Pacific Legal Foundation,* 445 U.S. 198, 214–215 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609, 620–621 (1973)). An allegation that a hearing is necessary to ''sharpen the issues'' or to ''fully develop the facts'' does not meet this test (*Georgia Pacific Corp.* v. *EPA,* 671 F.2d 1235, 1241 (9th Cir. 1982)). If a hearing request fails to identify sufficient factual evidence that would be the subject of a hearing, there is no reason to hold one. In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there are no genuine issues of material fact in dispute, and a party is entitled to judgement as a matter of law (see *Rule 56, Federal Rules of Civil Procedure*). The same principle applies to administrative proceedings (§ 12.24). In reviewing whether an objecting party made ''an adequate proffer of evidence'' to show that an ''actual dispute exist[s],'' courts consider whether the dispute lies in ''a highly technical area [within] the agency's expertise'' (see *Cerro Wire & Cable Co.* v. *FERC,* 677 F.2d 124, 129 (D.C. Cir. 1982)).

A hearing request must not only contain evidence, but that evidence also must raise a material issue of fact ''concerning which a meaningful hearing might be held'' (*Pineapple Growers Ass'n of Haw.* v. *FDA,* 673 F.2d 1083, 1085 (9th Cir. 1982)). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, an agency need not grant a hearing (see *Dyestuffs and Chemicals, Inc.* v. *Flemming,* 271 F.2d 281, 286 (8th Cir. 1959), *cert. denied,* 362 U.S. 911 (1960)). A hearing is justified only if the objections are made in good faith and if they raise '' 'material' issues of fact'' (*Pineapple Growers Ass'n,* 673 F.2d at 1085 (quoting *Pactra Indus., Inc.* v. *CPSC,* 555 F.2d 677, 684 (9th Cir. 1977)). The issues raised in objections ''must be material to the question involved; that is, the legality of the order attached'' (*Pineapple Growers Ass'n,* 673 F.2d at 1085 (quoting *Dyestuffs and Chemicals,* 271 F.2d at 286)). A hearing need not be held to resolve questions of law and policy (see *Kourouma* v. *FERC,* 723 F.3d 274, 278 (D.C. Cir. 2013) (citing *Citizens for Allegan County, Inc.* v. *FPC,* 414 F.2d 1125, 1128 (D.C. Cir. 1969)); *Sun Oil Co.* v. *FPC,* 256 F.2d 233, 240 (5th Cir. 1958)).

IV. Analysis of Objections and Response to Hearing Requests

The submission from the Environmental Defense Fund et al., contains eight numbered objections, some with multiple parts, and six requests for a hearing. We address each objection below, as well as any evidence and/or information filed in support of each. For each objection that requests a hearing, we evaluate whether the objection and any evidence and/or information submitted in support of it satisfies the standards for granting a hearing in § 12.24(b).

A. Objection 1

In Objection 1, the objectors argue that ''FDA unlawfully placed on the petitioners the burden of proving that the approved food-additive uses of phthalates are not safe'' (Objections at 8). The objectors assert that ''this legal error infected FDA's entire analysis and requires FDA to withdraw'' its order denying FAP 6B4815 (Objections at 13). Because this objection raises a purely legal dispute, no hearing is warranted to adjudicate it (§ 12.24(b)(1)). Even if a hearing were available, the objectors did not request one with respect to this objection and, therefore, waive any right to a hearing (§ 12.22(a)(4)). The only remaining issue on this objection, then, is whether it establishes that FDA's order denying FAP 6B4815 should be modified or revoked. As described below, we conclude that the objectors have not established a basis for modifying or revoking the denial order.

In Objection 1, the objectors assert that FDA reviewed FAP 6B4815 under an incorrect legal standard. The objectors argue that FDA must not expect revocation petitions to demonstrate the lack of safety of the food additives whose approvals the petitions seek to revoke. The objectors state that ''parties petitioning FDA to revoke approval of a food additive on safety grounds do not bear the burden of proving that the additive is unsafe, *i.e.,* that it will cause harm to human health under the intended conditions of use'' (Objections at 9). Placing such a burden on the party seeking revocation would, the objectors assert, ''be inconsistent with the Food Act's central premise for food-additive regulation, namely, that food additives are presumptively unsafe and may not be used unless the available evidence establishes with 'reasonable certainty' that their use 'will be safe' '' (id. (quoting section 409(c)(3)(A) of the FD&C Act)). (The reference to the ''Food Act'' is a reference to the FD&C Act.)

The objectors also assert that FDA's basis for denying FAP 6B4815 is inconsistent with our regulations. The objectors point to § 171.130 (21 CFR 171.130), which provides that petitions seeking amendments or repeals of existing food additive approvals must ''include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation may justify its amendment or repeal'' (Objections at 10). The objectors interpret this regulation to mean that repeal petitions are required only to ''[tender] new information regarding a food additive's toxicity or otherwise demonstrating that amendment or repeal of the additive's authorization may be justified'' but do not bear ''the burden of persuasion on the ultimate question of an additive's safety'' (id.). Therefore, the objectors contend, ''the burden of persuasion on the ultimate question of safety lies with the party advocating for continued authorization of the product'' (id. at 11). The objectors state that FDA applied an incorrect standard to evaluating FAP 6B4815 because ''FDA did not assess in the Order whether the petitioners provided 'new information' regarding the 'toxicity of the chemical[s]' at issue, as its regulations require, nor whether that information 'establish[es] the existence of safety questions significant enough to support a finding that there is no longer a reasonable certainty of no harm from the currently approved uses' '' (id. at 12 (quoting § 171.130(b) and the denial order at 87 FR 31066 at 31067)).

The objectors state that their position is consistent with *League of United Latin Am. Citizens* v. *Regan,* 996 F.3d 673 (9th Cir. 2021), a case involving the U.S. Environmental Protection Agency's (EPA's) regulation of pesticides (Objections at 10–11). The objectors further state their position is consistent with FDA's statement in a final rule concerning the food additive olestra (61 FR 3118, January 30, 1996) as well as the standard FDA applied in revoking food-additive authorizations for certain long-chain perfluorinated compounds (81 FR 5, January 4, 2016) (Objections at 12).

The crux of these arguments is that ''FDA unlawfully placed the burden of proof regarding the safety of the phthalate additives on the petitioners, asserting that FDA need only revoke a food additive authorization if presented with new evidence that 'approved additives *are in fact unsafe*' '' (Objections at 12 (emphasis in original)).

Finally, the objectors criticize FDA's approach in denying FAP 6B4815 on the same day that we amended our regulations to no longer provide for most phthalates to be used in food contact applications because these uses were abandoned by industry (Objections at 12). The objectors state that the abandonment action ''significantly altered the scope of food-additive authorizations for phthalates that remain in effect, and for which a safety evaluation is still required'' (id.). The objectors state that our action ''reflects FDA's erroneous position that it may leave the extant food-additive authorizations in effect unless and until petitioners prove that they are in fact unsafe'' (id. at 12–13).

FDA Response: We disagree with the assertion that FDA applied an incorrect legal standard in evaluating FAP 6B4815. It is fundamental that a food additive petition—whether requesting an authorization, modification, or repeal—must provide sufficient support for its request.

We denied FAP 6B4815 because it failed to provide sufficient support for its request to revoke the authorization for the 28 *ortho*-phthalates that were the subject of the petition. In reviewing FAP 6B4815, we observed that the petition was premised on three distinct assertions (which, for ease of reference, we referred to as Assertions A, B, and C). Assertion A claimed that the 28 subject *ortho*-phthalates are chemically and pharmacologically related and should therefore be treated as a class for purposes of evaluating their safety. Under Assertion B, the petition proposed applying a purported ADI for di(2-ethylhexyl) phthalate (DEHP) to all 28 *ortho*-phthalates (*i.e.,* the petition proposed applying the proposed ADI to the entire purported class). Assertion C stated that the estimated daily intake (EDI) for the asserted class of 28 *ortho*-phthalates significantly exceeded the proposed ADI, thus rendering the purported class unsafe for their authorized uses as food contact substances. Our denial order explained in detail why the petition did not adequately support any of these three assertions. Consequently, we concluded that the petition did not contain sufficient data to support a finding that there is no longer a reasonable certainty of no harm from the approved uses (87 FR 31066 at 31075). As an additional matter, we noted that, based on the information available to FDA, we did not have a basis to conclude that dietary exposure levels from authorized *ortho*-phthalates exceeded a safe level (id.). We stated that, as new information becomes available to us, we will continue to examine such data as appropriate to assess whether there remains a reasonable certainty of no harm (id.).

Objection 1 rests on a flawed interpretation of the FD&C Act's legal framework governing food additives—in particular, its provisions concerning the premarket review of food additives. Under this framework, food additives are deemed unsafe and prohibited except to the extent FDA authorizes their use (see, *e.g.,* sections 301(a), 301(k), and 409(a) of the FD&C Act (21 U.S.C. 331(a), 331(k), and 348(a))). Section 409 of the FD&C Act sets forth a process under which a person can submit a petition requesting that FDA issue a regulation prescribing the conditions under which a food additive may be safely used (see section 409(b)(1) of the FD&C Act). The statute specifies that a person must support such a petition by supplying the data specified in section 409(b)(2) of the FD&C Act. After a person submits a petition seeking approval of a food additive's use, FDA may issue a regulation authorizing the use only if the data before us establish that the proposed use of the food additive will be safe (see section 409(c)(3)(A) of the FD&C Act).

In addition to establishing the procedure for issuing regulations authorizing food additives, Congress directed FDA to establish a regulatory procedure prescribing how regulations authorizing food additives may be amended or repealed (see section 409(i) of the FD&C Act). Importantly, the

statute specifies that this regulatory ''procedure *shall conform* to the procedure provided in this section for the promulgation of such regulations'' (id.) (emphasis added) (section 409(i) of the FD&C Act). FDA's regulation at § 171.130 establishes the procedure by which interested persons may petition FDA for amending or repealing a food additive authorization.

