FDA AFFIRMS ITS DECISION TO REMOVE 25 PLASTICIZERS FROM THE FOOD ADDITIVE REGULATIONS

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US Policy and Regulatory Alert

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In a continuation of the US Food and Drug Administration's efforts to conduct post-market reviews evaluating the continued use and safety of chemicals authorized in its regulations, the agency is removing decades-old clearances for food-contact materials based on evolving toxicology concerns. Specialty chemical companies should take note of the development as an example of the way FDA may respond when safety concerns evolve for cleared substances.

Specifically, on October 2024, the Food and Drug Administration (FDA) responded to an objection to its 22 May 2022 final rule amending the food additive regulations (the Final Rule) and affirmed its decision to remove 25 ortho-phthalate plasticizers from 21 C.F.R. Parts 175, 176, 177, and 178. The FDA issued the Final Rule on 20 May 2022 in response to a food additive petition submitted by the Flexible Vinyl Alliance. Several non governmental organizations filed an objection to the FDA's Final Rule, and in the FDA's response, the FDA stated that the objection did not provide a basis for modifying the FDA's Final Rule. While the FDA affirmed its decision, the FDA noted that it is working on an updated safety assessment that will include the remaining authorized uses for phthalates that were not removed from the food additive regulations. The FDA will consider, in part, information it received through its “Ortho-phthalates for Food Contact Use” Request for Information in its evaluation. The FDA's response explained why the FDA's action with respect to the Final Rule was reasonable.

The FDA also received objections to the agency's denial of a separate food additive petition (food additive petition 6B4815) in which the National Resource Defense Council (NRDC) requested that the FDA revoke authorized food contact uses of 28 phthalates due to alleged safety concerns. The FDA concluded that the NRDC did not establish a basis for modifying or revoking the denial order as requested in their objections. According to the FDA, the NRDC failed to establish sufficient support to take the requested action of grouping the 28 phthalates as a class and revoking their authorizations for the 28 phthalates on the basis that they were unsafe as a class. The FDA took issue with reviewing all 28 phthalates together as a class by applying data from one chemical to the entire group as the NRDC suggested. The FDA found that available information did not support grouping the phthalate chemicals into a single-class assessment and noted that 23 of the 28 phthalates were no longer in use and had been revoked in the Final Rule issued at the same time as the denial of the safety-based petition.

The FDA's forthcoming post-market assessment(s) of the ortho-phthalates whose uses remain the subject of applicable food additive clearances may be an example of the procedures that the FDA will utilize for its post-market assessment of chemicals in food that is currently under development. The proposed post-market assessment process was the subject of a recent public meeting, attended by our Senior Scientific Advisor, Dr.

Peter Coneski, at the FDA's White Oak Campus on 25 September 2024. The public comment period for the FDA's proposal for an enhanced systematic process for the post-market assessment of chemicals in food remains open until 6 December 2024. We are monitoring these and other developments affecting the regulation of food contact materials in the United States and other jurisdictions.

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