Landscape Analysis of Drivers, Enablers, and Barriers to Plasticizer Substitution

DECEMBER 2021

A REPORT FOR

GREEN CHEMISTRY & COMMERCE COUNCIL

Acknowledgements

This report was produced by the Sustainable Chemistry Catalyst for the Green Chemistry & Commerce Council (GC3), a multi-stakeholder business collaborative whose members include major brands, retailers, chemical suppliers, and innovative startups, across sectors. The GC3 drives large scale commercial adoption of safer, sustainable, high-performing chemical solutions by fostering value chain collaboration, cultivating first-movers, convening industry decision-makers to secure major commitments, and creating a supportive policy environment.

Special thanks to the Lead Author, Amanda Cattermole of Cattermole Consulting; Joel Tickner, Rachel Simon, and Monika Roy of the Lowell Center for Sustainable Production at University of Massachusetts Lowell; and Monica Becker of Monica Becker Associates.

Contact

Find this document online: www.greenchemistryandcommerce.org/publications

The Sustainable Chemistry Catalyst is an independent research and strategy initiative, based at the Lowell Center for Sustainable Production (University of Massachusetts Lowell), focused on accelerating the transition to safer, more sustainable chemistry through research and analysis, and stakeholder engagement with scientists, policymakers, and commercial actors. The Catalyst works to understand barriers and opportunities to commercialization of safe and sustainable chemistry, identifies model solutions and strategies, develops methods to evaluate safer alternatives, and builds a community of expertise to support the transition to safer, more sustainable chemistries and technologies.

University of Massachusetts Lowell
Sustainable Chemistry Catalyst at the
Lowell Center for Sustainable Production
600 Suffolk Street, Suite 520
Lowell, MA 01826-2874
(978) 934-2997
www.uml.edu | www.sustainableproduction.org

UMASS University of Massachusetts Lowell

Lowell Center for Sustainable Production
UNIVERSITY OF MASSACHUSETTS LOWELL

EXECUTIVE SUMMARY

Purpose

The goal of this report is to identify barriers and enablers to the adoption of green and sustainable chemistry that can be effectively leveraged to accelerate commercialization and adoption actions in the future. The report focuses on identifying factors that have led to the successful substitution of plasticizers in some product categories and to understand what is holding substitution back in others.

Method

The GC3 framework for this analysis captures a broad universe of factors that can drive, enable, or serve as barriers to substitution. This framework was designed to understand what motivated substitution (a retrospective analysis) as well as to understand why substitution is not occurring for specific chemical in specific product categories or sectors (a diagnostic analysis).

To develop the framework, the GC3 drew on its experience in green chemistry innovation and adoption, chemical substitution, prior GC3 research including an analysis of alternative plasticizers, and the expertise of the GC3 Plasticizer Workgroup members, comprised of experts from companies along the plasticizer value chain, service providers, and other stakeholder organizations.

The framework was first used to conduct three case studies focused on product categories where plasticizer substitution has occurred widely. The researchers then applied the framework to two additional product categories to identify barriers and the lack of sufficiently strong drivers that are preventing substitution in those categories.

Case study information came primarily from interviews with industry experts along with literature reviews.

The three product category case studies where substitution of plasticizers has occurred widely are: i) luxury vinyl tile, ii) screen printing on apparel, and iii) inflatable polyvinyl chloride (PVC) toys. Two product category case studies for which substitution has largely not occurred are: i) garden hoses and ii) intravenous therapy fluid delivery products (IV FDPs).

What does this research tell us about the factors that have led to successful plasticizer substitution in luxury vinyl tile, screen printing and inflatable toys?

Given the technical challenges, cost, and potential for supply chain disruption, strong and clear drivers are needed for chemical substitution to occur, and these drivers can be closely interconnected. Brand action, customer expectations, non-governmental organization (NGO) action, and regulations were identified as important drivers for substitution in the three case studies where substitution is widespread. The availability of suitable substitutes was a key enabler.

Brand action: For product categories with strong brand awareness such as apparel, and to a certain extent, luxury vinyl tile and inflatable toys, brand action appeared to be the key driver because protecting brand reputation and minimizing company risk were considered critically important.

Customer expectations: Customers increasingly want more than quality alone and are looking for products and brands that align with their personal values. They want to spend their dollars on products that are healthy for them and their families.

NGO campaigns: NGO campaigns have successfully catalyzed substitution because they threatened brand and retailer reputation.