FDA's approach to evaluating FAP 6B4815 was fully consistent with the legal framework described above. The provisions of section 409 of the FD&C Act make clear that the evidentiary burden to support authorization of a food additive's use lies with the petitioner seeking such authorization (see section 409(b) and (c) of the FD&C Act). Given the FD&C Act's directive that the regulatory procedure for amending or repealing an authorization ''shall conform'' to the statutory procedure for granting an authorization, it follows that a person seeking amendment or repeal likewise must provide a well-supported petition adequately justifying such action. See section 409(i) of the FD&C Act; *In re Nat. Res. Def. Council,* 645 F.3d 400, 403 (D.C. Cir. 2011) (''When a food additive petition seeks to amend an existing regulation, the petitioner must include full information on each proposed change'') (internal quotations and citations omitted). FDA's denial order thoroughly explained why the petition did not provide adequate evidence to support its requested postmarket remedy: the repeal of already-authorized food additive uses. This conclusion did not conflict in any way with the premarket review framework invoked by the objectors.

Moreover, to the extent the objectors contend that FDA disregarded any general statutory obligation to remove unsafe products from the market, we note that we have made no finding that the subject food additives are unsafe. Indeed, our denial order stated that we did not have a basis to conclude that dietary exposure levels from authorized *ortho*-phthalates exceeded a safe level (87 FR 31066 at 31075).

The objectors' argument that FDA disregarded its own regulations is also in error. This argument relies on a portion of § 171.130(b) providing that petitions for amendment or repeal must include an assertion of facts, supported by data, showing that new information exists. Citing this excerpt, the objectors maintain that this regulation ''establishes that petitioners seeking revocation of a food-additive regulation bear a burden of production—specifically, the burden of tendering new information regarding a food additive's toxicity or otherwise demonstrating that amendment or repeal of the additive's authorization may be justified'' (Objections at 10). To the extent that the objectors assert that a repeal petition need only point to the existence of new toxicity data, this argument disregards the concluding sentence of § 171.130(b).

The concluding sentence provides that new data must be furnished in the form specified in § 171.1 (21 CFR 171.1) for submitting petitions. Under § 171.1(c), a petition must include ''full reports of investigations made with respect to the safety of the food additive.'' In addition, § 171.1(c) provides that a petition ''may be regarded as incomplete unless it includes full reports of adequate tests reasonably applicable to show whether or not the food additive will be safe for its intended use.'' Further, under § 171.1(c), for petitions seeking modification of existing regulations issued pursuant to section 409(c)(1)(A) of the FD&C Act (*i.e.,* a regulation authorizing the use of a food additive under specified conditions), ''full information on each proposed change that is to be made in the original regulation must be submitted.'' Accordingly, petitions seeking revocation of a food additive regulation must do more than merely identify the existence of new toxicity studies. See also *In re NRDC,* 645 F.3d at 403 (considering petition to repeal existing food additive authorization and citing § 171.1 to conclude that food additive petitions seeking to amend existing food additive authorizations must include full information on each proposed change). Thus, FDA's regulations make clear that repeal petitions such as FAP 6B4815 must include adequate supporting information. We therefore acted consistently with our regulations when we evaluated FAP 6B4815 to determine whether its assertions were supported and whether the petition contained sufficient data to support a finding that there is no longer a reasonable certainty of no harm from the currently approved uses.

Next, the objectors maintain that FDA's approach in evaluating FAP 6B4815 was inconsistent with the following: (1) the *League of United Latin Am. Citizens* v. *Regan,* 996 F.3d 673 (9th Cir. 2021), a case involving EPA's regulation of pesticides; (2) an FDA statement in a food additive proceeding involving olestra; and (3) FDA's action on three specific perfluoroalkyl ethyl-containing food-contact substances. We address each of these in turn.

First: The *League of United Latin Am. Citizens* (*LULAC*) case cited by the objectors is not germane because its holding was based on a distinct statutory scheme applicable to pesticides under section 408 of the FD&C Act (21 U.S.C. 346a) and factual circumstances different from the facts underlying this proceeding. In that case, EPA had received a petition asking the agency to prohibit foods that contained any residue of the insecticide, chlorpyrifos (996 F.3d at 673). EPA argued that the agency could leave in effect tolerances for the pesticide while the agency continued to evaluate the science (id. at 688). The *LULAC* court held that EPA has a continuing obligation under section 408 of the FD&C Act to ensure the safety of established pesticide tolerances that were previously found to be safe (id. at 691) (finding that EPA ''has its own continuing duty under [section 408 of the FD&C Act] to determine whether a tolerance that was once thought to be safe still is''). The court's conclusion regarding EPA's continuing obligation was based on statutory language in section 408 of the FD&C Act that is materially different from the language in section 409 of the FD&C Act at issue in this proceeding.

Under section 408(b)(2)(A)(i) of the FD&C Act, EPA ''may establish *or leave in effect* a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe'' (emphasis added). In contrast, section 409 of the FD&C Act does not contain anything comparable to the ''*leave in effect* a tolerance . . . *only* if the Administrator determines that the [substance] is safe'' language in section 408, which was the linchpin for the *LULAC* court's conclusion that EPA had ''a continuous duty'' to determine whether a tolerance for a pesticide chemical reside is safe (id. at 692 (''[Section 408 of the FD&C Act] imposes a continuous duty upon the EPA by permitting it to 'leave in effect' a tolerance 'only' if it finds it is safe. To 'leave' something in effect means 'to cause or allow [it] to be or remain in a specified condition. Denying the 2007 Petition caused the chlorpyrifos tolerances to remain in place . . . . But in so doing, the EPA did not '[determine] that the tolerance is safe.' '')) (Compare Sec. 409 of the FD&C Act).

Further, unlike section 408 of the FD&C Act, section 409 of the FD&C Act directs FDA to establish procedures for repealing food additive authorizations that ''shall conform'' to the statutory procedure for promulgating authorizations, under which the evidentiary burden to support authorization of a food additive's use

lies with the petitioner seeking such authorization (see section 409(c) and (i) of the FD&C Act). Given the statutory framework established in section 409 of the FD&C Act and the ways in which it differs from the framework established in section 408 of the FD&C Act, it was entirely reasonable that FDA assessed the information in the objectors' repeal petition to determine whether there was sufficient data to establish the existence of safety questions significant enough to support a finding that there is no longer a reasonable certainty of no harm from the approved *ortho*-phthalates' uses. Furthermore, the factual circumstances are distinct. In *LULAC,* the record showed that EPA ''repeatedly determined'' that the pesticide at issue was unsafe under the approved tolerance levels. Here, however, FDA has never determined the *ortho*-phthalates at issue in this proceeding to be unsafe. Instead, our denial order explained that FDA did not have a basis to conclude that dietary exposure levels from approved *ortho*-phthalates exceed a safe level (87 FR 31066 at 31075).

Second: The objectors cite as support for their argument the following statement in the **Federal Register** document announcing FDA's decision to approve olestra: ''It is important to recognize that to institute a proceeding to limit or revoke the approval of olestra, FDA would not be required to show that olestra is unsafe. Rather, the agency would only need to show that based upon new evidence, FDA is no longer able to conclude that the approved use of olestra is safe, *i.e.,* that there is no longer a reasonable certainty of no harm from the use of the additive'' (Objections at 11 (quoting 61 FR 3118 at 3169)). The objectors also refer to a statement in the olestra proceeding where FDA stated that ''in any proceeding to [withdraw] or limit the approval of olestra, Procter and Gamble would have the burden to establish the safety of the additive'' (Objections at 11, n. 39 (quoting 61 FR 3118 at 3169); see also § 12.87(c)). The objectors cite these excerpts from the olestra proceeding as support for the following proposition: ''FDA has stated plainly that when FDA is in the position of raising concerns about the safety of a food additive or other product that it has previously authorized, the agency bears only an initial burden of producing new information that calls into question its previous safety finding; the burden of persuasion on the ultimate question of safety lies with the party advocating for continued authorization of the product'' (Objections at 11). However, contrary to the objectors' suggestion, FDA did *not* say or imply that we would initiate revocation proceedings based merely on new information that might ''[call] into question its previous safety finding,'' nor did FDA say or imply that we would be required to initiate such a proceeding upon being presented with such information. Instead, FDA stated that, to initiate the withdrawal process, we would ''need to show that based upon new evidence, FDA is no longer able to conclude that the approved use of olestra is safe, *i.e.,* that there is no longer a reasonable certainty of no harm from the use of the additive'' (61 FR 3118 at 3169). Subsequently, in a hearing regarding the withdrawal of olestra, we stated that the sponsor, Procter and Gamble, would then have the burden of establishing safety (id. (citing § 12.87(c)). Our review of FAP 6B4815 was entirely consistent with the statements from the olestra proceeding cited by the objectors as to the evidence necessary to initiate the process of repealing a food additive authorization. In reviewing FAP 6B4815, we concluded that its assertions were not adequately supported, and therefore, the petition did not contain sufficient data to support a finding that there is no longer a reasonable certainty of no harm from the currently approved uses of the subject *ortho*-phthalate food additives (87 FR 31066 at 31075). Accordingly, we did not grant the petition's request that we institute proceedings to repeal the authorizations that were the subject of FAP 6B4815.

Third: Regarding FDA's action to revoke the authorizations for the food additive uses of three specific perfluoroalkyl-ethyl-containing food-contact substances (see 81 FR 5), the objectors state that FDA did so ''based on data raising 'significant questions as to the safety of the authorized uses' '' (Objections at 9). However, the objectors' characterization of what FDA's perfluoroalkyl ethyl action was ''based on'' misunderstands the basis for that action. FDA stated in the perfluoroalkyl ethyl order that ''we conclude that there is no longer a reasonable certainty of no harm for the food contact use of these [substances]'' and that we were, therefore, taking the revocation action (81 FR 5 at 7).

FDA did *not* state that the perfluoroalkyl ethyl revocation action was being instituted based on a finding of ''significant questions'' in isolation. Instead, FDA stated that ''[i]n order for FDA to grant a petition that seeks an amendment to a food additive regulation based upon new data concerning the toxicity of the food additive, such data must be adequate for FDA to conclude that there is no longer a reasonable certainty of no harm for the intended use of the substance'' (81 FR 5 at 7) (FDA's statements in the *ortho*-phthalates denial order were consistent, see 87 FR 31066 at 31067).

Finally, the objectors criticize FDA's approach in denying FAP 6B4815 on the same day that we amended our regulations to no longer provide for 25 *ortho*-phthalates to be used in food contact applications because these uses were abandoned by industry (*i.e.,* the abandonment final order). We issued the abandonment final order in response to a separate food additive petition that was based on abandonment, not safety (see 87 FR 31080). While the objectors assert that our decision to take action based on abandonment ''reflects FDA's erroneous position that it may leave the extant food-additive authorizations in effect unless and until petitioners prove that they are in fact unsafe,'' this assertion is unsupported.

