American Chemistry Council

Debunking Myths about Phthalates in Food

It is a myth that consumer exposure to phthalates is through food packaging, and that phthalates are present in consumer diets due to exposure from plastic food wraps and containers, potentially causing adverse health effects. In reality, phthalates are rarely, if ever, used in materials such as food wrappers and food packaging.

The term “phthalate” simply refers to a family of chemicals that happen to be structurally similar, but which are functionally and toxicologically distinct from each other. Phthalates are categorized as high and low, depending on their molecular weight.

High molecular weight phthalates have 7 or more carbon atoms in their chemical backbone that gives them increased permanency and durability.

Background

Recent legislative activity seeks to impose restrictions on the manufacture, sale, and distribution of a food package to which ortho-phthalates have been intentionally added in any amount greater than an incidental presence.

This legislation seeks to prohibit all ortho-phthalates from use in food packaging, including high molecular weight phthalates such as diisononyl phthalate (DINP) and diisodecyl phthalate (DIDP) that are currently permitted for use in food packaging across the globe and for which there is overwhelming evidence of safety when used as components of food packaging.

Phthalate Use in Food Packaging is Limited in the United States

Approximately 30 phthalates[1] were permitted for use as food contact substances (including in food packaging and packaging components) by the US Food and Drug Administration (FDA) until May of 2022. Because only four[2] phthalates are currently used in these applications, in 2018 the US Flexible Vinyl Industry filed a Food Additive Petition (FAP) requesting that the FDA revoke all food contact clearances for 26 phthalates,[3] as those uses have been abandoned.

In May of 2022 FDA granted the industry FAP, amending the food additive regulations to no longer provide for the use of 25 plasticizers in food contact applications because these uses have been abandoned.[4] Also in May of 2022, FDA denied a FAP submitted by several NGOs in 2016 requesting removal of all clearances for phthalates used in food contact applications.[5] After 6 years of study and deliberation, FDA found that: “based on the information currently available to FDA, we do not have a basis to conclude that dietary exposure levels from approved ortho-phthalates exceed a safe level.” Four of the ortho-phthalates authorized for food additive use by FDA are currently in use – DINP, DIDP, DCHP, and DEHP.

Additionally, the FDA[6] and Health Canada’s Bureau of Chemical Safety[7] recently conducted a survey of plasticizer[8] use in food packaging and components of food packaging. The survey found limited current use of relevant phthalates.[9]

[1] Any member of the class of organic chemicals that are esters of phthalic acid containing 2 carbon chains located in the ortho position.

[2] Diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), (di-(2-exylhexyl) phthalate (DEHP) and dicyclohexyl phthalate (DCHP).

[3] Federal Register :: Flexible Vinyl Alliance; Filing of Food Additive Petition (83 FR 56750).

[4] FDA ruling granting industry abandonment FAP: 87 Federal Register 31080

[5] FDA ruling denying NRDC FAP requesting a ban on phthalates: 89 Federal Register 31066

[6] Carlos, K.S., L.S. de Jager, and T.H. Begley: Investigation of the primary plasticisers present in polyvinyl chloride (PVC) products currently authorised as food contact materials. Food Addit Contam Part A Chem Anal Control Expo Risk Assess 35(6): 1214-1222 (2018).

[7] Cao XL, Zhao W, Churchill R, Hilts C. Occurrence of Di-(2-ethylhexyl) adipate and phthalate plasticizers in samples of meat, fish, and cheese and their packaging films. J Food Prot. 2014; 77(4):610-620.

[8] “Plasticizer” represents the broad spectrum of substances used to soften PVC including ortho-phthalates, tere-phthalates, aliphatics, epoxy, benzoates, trimellitates, phosphates, polymerics, etc. Ortho-phthalates are just one type of plasticizer, among many.

[9] DINP, DIDP, and di-(2-exylhexyl) phthalate (DEHP) – tubing, conveyor belts and cap gaskets. No phthalate was found to be used in food packaging applications like food service and commercial wraps (e.g. cling-film, wraps for meat, vegetables and sandwiches). Dicyclohexyl phthalate (DCHP) is mainly used as an adhesive component on the external surface of polypropylene bottles, an application that would not permit direct contact with food.

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EU Food Authority Concluded Phthlates Used in Food Contact Not a Public Health Concern

There is extensive available evidence on the safe use of high molecular weight phthalates including DINP and DIDP in current applications without restriction, including sensitive applications such as food contact. The safety-in-use of the four phthalates used in food packaging in the United States has been thoroughly evaluated by food safety regulatory authorities globally for **the last 10 years.** All have concluded that all four phthalates are safe as currently used.

Most recently, in December 2019, the European Food Safety Authority (EFSA) released an updated food safety assessment of phthalates (including DINP and DIDP) used in food contact materials in the European Union.[10] Responding to the question of whether any of these phthalates pose a safety concern, EFSA concluded “current exposure to these five phthalates from food is not a concern for public health.”

As a result, DINP and DIDP continue to be permitted for use in food contact applications in the European Union.

Other regulatory agencies that have confirmed the safety of DINP and DIDP in food contact applications include the Food Safety Authority of Ireland (FSAI),[11] Food Standards Australia and New Zealand (FSANZ),[12] the New Zealand Ministry of Primary Industries (MPI)[13] and the UK Food Standards Agency (FSA).[14]

We Cannot Rely on Misguided Measures

Promoting chemical safety is a shared responsibility throughout the value chain, and also provides an opportunity for collaboration among chemical manufacturers, brands, retailers, and others to develop safe, effective products that meet consumer needs. These potential restrictions put manufacturers at a distinct disadvantage and they will be forced to either drastically change their products or opt for more expensive materials causing major market disruptions and increased production costs.

It is critical to take into account the significant differences among the many compounds that are part of a chemical family. Rather than using a one-size-fits-all approach, a fact-based discussion about the nature of these substances, how they differ from each other, and what they do affect – and what they don’t – should determine the risks, if any, to human health and the environment. We need to insist these misguided measures are not enacted into law.

[10] FAQ: phthalates in plastic food contact materials | European Food (europa.eu).

[11] Report on a Total Diet Study carried out by the Food Safety Authority of Ireland.

[12] Survey of plasticisers in Australian foods.pdf (foodstandards.gov.au).

[13] Occurrence and risk characterisation of migration of packaging chemicals in New Zealand foods (mpi.govt.nz)

[14] Microsoft Word - phthalates statement 04-11.docx (food.gov.uk).