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**Issue Brief**

**FDA’s Active Petition to Revoke Clearances for Ortho-Phthalates in Food Contact:**

**Rationales for Response Through**

**the Ortho-Phthalates Coalition (OPC)**

**Issue Background**

**On April 12, 2016, the U.S. Food and Drug Administration (FDA) accepted a Food Additive Petition (FAP) submitted by a group of environmental concerns seeking to revoke existing clearances in the Agency’s food additive regulations for 30 different ortho-phthalates used in food-contact applications. FDA is currently reviewing the petition. The Flexible Vinyl Alliance successfully sought a 60-day extension to submit comments, which were submitted in September of 2016. Follow-on activity will occur through Q3 of 2017. Impact and response discussions are detailed below. Concerned industry groups in Q4 2016 formed and funded the Ortho-Phthalates Coalition (OPC) comprised of trade groups and impacted companies, to respond appropriately to the FAP. The OPC is managed by the Flexible Vinyl Alliance.**

**Potential Impact of the FAP**

The petition potentially impacts more than a dozen separate food additive regulations that permit the use ortho-phthalates in a wide variety of food-contact applications, ranging from adhesives to can coatings. The FAP is the latest in a series of petitions filed by the same groups seeking to remove a number of chemicals currently approved by the FDA for use in food-contact applications. The ortho-phthalate petition is, by far, the largest and most aggressive petition the groups have filed to-date.

**Why a Coalition Response to the Food Additive Petition by Industry is Important, Now**

* FDA unlikely has sufficient information in its files about exposures to ortho-phthalates in food-contact applications to defend the safety of those exposures, and, therefore, it can be expected that FDA will revoke the current clearances without input from industry.
* If FDA determines the current exposures to ortho-phthalates are not safe, a significant amount of negative public attention will be directed towards phthalates, including their use in areas outside of FDA’s jurisdiction. For example:
  + FDA could reconsider the use of phthalates in medical devices.
  + Other U.S. agencies and foreign governments may scrutinize the safety of phthalate in various applications and take further regulatory action.
  + States and localities may consider bans and labeling mandates for phthalate-containing products.
* FDA has repeatedly raised concerns that it needs help to respond to the Food Additive Petition, or it runs the risk of not being able to devote resources to its food-additive premarket clearance programs.
* Failure to respond to the petition will only embolden activist groups to further attack phthalates and file more food additive petitions for other chemicals.
* The public may develop a more negative view of plastic packaging.

If industry determines it would like to formally respond to the Food Additive Petition, we envision that a response will occur through a coalition, and focus on three main elements to ensure that FDA does not need to reach a conclusion on the safety of all ortho-phthalates:

1. Based on the results of a survey, a coalition would file a separate petition with the agency requesting that many of the current clearances for ortho-phthalates be revoked because their use has been abandoned. Preliminary survey results indicate this abandonment petition should cover all but roughly five or six ortho-phthalates referenced in the NGO’s FAP.
2. The Coalition will develop a model, based on feedback from industry, to calculate the current dietary exposures to the roughly five or six ortho-phthalates we intend to defend.
3. The Coalition will present information and argue that the available toxicity data for those five or six ortho-phthalates is sufficient to support their safety at the calculated exposure levels.

**To Participate in the Ortho-Phthalates Coalition, Please Contact:**

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