We did not deny FAP 6B4815 for the reason that the petition failed to prove that the *ortho*-phthalates are in fact unsafe (*i.e.,* they cause harm under their intended conditions of use); that was not the necessary showing. Instead, we denied FAP 6B4815 because the assertions in the petition were not adequately supported and the petition did not contain sufficient data to support a finding that there is no longer a reasonable certainty of no harm from the approved uses (*i.e.,* FAP 6B4815 did not contain sufficient data to support a finding that there is no longer a reasonable certainty in the minds of competent scientists that the substances are not harmful under the conditions of their intended use, see § 170.3(i) (21 CFR 170.3(i)). Our denial order (87 FR 31066) correctly stated that a petition that seeks to amend or repeal existing regulations based on safety must contain sufficient data to establish the existence of safety questions significant enough to support a finding that there is no longer a reasonable certainty of no harm from the currently approved uses (see 87 FR 31066 at 31067 (citing section 409(c) of the FD&C Act) (describing the data requirements); §§ 171.1 through 171.130 (prescribing food additive petition regulations)).

For all these reasons, we disagree with the objectors' assertion that we committed any legal error that justifies modifying or revoking our denial order.

B. Objection 2

In Objection 2, the objectors state that ''FDA unlawfully failed to evaluate the safety of the food-additive uses of phthalates that remain authorized'' (Objections at 13). The objectors refer to the fact that FDA issued the denial order

on the same day that we issued the abandonment final order, which amended our regulations to remove food additive authorizations for the use of 25, but not all, authorized *ortho*-phthalates that were the subject of FAP 6B4815 (see 87 FR 31080). FDA took this action based on evidence that the authorized food additive uses of most, but not all, of those *ortho*-phthalates were abandoned (id. at 31086). We did not receive evidence showing abandonment for the following five *ortho*-phthalates that remain authorized as food additives for specified uses: diisononyl phthalate (DINP) (CAS No. 28553–12–0), diisodecyl phthalate (DIDP) (CAS No. 26761–40–0), di(2-ethylhexyl) phthalate (DEHP) (CAS No. 117–81–7), dicyclohexyl phthalate (DCHP) (CAS No. 84–61–7), and diallyl phthalate (DAP) (CAS No. 131–17–9, for use as a monomer). Therefore, the food additive authorizations for these five *ortho*-phthalates remain in place.

The objectors assert that FDA failed to meet its obligation to oversee the safety of the food supply by not conducting a new safety analysis for these five *ortho*-phthalates that remain authorized as food additives (Objections at 13). The objectors assert that FDA failed to satisfy its obligations to evaluate whether FAP 6B4815 contained '' 'new data . . . that would justify amendment' of the applicable authorizations'' by assessing both ''the data and information in the petition and other available relevant material.' '' (id. at 14 (quoting 81 FR 7, FDA's revocation of certain perfluoroalkyl ethyl-containing food-contact substances)). The objectors also state that FDA's separate RFI (87 FR 31090) regarding the still-authorized *ortho*-phthalates constituted an ''attempt to kick the proverbial can down the road'' that discredits FDA's assertion in its response to FAP 6B4815 that it had adequately assessed currently available research regarding phthalates, and that ''unlawfully . . . defer[red]'' consideration of an ''[issue] that FDA was required to address—years ago—in response to [FAP 6B4815]'' (id. at 15–16).

The objectors do not request a hearing. Therefore, the objectors waive their right to a hearing on this objection (§ 12.22(a)(4)). The only remaining issue on Objection 2, then, is whether it establishes that FDA's order denying FAP 6B4815 should be modified or revoked. As described below, we conclude that the objectors have not established a basis for modifying or revoking the denial order.

FDA Response: We do not agree with the objectors' assertions that FDA's response to FAP 6B4815 was unlawful because FDA did not conduct a new safety analysis of DINP, DIDP, DEHP, DCHP, and DAP; *i.e.,* the five *ortho*-phthalates that were the subject of their petition that still have food additive authorizations in effect. When we originally authorized the use of these five additives, we concluded that the use of the food additives satisfied the statutory safety standard.

FAP 6B4815 did not identify deficiencies with our original approval of phthalates for food contact use. Instead, FAP 6B4815 proposed a class-based grouping approach for evaluating the safety of the subject *ortho*-phthalates. In FAP 6B4815, the petitioners proposed that the authorizations should be revoked because, according to the petition: the subject *ortho*-phthalates share common chemical and pharmacological characteristics that justify grouping them as a class; a single ADI value from one *ortho*-phthalate should be applied to all members of the proposed class collectively; and both the EDI value for select phthalates as well as the cumulative estimated daily intake for the proposed class significantly exceeds the purported ADI value for the proposed class. In Objection 2, the objectors turn their attention to the phthalates that remain authorized as food additives. Regarding these *ortho*-phthalates that remain authorized, we conducted additional analysis by evaluating, in a supplementary memorandum, whether the core premise of FAP 6B4815 (*i.e.,* the assertion that the subject *ortho*-phthalates should be grouped as a class for purposes of a safety assessment) could be applied to the five still-authorized *ortho*-phthalates. Our review used the information contained in the petition as well as other available information, including assessments from other regulatory bodies (Ref. 1). In that memorandum, which we made publicly available on the docket, we explained why the information before us did not support the grouping of these five substances for purposes of a safety assessment (id.). We based this conclusion on the structural variations and the differences in metabolites, metabolism, and toxicological endpoints across the substances. We described these differences and the scientific literature we reviewed in the memorandum (id.).

Objection 2 urges us to disregard the very approach for analyzing food additive safety that the petitioners proposed in FAP 6B4815. Specifically, Objection 2 asserts that FDA committed legal error by not conducting a new safety assessment for the five still-authorized *ortho*-phthalates even though FDA analyzed these substances in accordance with the class-grouping approach proposed by FAP 6B4815. Therefore, Objection 2 ignores the fact that we assessed the appropriateness of class grouping the five still-authorized *ortho*-phthalates (Ref. 1). Objection 2 largely recasts the arguments made in Objection 1 but with respect to the five still-authorized *ortho*-phthalates. It does this by citing FDA's statement in the **Federal Register** document in which we authorized olestra, where we referred to ''the agency's continuing obligation to oversee the safety of the food supply'' (61 FR 3118 at 3168; see also Objections at 13–14 and 16).

Our responses to Objection 1's assertions apply with equal force to Objection 2's assertions that we are required to conduct a new safety assessment with respect to the five still-authorized *ortho*-phthalates; as explained earlier, a petition that seeks to amend or repeal existing regulations based on safety must contain sufficient data to establish the existence of safety questions significant enough to support a finding that there is no longer a reasonable certainty of no harm from the currently approved uses. This standard for review is consistent with FDA's actions in the olestra proceeding. Moreover, the administrative record makes it clear that we satisfied our duties in reviewing FAP 6B4815. We reviewed the assertions in FAP 6B4815 in detail. In a separate memorandum, we evaluated the five still-authorized *ortho*-phthalates, using the same core premise of class grouping proposed in FAP 6B4815 (Ref. 1).

Objection 2 also accuses FDA of publishing its RFI (87 FR 31090) to ''unlawfully . . . defer its evaluation of whether the agency's current authorizations for food-contact uses of phthalates are in fact safe'' (Objections at 15). However, our publication of the RFI, which sought scientific data and information on current uses, use levels, dietary exposure, and safety data of certain *ortho*-phthalates, was intended to seek any data that we do not possess, which ''may add to our knowledge of *ortho*-phthalates that remain authorized for use'' (see 87 FR 31090–31091). The fact that we sought data from the public to inform our oversight of authorized *ortho*-phthalates does not reflect any deficiency in our evaluation of the specific assertions in FAP 6B4815 based on the information that was in the record.

Objection 2 also takes issue with FDA's response to a comment to the docket concerning FAP 6B4815, in which we stated that ''FDA is aware of

the research that has been conducted with respect to phthalates and that FDA considered 'the research in its evaluation of the petition' '' (Objections at 14 (quoting 87 FR 31066 at 31076)). The objectors criticize FDA for not disclosing how we considered ''the research that has been conducted with respect to phthalates'' (Objections at 14). The objectors also assert that FDA's statement about having considered the research related to phthalates ''cannot be credited'' given that we issued the RFI on the same day that we denied FAP 6B4815. The statements that the objectors excerpt in Objection 2 were made in response to comments that referred to literature describing phthalates as hormone disrupting chemicals that are linked to certain adverse health outcomes (see 87 FR 31066 at 31076). We responded to the comments by stating that we are generally aware of the research on phthalates and considered the research cited in the comments (id.).

The denial order, as well as the memoranda we made publicly available when we published the denial order (specifically, the chemistry memorandum, the toxicology memorandum, and the memorandum evaluating the five still-authorized *ortho*-phthalates), demonstrate that we considered the numerous research studies in the administrative record, including the research cited in the comments (Refs. 1, 3, and 4). While we are generally aware of updated toxicological and use information that is publicly available, we published the RFI so that we could obtain a more complete picture of the data relevant to the general safety, dietary exposure, and usage of *ortho*-phthalates, which may include data that stakeholders have not made public (see 87 FR 31090).

Objection 2 also includes certain other arguments. In the last paragraph of Objection 2, the objectors repeat arguments they made in Objection 1 regarding the type of evidence that FAP 6B4815 was required to proffer (Objections at 16). Because we address these arguments in response to Objection 1, we do not repeat our evaluation of these arguments here. A footnote in Objection 2 also refers to the premarket review requirements for food additives (Objections at 14, n.48). However, as explained in response to Objection 1, FAP 6B4815 is a request for postmarket action, and our response to the petition did not conflict with the premarket review framework invoked by the objectors. Additionally, Objection 2 asserts that FDA should have evaluated FAP 6B4815 to determine whether it presented new data (Objections at 16). As explained in our response to Objection 1 regarding the olestra proceeding, repeal petitions must do more than merely point to the existence of new data.

For these reasons, we disagree with the objectors' assertion that we committed any legal error that justifies modifying or revoking our denial order.

