



Flexible Vinyl Alliance

August 24, 2020

Toxics in Packaging Clearinghouse
c/o Northeast Recycling Council
139 Main Street
Suite 401
Brattleboro, Vermont 05301

Re: Draft Update to the Toxics in Packaging Model Legislation

The Flexible Vinyl Alliance (FVA) appreciates the opportunity to provide comments on the Toxics in Packaging Clearinghouse Draft Update to the Toxics in Packaging Model Legislation (“Model Legislation”).

FVA is a coalition of trade organizations, materials suppliers, compounders, formulators, molders and fabricators, who are currently concerned with regulatory and legislative attempts to debate, limit or “de-select” flexible vinyl products in commerce. FVA provides messaging and advocacy on the proven safety, economy and utility of flexible PVC, a material used in a wide range of health care, recreational, military, automotive, building, flooring, construction and packaging applications.

By design, these comments are limited to the topic of ortho-phthalates. And, while we note that packaging as a whole is the intended focus of the Model Legislation, we consider food packaging to be the most sensitive application in which ortho-phthalates might be employed, albeit minimally. Therefore, if substances, such as ortho-phthalates, are found to be safe in food contact there is little basis to consider them unsafe for use in any packaging.

In this light, on [the](#) matter of the inclusion of ortho-phthalates in the TPCH Model Legislation we submit the following:

1. We question the inclusion of ortho-phthalates in the Model Legislation. It is both an ill-advised and unnecessary element: already, the U.S. Food and Drug Administration (FDA) regulates the safety of our nation’s food packaging through a carefully crafted and comprehensive regulatory scheme established by the U.S. Congress. To this end, in 1958, Congress amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to establish a single premarket clearance procedure for food additives and food packaging materials. This premarket clearance process requires the Agency to review the safety of a material before it is placed on the market, unless a pre-existing regulatory clearance or exemption applies.

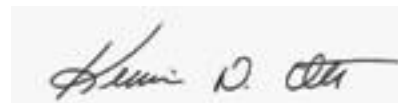
2. Secondly, we would note that FDA experts are currently reevaluating the safety of the few phthalates that are still used in food contact applications in very low volumes, based on the current scientific evidence available. FVA has formally petitioned FDA to remove the existing clearances for 26 ortho-phthalates authorized for use in food contact on the basis that these uses are abandoned.
3. Finally, FDA is now actively reviewing FVA's petition. The decision from FDA is pending. TPCH, in our estimation, should consider the forthcoming FDA decision before recommending any actions to regulate ortho-phthalates in packaging at the state level. We would also note that the European equivalent of the FDA, the European Food Safety Authority (EFSA) recently reviewed the safety of phthalates in food contact materials. The Agency concluded that phthalates are not a public health concern.

In summary, permitting states to scrutinize and ban products that FDA has already determined to be safe thwarts the single market for the nation's food supply that Congress and FDA have, quite explicitly, intended to create. State scrutiny and prohibitions for food packaging materials create consumer confusion and erode public confidence in FDA and in the safety of the nation's food supply. The costs of food and food packaging materials simultaneously increase with the establishment of varying state initiatives that create legal uncertainty and force label changes. The lack of a single federal framework for regulating food and food packaging materials also increases food waste.

Due to the existing Federal food safety framework at FDA, and because FDA's ortho-phthalates assessment is expected to be concluded soon, we strongly urge the Toxics in Packaging Clearinghouse to remove the consideration of ortho-phthalates in its Draft Model Legislation and await the FDA's assessment. This seems like a sensible approach, and one that could build future consensus among all stakeholders, once FDA's assessment is in-hand, which we believe to be an important consideration in your efforts.

Thank you for your consideration.

Sincerely,



Kevin D. Ott
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