C. Objection 3

In Objection 3, the objectors argue that FDA's denial order ''fails to address new toxicity information that raises significant questions about the safety of the approved food-additive uses of phthalates'' (Objections at 17). In particular, the objectors state that new information became available since petitioners last supplemented the record for FAP 6B4815 in 2017. The objectors point to numerous studies and declarations concerning the health effects of *ortho*-phthalates. Most of these studies and declarations were submitted to the docket dedicated to their citizen petition addressing *ortho*-phthalates. In light of these studies and declarations, the objectors state that FDA should not have allowed DAP, DCHP, DEHP, DINP, and DIDP to remain authorized for food-contact use ''without addressing the substantial body of relevant toxicity information'' (Objections at 17).

The information that the objectors identify in Objection 3 includes studies that they describe as linking DEHP exposure to developmental toxicity, developmental neurotoxicity, adult neurotoxicity, reproductive toxicity, endocrine disruption, hepatoxicity, metabolic toxicity, immunotoxicity, and epigenetic alterations (id. at 17–18). The objectors describe these studies as ''provid[ing] evidence for a number of DEHP-related adverse health outcomes, including altered adult sex behavior, delayed puberty, insulin sensitivity, obesity, hypothyroidism, cognitive impairment, and even depressive-link behaviors'' (Objections at 18). The objectors further assert that animal studies have linked DINP exposure to hepatoxicity and exacerbated nerve cell damages and decline in learning and memory, as well as elevated cholesterol (id.). In addition, the objectors assert that two studies ''found that phthalate mixtures induced reproductive tract malformations in male rats'' and point to epidemiological studies they describe as ''providing relevant toxicity information'' with respect to associations between DEHP and multiple adverse health outcomes (id. at 18). The objectors reference studies they describe as linking DINP and/or DEHP to insulin resistance, delayed puberty onset in boys, preterm birth, and neurodevelopmental harm (id. at 19). The objectors further point to certain publications by federal and European agencies (id.). Finally, the objectors point to the declarations they submitted to FDA that assert that phthalate exposure causes harm (id. at 20). The objectors request a hearing on Objection 3. They state that the hearing would address ''whether the many years' worth of data and information regarding the human health hazards of phthalates found in the diet presented in support of the Petition and Objections raise significant questions regarding the safety of the authorized food-additive uses of DAP, DCHP, DEHP, DINP, and DIDP'' (Objections at 21).

FDA Response: To justify a hearing on this objection, it is not enough for the objectors to simply name health effects linked to the still-authorized *ortho*-phthalates or to list publications and declarations that address the topic of *ortho*-phthalates generally. The objectors cite numerous recent studies and publications but do not provide meaningful analysis or explanation for why these materials support a finding that there are significant questions about the safety of the still-authorized *ortho*-phthalates for their currently authorized conditions of use. The objectors' mere citation of these studies and declarations is not adequate to justify resolution in the objectors' favor of the factual question about safety of the still-authorized food additive uses of *ortho*-phthalates; the existence of toxicity findings, alone, is insufficient to establish significant questions about whether there is no longer a reasonable certainty of no harm for an authorized use and is, therefore, insufficient to justify resolution of the factual question of safety (§ 12.24(b)(3)).

All substances exhibit toxic effects at high enough exposure levels, and most substances exhibit an exposure threshold below which they do not exhibit a toxic effect. To support an assertion that the authorized use of a substance is unsafe or presents significant safety questions, it is not sufficient to cite studies that indicate that a substance is associated with a toxic effect; rather, that effect must be placed in the context of exposure. For this reason, when evaluating the safety of a substance, scientists will often determine the ''dose-response'' relationship of substance exposure and toxic effect.

To establish with reasonable certainty whether a food additive is harmful under its intended conditions of use, FDA considers the projected human dietary exposure to the food additive, the additive's toxicological data, and

other available relevant information (such as published literature). To determine safety, one approach we may use is to compare the estimated dietary intake of the food additive to an ADI level established by appropriate toxicological data. An ADI is the amount of a substance that is considered safe to consume each day over the course of a person's lifetime (Ref. 2). The ADI is typically based on an evaluation of toxicological studies to determine the highest appropriate experimental exposure dose level in animal studies that was shown to cause no adverse effect (also known as the no-observed-adverse-effect level, or NOAEL), divided by an appropriate safety factor (id.). A calculated dietary exposure to the food additive (*i.e.,* the EDI) at or below the ADI is considered consistent with a reasonable certainty of no harm (id.).

The objectors list publications of various animal and *in vitro* studies in Objection 3, yet they do not attempt to address whether the publications are relevant to assessing an appropriate ADI, calculating an EDI, or whether the dietary exposure could result in a toxic effect (*i.e.,* the estimated daily exposure exceeds an appropriate ADI). The petitioners proposed an ADI in their underlying food additive petition, but our denial order explained why the proposed ADI was not supported and Objection 3 does not address or otherwise engage with FDA's identified concerns. Furthermore, the ADI that FAP 6B4815 proposed in the underlying petition was not based on any of the studies cited in Objection 3.

The information provided in Objection 3 consists largely of studies that link some phthalates to certain identified health effects. Some studies are useful for hazard identification to determine additional hypotheses for future research, but these studies are not designed to provide information to show at which threshold level of dietary exposure these effects may occur. Such hazard identification is the first step in a risk assessment, but the existence of a possible effect does not necessarily mean that the effect is the appropriate endpoint to use for a risk assessment, that the effect will occur at the level of the substance in the diet, or that the substance is in fact unsafe for its intended use. As the hazard identification studies do not examine a dose-response relationship, these data are not adequate for identifying a NOAEL to perform a risk assessment for the food contact uses of the still-authorized phthalates. The data from such hazard identification studies are, therefore, not adequate to establish significant questions about whether there is no longer a reasonable certainty of no harm from the authorized uses and are insufficient to justify resolution of the factual question of safety.

The other information the objectors cite in Objection 3 includes epidemiological studies. While epidemiological studies may suggest a possibility of occurrence of an effect, they are generally not useful for risk assessment due to a lack of control of confounders such as dietary, medical, and lifestyle factors, socioeconomic status, and characterization of past exposures. Some studies may also include self-reported data by the test subjects which increases the potential for biases and inaccuracies, making it challenging to establish a consistent and reliable relationship between the cause and effect. Therefore, although epidemiological studies may be considered supplementary to the available toxicological data for conducting a safety evaluation, in general, they are not suitable to provide primary or sufficient basis for performing a risk assessment.

The objection also cites the two declarations that were also submitted to the docket for the *ortho*-phthalates citizen petition. The declarations cite numerous epidemiological studies and a few animal studies that provide information on potential hazard identification. The declarations do not provide any dietary exposure estimates for the remaining five phthalates from their authorized food additive uses or additional supporting information for assessing the safety of the uses of the phthalates studied as food contact substances.

The Federal and European publications cited in Objection 3 are the ''Toxicological Profile for DEHP'' released by the Agency for Toxic Substances and Disease Registry (''ATSDR'') (Ref. 5), the ''Technical Report on the Toxicology and Carcinogenesis Studies of Di(2-etyhylhexyl) Phthalate'' (Ref. 6) released by the National Toxicology Program (NTP), and an updated risk assessment of DEHP, DBP, BBP, DINP, and DIDP (Ref. 7) for use in food-contact materials released by the European Food Safety Authority (EFSA). Objection 3 states that these studies ''provide novel insights and weight of evidence analyses that are relevant to the safety reevaluations that FDA must conduct'' (Objections at 19). However, the objection does not provide any explanation for how these studies would be adequate to assess the safety of the substances' authorized food additive uses and, therefore, the objection does not establish that these studies create significant questions about whether there is no longer a reasonable certainty of no harm such that they would resolve the factual question of safety.

The objection also cites two dose-response studies to state that ''examining the cumulative effects of several phthalates (including DCHP and DEHP) found that phthalate mixtures induced reproductive tract malformations in male rats at doses well below those associated with harm from individual chemicals'' (Objections at 18). However, the objection fails to mention that, while the study referenced (Conley, et al. 2021) (Ref. 8) did include two of the five phthalates that still have food additive uses in the United States (DEHP and DCHP), the study examined effects using a mixture of nine phthalates and five non-phthalate pesticides cumulatively, which cannot separate adverse effects caused by either a single phthalate, group of phthalates, or the non-phthalate pesticides. Similarly, the other study referenced (Conley, et al. 2018) (Ref. 12) dosed the rats using a mixture of 18 chemicals, which included 9 phthalates (including DEHP and DCHP) and nine non-phthalate pesticides or drugs. Therefore, the two dose-response studies cited in Objection 3 do not directly address the safety of the food contact uses of the five still-authorized *ortho*-phthalate food additives.

For these reasons, the objectors failed to demonstrate how the cited studies, publications, declarations, and facts asserted would be sufficient to justify resolution of the safety question in the objectors' favor. The objectors did not justify why the studies cited in Objection 3 would establish questions significant enough to support a finding that there is no longer reasonable certainty of no harm or that there are ''significant questions regarding the safety of the authorized food-additive uses of DAP, DCHP, DEHP, DINP, and DIDP.'' In other words, the objectors did not establish that the information in the record is adequate to justify their factual assertion regarding safety. Accordingly, § 12.24(b)(3) supports denial of the request for the hearing. A hearing will not be granted when the information cited is not sufficient to support the factual assertion (§ 12.24(b)(3)).

Furthermore, a hearing will not be held unless resolution of the factual issue in the way sought by the objector is adequate to justify the action requested (§ 12.24(b)(4)). In Objection 3, the objectors alter the action requested from what they originally sought in FAP

6B4815, which was the revocation of food additive approvals for 28 *ortho*-phthalates. They now seek a hearing ''regarding the safety of . . . DAP, DCHP, DEHP, DINP, and DIDP'' (Objections at 21)—the five *ortho*-phthalates that remain authorized for use as food additives. This objection does not demonstrate how the outcome of the proceeding would be different if the factual issues addressed in this objection were resolved in the way sought, because this objection does not address the underlying requested action.

The underlying requested action was that FDA revoke the food additive authorizations for the 28 subject *ortho*-phthalates based on their grouping as a class. The basis for the underlying requested action was that FDA should: (1) consider the 28 subject *ortho*-phthalates to be a single class of chemically and pharmacologically related substances for safety evaluation; (2) apply FAP 6B4815's proposed ADI to the purported class; and (3) determine that the EDI for the class exceeds that ADI. However, Objection 3 focuses only on five of the 28 *ortho*-phthalates and asks that we take action with respect to these five. Thus, we are denying the request for a hearing in Objection 3 because a hearing will not be granted on factual issues that are not determinative of the action requested in the proceeding (§ 12.24(b)(4)).

It is important to note that the objectors claim that our denial order was deficient because it did not address questions they failed to ask, and to take actions they failed to request, in the petition that is the subject of this proceeding.[1] Such matters are outside the scope of the process set forth in section 409(f)(1) of the FD&C Act, which requires objections to ''[to specify] . . . the provisions of the [denial] order deemed objectionable.'' Because this objection and the corresponding request for a hearing seek determinations regarding issues that are outside the scope of the provisions of FDA's denial order, the objection and hearing request are improper. The assertions and information cited in Objection 3 regarding the health effects of the five still-authorized *ortho*-phthalate food additives would not change our conclusion that the requested action in FAP 6B4815 to remove the food contact authorizations for a purported class of 28 *ortho*-phthalates was not adequately supported. A hearing will not be granted unless resolution of a factual issue in the way sought by the objector is adequate to justify the action requested (§ 12.24(b)(4)). This conclusion does not change the fact that FDA may, in the future, consider a subset of *ortho*-phthalates that remain authorized for use in food contact applications to be a single class of chemically and pharmacologically related substances for purposes of a safety evaluation.

D. Objection 4

In Objection 4, the objectors take the position that we misapplied section 409(c)(5)(B) of the FD&C Act, which provides that, in determining whether a food additive is safe under section 409 of the FD&C Act, FDA is to ''consider among other relevant factors'' the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet. The objectors assert that to ''conduct the safety evaluations the Food Act demands, FDA must withdraw the Order and properly apply the statutory standard for chemically or pharmacologically related substances to account for the cumulative effects of all related phthalates in the diet'' (Objections at 26). Because this objection raises a purely legal dispute, no hearing is warranted to adjudicate it (§ 12.24(b)(1)). Even if a hearing were available, the objectors did not request one with respect to this objection and therefore waive any right to a hearing (§ 12.22(a)(4)). The only remaining issue on Objection 4, then, is whether the objection establishes that FDA's order denying FAP 6B4815 should be modified or revoked. As described below, we conclude that the objectors have not established a basis for modifying or revoking of the denial order.

The objectors assert that while the denial order ''does not articulate FDA's interpretation of what constitutes a 'related' substance,'' FDA nevertheless ''applied an erroneous interpretation of 'chemically or pharmacologically related' substances for which the Food Act mandates a cumulative effects analysis'' (Objections at 22). In describing our review of FAP 6B4815, the objectors assert that FDA ''appeared to interpret'' this provision of the FD&C Act as only applying if substances that are known to share *all* of the following three factors: ''(1) well-defined similarities in chemical structure, and (2) a common defined toxicological endpoint, and (3) a common mechanism of action associated with that common endpoint'' (internal quotations omitted) (Objections at 23). The objectors disagree with this purported requirement and state that ''FDA's regulations make the focus on common effects, as opposed to a common mechanism of action'' (citing § 170.18(a)) (Objections at 24). The objectors assert the proper focus is on common health effects (id.). The objectors state, ''it would be irrational and contrary to the Food Act's safety mandate to ignore the cumulative effects of substances in the diet that are known to contribute to the same adverse health effect because the mechanism of action is not known to be the same for both substances or is not known at all'' (id.). Finally, the objectors assert in Objection 4 that we ''erred in asserting that it is only required to consider the cumulative effects of substances that would be suitable for grouping into a single category for risk assessment'' (internal quotations omitted) (id.).

FDA Response: Objection 4 questions FDA's evaluation of the claim made in FAP 6B4815 that the 28 subject *ortho*-phthalates are chemically and pharmacologically related and should therefore be treated as a class for purposes of evaluating their safety. In describing FDA's evaluation of this claim, the objectors assert that FDA required all of the following three factors to be satisfied: ''(1) well-defined similarities in chemical structure, and (2) a common defined toxicological endpoint, and (3) a common mechanism of action associated with that common endpoint'' (Objections at 23). As support for the proposition that FDA imposed such a requirement, Objection 4 cites to both the denial order and FDA's toxicology memorandum supporting the denial order (Ref. 4).

There is no place in the denial order where we imposed such a requirement. In the denial order, we noted that other regulatory and scientific bodies have grouped phthalates based on these three considerations (87 FR 31066 at 31071). We also noted in our denial order that FAP 6B4815's approach to class grouping was not consistent with the approach taken by other regulatory and scientific bodies, given that FAP 6B4815 identified the work of those other bodies as a basis for the requested action (id.).

To support their claim in Objection 4 that FDA required FAP 6B4815 to satisfy the three factors that the objectors identify, the objectors cite page 10 of our toxicology memorandum for FAP 6B4815 (Ref. 4). The toxicology memorandum, however, did not suggest that FDA required the three factors as a

[1] While FDA is denying this request for a hearing, we again note that, in the **Federal Register** of May 20, 2022, we issued an RFI seeking scientific data and information on current uses, use levels, dietary exposure, and safety data for *ortho*-phthalates that remain authorized for use in food contact applications (87 FR 31090). Any future evaluation may be informed by, among other things, appropriate scientific data and information submitted in response to the RFI.

condition for grouping. Rather, this portion of the toxicology memorandum addressed the claim in FAP 6B4815 that the 28 subject *ortho*-phthalates have similar health effects. In doing so, the toxicology memorandum noted that while FAP 6B4815 asserted that all *ortho*-phthalates must be assumed to have ''reproductive/developmental, and endocrine health effects,'' the terms ''reproductive, developmental, and endocrine effects are broad terms that cover a wide range of toxicological effects that are not necessarily similar and can be caused by a variety of mechanisms.''

The toxicology memorandum also noted that the endocrine system is a generic term which encompasses multiple organs and multiple hormonal pathways, and disruption of different hormonal pathways may not result in common health outcomes (*i.e.,* are not related). The toxicology memorandum further stated that the proposed grouping of phthalates based on these broad terms was not consistent with the types of grouping undertaken by other scientific bodies. As with the denial order, the toxicology memorandum discussed the considerations underlying the groupings undertaken by these other scientific bodies because FAP 6B4815 pointed to the evaluations by these bodies as support for the requested action—not because FDA was presenting or imposing the three factors that the objectors identify. Thus, Objection 4 is incorrect in asserting that FDA required the three factors the objectors identify.

Likewise, the objectors mischaracterize FDA's denial order by stating that, in assessing whether the subject *ortho*-phthalates are pharmacologically related, we erred in assessing whether the 28 *ortho*-phthalates exhibit a common mechanism of action; the objectors state that the more appropriate focus is whether there are common health effects (Objections at 24). According to Objection 4, ''it would be irrational and contrary to the Food Act's safety mandate to ignore the cumulative effects of substances in the diet that are known to contribute to the same adverse health effect because the mechanism of action is not known to be the same for both substances or is not known at all'' (id.). In fact, we did evaluate the claim in FAP 6B4815 regarding common health effects, and our denial order explained why this claim was lacking. Specifically, our denial order explained that the generalized assertion in FAP 6B4815 that all the cited effects are pharmacologically related because they ''result from the effects of *ortho*-phthalates on the endocrine system'' does not acknowledge that the endocrine system is a generic term that encompasses multiple organs and multiple hormonal pathways (87 FR 31066 at 31070). A substance that exhibits activity in one hormonal pathway may not have any effect on a different hormonal pathway, and disruption of different hormonal pathways may not result in common health outcomes (id.).

Our denial order also explained that the claim in FAP 6B4815 that all studied *ortho*-phthalates demonstrate similar effects on the endocrine system was directly contradicted by data cited in the petition (id.). We explained that one of the most commonly studied pharmacological effects for phthalates is antiandrogenicity and that the data cited in the petitioners' literature search indicates that, among the 12 phthalates with available toxicological information, seven phthalates exhibit antiandrogenic effects, but four phthalates have been shown to *not* exhibit antiandrogenic effects (id. at 31070 through 31071). Thus, FDA's evaluation of FAP 6B4815 did, in fact, evaluate whether the 28 *ortho*-phthalates have common health effects. Objection 4, therefore, errs in suggesting that FDA's evaluation was ''irrational and contrary to the Food Act'' by virtue of disregarding evidence that the 28 *ortho*-phthalates cause common health effects.

Finally, Objection 4 is misplaced in asserting that FDA's denial order maintained that FDA ''is only required to consider the cumulative effects of substances that would be suitable for grouping into a single 'category for risk assessment' '' (Objections at 24). FDA's denial document made no such statement. The internal quotation appears to refer to the following sentence in our denial order: ''the common functional group rationale *should* be supported with a discussion of any structural variations within that common functional group definition and an explanation of why the chemical-structural differences between members would not impact the suitability of the category for risk assessment'' (87 FR 31066 at 31069) (emphasis added). Contrary to the claim in Objection 4, this sentence does not announce any legal interpretation regarding when FDA may consider the cumulative effects of different food additives. Rather, it addresses one of the rationales offered by FAP 6B4815 for grouping the 28 *ortho*-phthalates: that the substances share a common functional group. In the sentence that petitioners quote from in Objection 4, we explain the type of scientific evidence that is recommended to support an assertion of a common functional group, as outlined in the Organization for Economic Co-operation and Development (OECD) guidance that the original petition cites as support of its assertion that the 28 *ortho*-phthalates share a common functional group (Ref. 9).

For these reasons, we disagree with the assertion in Objection 4 that FDA committed legal error that justifies modifying or revoking our denial order. We also note that, even if there was a legal error with FDA's application of section 409(c)(5)(B) of the FD&C Act, our resolution of FAP 6B4815 would have been the same. Our denial order did not rest solely on the question of whether the 28 *ortho*-phthalates should be considered a class for purposes of safety evaluation. Our denial order also rested on our conclusion that petitioners did not adequately support the other key assertions in FAP 6B4815 (*i.e.,* the assertion proposing a purported ADI for DEHP, the assertion that the purported ADI should be applied to all 28 phthalates, and the assertion that the EDI for the asserted class of *ortho*-phthalates significantly exceeds the proposed ADI). Thus, even if FAP 6B4815 had established that there was sufficient evidence to support treating the 28 subject *ortho*-phthalates as a class, FDA would have denied the petition because it failed to establish the two subsequent assertions supporting the petition's request to revoke the authorizations of such substances.

E. Objection 5, 5–A, 5–B, and 5–C

In Objection 5, the objectors argue that ''FDA acted arbitrarily and unlawfully'' by not considering the relatedness of smaller groups of *ortho*-phthalates (Objections at 26). The objection contends that the relatedness of different groups of *ortho*-phthalates would mean that ''FDA must consider their cumulative effects'' (id. at 26). The premise of this objection is that FDA's denial order erred in analyzing the relatedness of all the 28 *ortho*-phthalates that were the subject of FAP 6B4815, because on the same day that FDA issued the denial order we also issued the abandonment order. In Objection 5, the objectors assert that FDA's analysis of the relatedness of the 28 *ortho*-phthalates was ''irrational on its face'' (id.). The objectors separate Objection 5 into three separate sub-objections. In each sub-objection, the objectors propose that FDA grant a public hearing to determine that the proposed groupings of phthalates show that the phthalates are chemically or pharmacologically ''related.'' The

specific groupings proposed in Objection 5 are:

(A) A group of nine *ortho*-phthalates, consisting of the five *ortho*-phthalates that remain approved as food additives following FDA's abandonment order combined with four *ortho*-phthalates that are authorized for use as food-contact substances because they were sanctioned prior to the food additive amendments to the FD&C Act (*i.e.,* they are prior sanctioned). A ''prior sanction'' is ''an explicit approval granted with respect to use of a substance in food prior to September 6, 1958,'' by the FDA or the United States Department of Agriculture, pursuant to the FD&C Act, the Poultry Products Inspection Act, or the Meat Inspection Act (§ 170.3(l)). The term ''prior sanction'' derives from section 201(s)(4) of the FD&C Act (21 U.S.C. 321(s)(4)), which excepts from the definition of a ''food additive'' any substance ''used in accordance with a sanction or approval granted prior to'' September 6, 1958, the date of enactment of the Food Additives Amendment to the FD&C Act. Before that date, FDA had approved specific uses of various food-contact materials or food ingredients by issuing letters and other statements that stated that in FDA's view these substances were ''not considered unsafe,'' that they did ''not present a hazard,'' or that FDA ''did not object to their use.''

The nine *ortho*-phthalates that are at issue in this sub-objection are Di(2-ethylhexyl) phthalate (DEHP), Dicyclohexyl phthalate (DCHP), Diisononyl phthalate (DINP), Diisodecyl phthalate (DIDP), Dialyl phthalate (DAP), Diethyl phthalate (DEP), Butyl phthalyl butyl glycolate (BPBG), Diisooctyl phthalate (DIOP), and Ethyl phthalyl ethyl glycolate (EPEG). The objectors assert that these nine *ortho*-phthalates should be grouped because they are ''chemically related'' and grouping them due to a common functional group would be consistent with the Organization for Economic Co-operation and Development (OECD) Guidance on Grouping Chemicals (Objections at 28).

(B) A group of seven *ortho*-phthalates, which consist of a subgroup of the nine *ortho*-phthalates that remain either approved in our food additive regulations or authorized because they are prior sanctioned. These *ortho*-phthalates are DCHP, DEHP, DINP, DAP, DEP, DIDP, and DIOP. The objectors state that these *ortho*-phthalates are ''pharmacologically related substances on account of their common effect on developmental toxicity'' (Objections at 31).

(C) A group of four *ortho*-phthalates, which consist of a subgroup of the nine *ortho*-phthalates that remain approved in our food additive regulations or authorized because they are prior sanctioned. These *ortho*-phthalates are DCHP, DEHP, DINP, and DIOP. The objectors state that these *ortho*-phthalates should be considered cumulatively ''based on their structural similarity and common antiandrogenic effects associated with the mechanism of action of reduced fetal testosterone production'' (Objections at 35).

FDA Response: Even if the objectors' statements regarding the asserted relatedness of these different groups of *ortho*-phthalates were shown to be correct, the outcome of FDA's denial order would not be altered. FAP 6B4815 did not seek to establish the relatedness of these different groups of *ortho*-phthalates, consisting of both food additives and prior sanctioned substances, for purposes of safety assessment. Rather, FAP 6B4815 proposed that FDA take a different approach. Specifically, FAP 6B4815 requested that we treat 28 *ortho*-phthalates authorized for food contact use in our food additive regulations as a class, apply a single ADI to the purported class, and then compare exposure estimates for the 28-member class to the proposed ADI. FAP 6B4815 did not ask us to consider these proposed groups of nine, seven, and four *ortho*-phthalates. As Objection 5 does not demonstrate how the outcome of this proceeding would be different based on the new assertions of the new proposed groupings, we deny the request for a hearing. A hearing will not be granted unless resolution of a factual issue in the way sought by the objector is adequate to justify the action requested (§ 12.24(b)(4)). As courts have recognized, the issues raised in objections ''must be material to the question involved; that is, the legality of the order attached'' (*Pineapple Growers Ass'n of Haw.,* 673 F.2d at 1085).

The objectors claim that our denial order was deficient because it did not address questions they failed to ask, and to take actions they failed to request, in the petition that is the subject of this proceeding. Such matters are outside the scope of the process set forth in section 409(f)(1) of the FD&C Act, which requires objections to ''[to specify] . . . the provisions of the [denial] order deemed objectionable.'' The type of information necessary to consider for grouping chemicals for safety assessment is complex and proposing new groupings at the objection phase—when those groupings were not within the scope of the denial order—does not allow for full consideration of the complex scientific issues involved (see *e.g.,* Ref. 1). Because Objection 5 and the corresponding request for a hearing seek determinations regarding issues that are outside the scope of the provisions of FDA's denial order, the objection and hearing request are improper.

Separately, the objectors claim that FDA's review of FAP 6B4815 failed to account for our abandonment order (Objections at 26). We disagree. On the same day that we issued our denial order, we published a detailed memorandum in which we addressed the purported relatedness of the five *ortho*-phthalates that remained approved as food additives following FDA's action on the abandonment petition (Ref. 1). FDA evaluated whether the five still-approved *ortho*-phthalates should be treated as a class for purposes of safety assessment and concluded that the five substances should not be grouped together for safety assessment. We based this conclusion on the structural variations and the differences in metabolites, metabolism, and toxicological endpoints across the substances. We described these differences in the memorandum that is in the docket (id.).

F. Objection 6

In Objection 6, the objectors assert that FDA should have treated a group of eight *ortho*-phthalates as a class because the eight *ortho*-phthalates, are ''antiandrogenic and are likely present in the diet'' (Objections at 38). The eight *ortho*-phthalates that Objection 6 identifies for treatment as a class are Di(2-ethylhexyl) phthalate (DEHP), Dicyclohexyl phthalate (DCHP), Diisononyl phthalate (DINP), Diisooctyl phthalate (DIOP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DiBP), and Dihexyl phthalate (DnHexP). The eight *ortho*-phthalates are a subset of the 28 *ortho*-phthalates that were the subject of FAP 6B4815. This proposed class consists of a subgroup of the *ortho*-phthalates that remain approved for food-contact use under our food additive regulations (DCHP, DEHP, and DINP), one that is prior sanctioned (DIOP), and four that are no longer authorized for food-contact use due to our abandonment order (DiBP, DBP, BBP, and DnHexP). The objection contends that the relatedness of these eight *ortho*-phthalates triggers FDA's obligation to take into account their cumulative effect, and the fact that FDA's denial order did not identify them as a class means that FDA acted ''contrary to the Food Act and its regulations by failing to account for the

cumulative effects of dietary exposure'' to this proposed group (id.).

The objectors request a hearing on Objection 6. They state that the hearing would address ''whether FDA unlawfully failed to consider the cumulative effects of phthalates in the diet that are chemically or pharmacologically related to phthalates that remain approved for food-additive use'' (internal quotations omitted) (Objections at 39 through 40). The objectors state that at a hearing they would ''offer expert testimony regarding the presence of BBP, DBP, DIBP, and DnHP in the diet; the chemical and pharmacological relationship among these substances and DEHP, DINP, DCHP, and DIOP; and the approach or approaches FDA could take to appropriately account for the cumulative effects of these substances'' (id. at 40).

FDA Response: Even if the objectors' asserted statements regarding the chemical and pharmacological relatedness of this group of eight *ortho*-phthalates were shown to be correct, the outcome of FDA's denial order would not be altered. The underlying proceeding did not address the relatedness of this smaller group of *ortho*-phthalates for purposes of safety assessment. FAP 6B4815 proposed that FDA take a different course of action. Specifically, as stated earlier, FAP 6B4815 requested that we group together 28 *ortho*-phthalates approved for food contact use in our food additive regulations, apply a single ADI to the purported class, and then compare exposure estimates for the 28-member class to the proposed ADI. FAP 6B4815 did not ask us to consider this new proposed group of eight *ortho*-phthalates.

As Objection 6 does not demonstrate how the outcome of this proceeding would be different if the assertions regarding the new proposed grouping in Objection 6 were shown to be correct, we deny the request for the hearing. A hearing request will not be granted unless resolution of a factual issue in the way sought by the objector is adequate to justify the action requested (§ 12.24(b)(4)). As courts have recognized, the issues raised in objections ''must be material to the question involved; that is, the legality of the order attached'' (see *Pineapple Growers Ass'n of Hawaii,* 673 F.2d at 1085). With this Objection, petitioners would have us address a question that was not involved in the underlying proceeding. As noted earlier, the objectors claim that our denial order was deficient because it did not address questions they failed to ask, and to take actions they failed to request, in the petition that is the subject of this proceeding. However, such matters are outside the scope of the process set forth in section 409(f)(1) of the FD&C Act, which requires objections to ''[to specify] . . . the provisions of the [denial] order deemed objectionable.'' Because Objection 6 and the corresponding request for a hearing seek determinations regarding issues that are outside the scope of the provisions of FDA's denial order, the objection and hearing request are improper.

Additionally, FDA *did* consider the relatedness of the 28 *ortho*-phthalates that were the subject of FAP 6B4815 as well as the five *ortho*-phthalates that remain approved for food-contact use in our food additive regulations and did not find that the substances should be grouped as a class for purposes of safety assessment (87 FR 31066 at 31075 and Ref. 1).

G. Objection 7

In Objection 7, the objectors argue that ''FDA erred insofar as it required the petitioners to prove that current dietary exposure to the approved phthalates exceeds a safe level'' (Objections at 40). The objectors assert that FDA's evaluation of the information in FAP 6B4815 related to exposure ''is contrary to the applicable statutory and regulatory provisions, the proper burden of proof, and FDA's past practice'' (Objections at 42). Because this objection raises a purely legal dispute, no hearing is warranted to adjudicate it (§ 12.24(b)(1)). Even if a hearing were available, the objectors did not request one with respect to this objection and therefore waive any right to a hearing (§ 12.22(a)(4)). The only remaining issue on Objection 7, then, is whether this objection establishes that FDA's order denying FAP 6B4815 should be modified or revoked. As described below, we conclude that the objectors have not established a basis for modifying or revoking the denial order.

In Objection 7, the objectors assert that, while FDA is to consider exposure data when approving new food additives, ''FDA's regulation governing petitions to amend or repeal food additive regulations does not require the petitioners to tender exposure data'' (Objections at 40). The objectors contend that, rather than requiring repeal petitions to provide exposure data, FDA's regulations provide that repeal petitions ''may be based solely on 'new data as to the toxicity of the chemical' or other 'new information' showing 'that experience with the existing regulation may justify its amendment or repeal' '' (quoting § 171.130(b)) (id.). The objectors acknowledge that § 171.130(b) provides for new data to be furnished in the form specified in § 171.1 but argue that ''[t]o the extent that the substantive requirements of section 171.1 are applicable to petitions seeking revocation or repeal of food additive regulations, that provision also does not require exposure data'' (Objections at 41). The objectors further state that ''to the extent that FDA interprets [§ 171.1] to require exposure information, it must apply that requirement in a manner that comports with the burden of production the Food Act places on petitioners seeking revocation of food additive authorizations based on safety concerns,'' such that ''FDA cannot lawfully require such petitioners to tender data proving that existing exposure to the additives at issue and related substances is unsafe'' (id. at 41). The objectors assert that FDA's action on certain long-chain perfluorinated compounds (81 FR 5) was consistent with this interpretation (id. at 41 through 42).

FDA Response: We disagree with the assertion that we applied an incorrect legal standard in evaluating FAP 6B4815. We reviewed the exposure information provided in FAP 6B4815 based on the petition's specific assertions. FAP 6B4815 asserted that the estimated dietary exposure for the asserted class of *ortho*-phthalates significantly exceeded the proposed ADI for the purported class, and the petition included dietary exposure estimates for select phthalates. In our denial order, we evaluated the proposed dietary exposure values and explained why they were not adequately supported. Specifically, we observed that FAP 6B4815 did not account for: (1) The imprecision of relying on exposures estimates derived from biomonitoring studies to assess dietary exposure; (2) the diverse parameters used in the cited dietary exposure analyses to determine which analysis, if any, most accurately reflects true U.S. dietary exposure; and (3) the contradiction in reported dietary exposure values between those analyses (87 FR 31066 at 31075; see also Ref. 3). Under our food additive regulations, petitioners must do more than request changes to FDA's food additive regulations. Petitioners must provide support for the requested changes. Food additive petitions seeking amendments to existing authorizations ''must include full information on each proposed change'' (*In re Natural Resources Defense Council,* 645 F.3d 400, 403 (D.C. Cir. 2011) (internal quotations and citations omitted)). Here, FAP 6B4815

included dietary exposure estimates, and our denial order evaluated those estimates and explained why they were lacking. In doing so, we did not advance any new standards for the type of information that must be included in repeal petitions.

Further, our denial order was not inconsistent with our action on long-chain perfluorinated compounds. In that action, we evaluated available exposure information and explained why we were not able to determine migration of the relevant food contact substances (FCSs) into food as a result of their approved food-contact use. For this reason, FDA was unable to calculate consumer exposure to the substances in a manner which would allow a quantitative assessment of the safety of that exposure. However, FDA's review noted that available data demonstrate that long-chain perfluorocarboxylic acids and fluorotelomer alcohols biopersist in animals and that this biopersistence also occurs in humans. Although available migration information did not allow a quantitative assessment of the safety of exposure to these FCSs, the reproductive and development toxicity of the three food contact substances could be qualitatively assessed in the context of biopersistence and the expectation that chronic dietary exposure to these substances would result in a systemic exposure to the substances or their metabolic by-products at levels higher than their daily dietary exposure (81 FR 5 at 7). There is not comparable evidence in the administrative record for FAP 6B4815 to allow FDA to conclude that there is no longer a reasonable certainty of no harm regarding the subject *ortho*-phthalates for their intended use in the absence of adequate exposure information. While FDA had a basis for qualitatively assessing exposure in the action on long-chained perfluorinated compounds, the record here does not support that approach.

For these reasons, we disagree with the objectors' assertion that FDA committed any legal error that justifies modifying or revoking our denial order.

H. Objection 8

The final objection argues that ''contrary to FDA's conclusion, the available exposure information raises serious safety questions regarding the approved food additive uses of phthalates'' (Objections at 43). The objectors request a hearing on Objection 8 and state that the hearing would address whether biomonitoring data from the National Health and Nutrition Examination Survey (NHANES) ''and other available exposure information together establish significant questions concerning the safety of the food additive uses of phthalates that remain approved'' (Objections at 49). The objectors state that ''FDA did not address this issue in the order. Instead, it dismissed the NHANES biomonitoring data provided with the Petition based on arguments that are legally and factually unsupported, and it did not evaluate the most recent NHANES data in conjunction with ATSDR's MRL for DEHP'' (id. at 49).

FDA Response: A hearing will not be granted on factual issues that are not determinative with respect to the action requested (§ 12.24(b)(4)). In this objection, the objectors challenge our evaluation of the information they provided in FAP 6B4815 related to exposure. However, our denial order made clear that our evaluation of exposure data was not the sole reason we denied FAP 6B4815. Instead, we based our denial on the lack of adequate support for each of the three assertions made in FAP 6B4815: (1) that the 28 *ortho*-phthalates should be treated as a class for purposes of evaluating their safety; (2) that a purported ADI for DEHP should be applied to all 28 *ortho*-phthalates that were the subject of the petition; and (3) that the EDI for the asserted class of *ortho*-phthalates significantly exceeded the proposed ADI, thus rendering the purported class unsafe for their use as food contact substances. Our denial order explained in detail why the petition did not adequately support any of these three assertions. Because we found that the petition was not adequately supported, we concluded that the petition did not contain sufficient data to support a finding that there is no longer a reasonable certainty of no harm from the approved uses (87 FR 31066 at 31075).

To the extent that Objection 8 is based on the premise that FDA's evaluation of the exposure data was determinative to how we evaluated FAP 6B4815, that premise is incorrect. Even if FDA were to have found, as Objection 8 urges, that the data in the record show that the exposure to certain *ortho*-phthalates significantly exceeds the ADI proposed by FAP 6B4815 for the reference *ortho*-phthalate selected (DEHP), such a finding would not have answered the antecedent questions of whether the 28 *ortho*-phthalates should be treated as a class or whether the proposed ADI for the selected *ortho*-phthalate should be applied to the purported class of 28 *ortho*-phthalates. Because FDA's conclusion regarding exposure data in the record was not determinative with respect to the repeal action requested in FAP 6B4815, the objectors' request for a hearing on this subject is denied.

In addition, we are denying the request for a hearing on this objection because the data and information identified by the objectors in support of the objection, even if established at a hearing, would not be adequate to justify the factual determination about unsafe exposure urged by the objectors (see § 12.24(b)(3)). This is for two distinct reasons.

First, Objection 8 claims that ''diet is a major, if not primary, source of exposure to the phthalates at issue'' (Objections at 43). The objection points to the 2014 report from the Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives (CHAP report), two declarations that cite the CHAP report as support, and a statement in ATSDR's 2022 toxicological profile of DEHP that ''the principal route of human exposure to DEHP is oral,'' and that the ingestion of food accounts for the majority of total oral exposure to DEHP (Objections at 45) (Ref. 10). The objectors state that FDA's denial order ''does not dispute the CHAP's conclusions regarding the primacy of diet as an exposure source for multiple approved phthalates and related substances'' and that FDA ''must qualitatively consider'' conclusions by CHAP or ATSDR that diet is a ''critically important source of exposure to DEHP and other phthalates at issue'' (id. at 45). This criticism is misplaced. Even if FDA were to reach the general conclusion that the diet is a major source of exposure to approved *ortho*-phthalates, that would not answer the question of whether or not a specific approved food additive use is safe. Regarding the CHAP report, it did not answer the question of whether specific food additive uses of *ortho*-phthalates are safe. To the extent that this objection asserts that FDA did not evaluate the CHAP report in responding to FAP 6B4815, that is not the case. The denial order and FDA's supporting memoranda discussed the CHAP report at length (Refs. 3 and 4). Regarding ATSDR's report on DEHP, this report states that the intake approximations calculated for DEHP indicate that the general population is exposed to DEHP at levels that are 3–4 orders of magnitude lower than those observed to cause adverse health effects in animal studies. Accordingly, the ATSDR report does not justify resolution of the factual question about unsafe exposure in the objectors' favor.

The second reason the data and information identified by the objectors in support of the objection, even if established at a hearing, would not be

adequate to justify resolution of the factual question about unsafe exposure relates to FDA's evaluation of biomonitoring studies. Objection 8 asserts that ''FDA irrationally dismissed the relevance of biomonitoring data from the CDC's NHANES, which tracks metabolites of DEHP, DCHP, DEP, and DINP, among other phthalates, in human urine'' (Objections at 45). The objectors assert that FDA's denial order was mistaken in stating that petitioners relied on biomonitoring data ''alone'' as information presented in the petition established the primacy of diet as a source of exposure to multiple phthalates (Objections at 46). The objectors state that ''the NHANES biomonitoring data must be evaluated in light of evidence that most human exposures to these phthalates come from the diet'' (id.). Here, the objectors make several claims that are not supported. We did not, in fact, dismiss the potential relevance of biomonitoring evidence presented in the petition. Rather, our denial order specifically noted that human biomonitoring studies can be ''part of an appropriate postmarket approach to determine dietary exposure for a substance that is already authorized for use as a food contact substance'' (87 FR 31066 at 31074). However, we also explained that ''many factors should be addressed to determine the suitability of any given dataset for determining dietary exposure'' (id.). We explained that the approach of directly comparing biomonitoring-based exposure values to a proposed ADI for the purpose of assessing the safety of a food additive is not scientifically appropriate (id.). Relying on biomonitoring data alone does not differentiate the amount of exposure that results from the diet compared to environmental and other sources (id.). Because FAP 6B4815 did not account for these limitations by addressing how the biomonitoring data accounts for dietary exposure, we concluded that the petition's direct comparison of biomonitoring-based exposure values to the purported ADI was scientifically flawed. Our evaluation did not amount to a summary dismissal. We considered the information provided in the petition and found it lacking. The objectors' claim that we stated that FAP 6B4815 relied on biomonitoring data ''alone'' is also wrong. In our denial order, we discussed other evidence in FAP 6B4815 that was related to exposure (and identified shortcomings with the petition's evaluation of that data) (id.). Thus, the record shows that we considered all relevant exposure-related data included in the petition.

The objectors' claims regarding the primacy of the diet and FDA's dismissal of biomonitoring data, even if established at a hearing, would not be sufficient to justify resolution of the factual conclusion urged by the objectors (§ 12.24(b)(3)). These claims were intended to support a conclusion that the available exposure information raises serious safety questions regarding the approved food-additive uses of phthalates. The information presented to support these claims do not provide a factual basis for determining that any *ortho*-phthalates have unsafe dietary exposure levels or that there are significant safety questions regarding the dietary exposure levels because these claims do not proffer evidence of unsafe dietary exposure levels for any *ortho*-phthalates with authorized uses. These arguments do not provide a basis for a hearing.

A separate argument that objectors put forth in Objection 8 purports to provide more direct data regarding exposure. The objectors described a new exposure analysis and provided a supporting memorandum (Objections at 48, n. 174) that calculated EDIs for 10 phthalates (DEHP, BBP, DBP, DIBP, DCHP, DEP, DIDP, DINP, DMP, and DnOP) using urinary metabolite concentrations from the most recent NHANES biomonitoring data (collection occurred from 2015 to 2016). The objectors state that the EDI estimate for DEHP (at the 90th and 95th percentiles) is above the 0.10 micrograms per kilogram body weight per day intermediate minimal risk level (MRL) for oral exposure established for DEHP by ATSDR in 2022 (id. at 48). The objectors state that this ''indicate[s] unsafe exposure levels across the U.S. population'' (id.). As explained in our denial order and above, relying on biomonitoring data alone to calculate an exposure estimate does not differentiate the amount of exposure that results from the diet compared to other sources. Neither the objectors nor the supporting memorandum accounts for these limitations by addressing how the biomonitoring data is representative of an estimate to dietary exposure only. Furthermore, the MRL for DEHP cited by the objectors was determined based on a single study that used only one dose level and only a limited number of animals. Due to the use of a single dose and limited animals, there is not enough supporting information to rely on this value for the purposes of a safety assessment for DEHP or to apply it as a value for risk assessments of the other substances cited by the objectors.

The objectors also assert that certain studies involving mixtures of *ortho*-phthalates ''underscore the need for FDA to consider the available exposure information in response to these objections, and the importance of cumulative effects analysis to that assessment'' (Objections at 49). The objectors state that ''EPA scientists [who] have documented the magnitude of the cumulative effect of mixtures of anti-androgenic *ortho*-phthalates, and mixtures of anti-androgenic *ortho*-phthalates and other substances with similar anti-androgenic effects. Collectively, these studies found that *ortho*-phthalates in mixtures with structurally and pharmacologically related substances induced anti-androgenic effects at doses that were orders of magnitude lower than those associated with anti-androgenic effects of individual phthalates'' (id. at 48). However, the objectors do not provide any dietary exposures to the proposed related anti-androgenic substances in the diet, nor do they identify what those related anti-androgenic substances are. While the Howdeshell (2017) (Ref. 11) and Conley et al., (2018 and 2021) (Refs. 8 and 12) studies demonstrate some additive effects of mixtures of anti-androgenic substances, the Conley et al., (2018 and 2021) studies also report a level of exposure of these phthalate and non-phthalate mixtures where no antiandrogenic effects were detected. Likewise, beyond the MRL for DEHP, the objectors do not provide a suitable safe level or a risk assessment value to compare that cumulative dietary exposure level for the purposes of conducting a safety assessment. The objectors do not demonstrate how determining that anti-androgenic effects from multiple substances may be additive would demonstrate Objection 8's assertion that the available exposure information raises serious safety questions regarding the approved food-additive uses of phthalates.

Separately, the objectors contend that FDA committed legal error in evaluating the exposure information included in FAP 6B4815. The objectors assert that FDA evaluated their petition ''as if diet were the sole source of exposure to the approved phthalates,'' which Objection 8 describes as being in tension with the ''among other relevant factors'' text in section 409(c)(5) of the FD&C Act (Objections at 46). The applicability of the ''among other relevant factors'' text in section 409(c)(5) of the FD&C Act is a legal issue, and a hearing will not be granted on issues of law (§ 12.24(b)(1)). We note that, in determining whether a food additive is safe under section

409(c)(5) of the FD&C Act, FDA is to ''consider among other relevant factors'' the following: (1) probable consumption of the additive; (2) cumulative effect of such additive ''in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet;'' and (3) safety factors ''generally recognized'' by qualified experts ''as appropriate for the use of animal experimentation data.''

Section 409(c)(5) of the FD&C Act does not impose a ''legal obligation'' for FDA to consider exposure from non-dietary sources in determining safety. Rather, section 409(c)(5) of the FD&C Act makes clear that FDA has discretion to review a number of factors to determine whether a food additive is safe. Besides the factors enumerated in subparagraphs (A), (B), and (C), section 409(c)(5) of the FD&C Act gives us discretion to decide, in our scientific expertise, whether there are other factors that are ''relevant'' to the safety of a food additive in the context of a particular petition. Moreover, the text of subparagraphs (A) and (B), which contemplate FDA considering *food-related* uses in assessing safety, provides additional support that it is not required for FDA to consider exposure from non-dietary sources as a relevant factor. Specifically, subparagraph (A) states that in determining safety, the Secretary shall consider ''the probable *consumption* of the additive and of *any substance formed in or on food because of the use of the additive,*'' and subparagraph (B) refers to the *diet* of man or animals'' (emphasis added). Subparagraph 409(c)(5)(C) of the FD&C Act, which directs FDA to consider safety factors that ''are generally recognized as appropriate for the use of animal experimentation data,'' does not suggest that FDA must consider exposure from non-dietary sources. Therefore, the objectors' argument that non-dietary exposure must be part of the safety analysis under section 409(c)(5) of the FD&C Act is incorrect. While the objectors state that other federal agencies ''frequently consider background exposures when evaluating and regulating harmful chemicals,'' we administer the FD&C Act and not authorities that are applicable to other Federal agencies.

V. Summary and Conclusions

After evaluating the objections, we conclude that the submission does not provide a basis to support modifying or revoking the denial of FAP 6B4815. Therefore, we are overruling the objections and denying the requests for a public hearing.

VI. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. * FDA Memorandum from J. Urbelis to Administrative File for Food Additive Petition (FAP) 6B4815, May 11, 2022.
2. * FDA, Guidance for Industry, ''Toxicological Principles for the Safety Assessment of Food Ingredients: Redbook 2000,'' July 2007 (available at *https://www.fda.gov/media/79074/download*).
3. * FDA Chemistry Memorandum from R. Brinas to J. Urbelis, May 11, 2022.
4. * FDA Toxicology Memorandum from T–F. Cheng to J. Urbelis, May 11, 2022.
5. * Agency for Toxic Substances and Disease Registry (ATSDR) ''Toxicological Profile for Di(2-ethylhexyl) Phthalate (DEHP),'' January 2022.
6. * ''NTP Technical Report on the Toxicology and Carcinogenesis Studies of Di(2-ethylhexyl) Phthalate Administered in Feed to Sprague Dawley Rats,'' December 2021.
7. European Food Safety Authority Panel on Food Contact Materials, Enzymes and Processing Aids, ''Update of the Risk Assessment of Di-Butylphthalate (DBP), Butyl-Benzyl-Phthalate (BBP), Bis(2-ethylhexyl)Phthalate (DEHP), Di-Isononylphthalate (DINP) and Di-Isodecylphthalate (DIDP) for Use in Food Contact Materials,'' *European Food Safety Authority Journal,* 17(12):5838, 2019.
8. Conley, J., C.S. Lambright, N. Evans, et. al., ''A Mixture of 15 Phthalates and Pesticides Below Individual Chemical No Observed Adverse Effects Levels (NOAELs) Produces Reproductive Tract Malformations in the Male Rat,'' *Environment International,* 156:106615, 2021.
9. ** 2014 Organization for Economic Cooperation and Development (OECD) Guidance on Grouping of Chemicals.
10. ** 2014 Chronic Hazard Advisory Panel (CHAP) on Phthalates and Phthalate Alternatives Final Report.
11. Howdeshell, K., A.K. Hotchkiss, L.E. Gray Jr., et al., ''Cumulative Effects of Antiandrogenic Chemical Mixtures and Their Relevance to Human Health Risk Assessment,'' *International Journal of Hygiene and Environmental Health* 220 (2Pt A):179, 2017.
12. Conley, J., C.S. Lambright, N. Evans, et. al., ''Mixed Antiandrogenic Chemicals at Low Individual Doses Produce Reproductive Tract Malformations in the Male Rat,'' *Toxicological Sciences* 164(1):166, 2018.

Dated: October 22, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–25120 Filed 10–29–24; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2024–0207; FRL–12341–01–R8]

Air Plan Approval; Revisions to Colorado Common Provisions Regulation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Common Provisions Regulation of the Colorado State Implementation Plan (SIP). These revisions were submitted by the State of Colorado in response to the EPA's June 12, 2015, Findings of Substantial Inadequacy and ''SIP call'' for certain provisions in the SIP related to affirmative defenses applicable to excess emissions during startup, shutdown, and malfunction (SSM) events. The EPA is proposing approval of these SIP revisions because the Agency has determined that they are in accordance with the requirements for SIP provisions under the Clean Air Act (CAA or the Act).

DATES: Written comments must be received on or before November 29, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2024–0207, to the Federal Rulemaking Portal: *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *https://www.regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business