Regulations: Plasticizer substitution in toys and to some degree in apparel was driven by regulation, with Europe leading the way in policy action. However, some toy companies switched to alternatives prior to regulations to minimize company risk based on an understanding of emerging drivers.

Availability of suitable substitutes: In all three cases, suitable plasticizers were available for substitution, i.e., available alternatives performed adequately and met cost requirements, although in some cases, new supply networks were required. As with any formulation change, significant time and investment was required to reformulate and qualify products with new plasticizers, though this varied among the cases.

What is preventing substitution in other product categories?

Although there is some substitution in garden hoses and IV FDPs, drivers do not appear to be sufficiently strong or consistent to significantly motivate substitution. Lack of brand recognition and reputation, combined with limited policy drivers and low relative cost of incumbent plasticizers, could underlie the slow substitution in these categories. Consumers may not have strong knowledge of garden hose brands and are not often involved with the purchasing decisions of IV FDPs, and as such cannot exercise brand preference. In the case of IV FDPs, substitution may be hindered by lack of clear FDA policy and hospital purchasing, where experience with specific products and cost drive decisions.

What does this analysis tell us?

This analysis demonstrates that the substitution process is complex (beyond just identifying an alternative) and that the enablers and barriers are often context dependent.

Several key lessons from the cases:

- Strong drivers are needed to motivate action. Such drivers create a “pressurized” system that can overcome the incumbency of existing technologies that are cost-effective and highly integrated into the value chain.
- Barriers must be clearly identified and addressed. A detailed understanding of barriers to change enables effective strategies and interventions to facilitate substitution.
- Sectoral and supply chain collaboration can overcome barriers to change. Such collaboration amplifies the demand signal for substitution, promotes greater understanding of drivers and barriers, and addresses technical impediments to substitution.
- A clear, nuanced understanding of enablers and barriers can support executive level commitments across the value chain that pull through green and sustainable chemistry options.

TABLE OF CONTENTS

INTRODUCTION

The Green Chemistry & Commerce Council (GC3) is a multi-stakeholder collaborative that drives the commercial adoption of green chemistry by catalyzing and guiding action across all industries, sectors, and supply chains. GC3's members include major brands, retailers, chemical suppliers, and innovative start-ups, across sectors. The GC3 envisions a global economy where all chemicals, materials, and products are safe and sustainable throughout their lifecycle. The GC3 drives large scale commercial adoption of safer, sustainable, high-performing chemical solutions by fostering value chain collaboration, cultivating first-movers, convening industry decision-makers to secure major commitments, and creating a supportive policy environment.

The goal of the GC3 Collaborative Innovation Program is to advance R&D, commercialization, scaling, and adoption of green chemistry technologies. The program creates opportunities for precompetitive collaboration to accelerate innovation where companies making and selling products have common green chemistry technology needs. The GC3 engages the entire supply chain in this work and connects innovators to development and commercialization partners.

Criteria to select topics for GC3 Collaborative Innovation projects, include:

- Potential for a beneficial impact on a health or environmental problem, by accelerating innovation and adoption of safer chemistries
- Strong regulatory/market pressure for substitution
- Pre-competitive space for product manufacturers/brands and retailers
- Alignment with other GC3 efforts (e.g., Retailer Leadership Council (RLC), a group of 14 major retailers) and general interest within the GC3 member community

Based on these criteria, and identification by GC3 members as an innovation priority, plasticizers were identified as a good candidate for the GC3 Collaborative Innovation Program.

This Landscape Analysis was recommended by the GC3 Plasticizer Workgroup at a Collaborative Innovation Workshop on Plasticizers on March 5, 2019, hosted by the Target Corporation. The workshop was designed to understand market drivers for the adoption of more sustainable plasticizers, learn about alternatives to ortho-phthalates, and to identify collaborative GC3-led activities that will advance the adoption of alternatives.

One of the outputs of the workshop was a recommendation to conduct a landscape analysis to identify what is driving successful substitution of (adoption of alternative) plasticizers in certain product categories and what is holding back substitution in other categories.

Purpose of the Report

The purpose of this report was to identify factors enabling successful plasticizer substitution in specific product categories and understand what is holding back substitution in others.

Method

The GC3 analytical framework developed for this effort captures a broad universe of factors that could drive, enable, or serve as barriers to substitution/adoption of alternative plasticizers or technologies. This framework is general and not specific to plasticizers. It was designed to help build a nuanced understanding of why substitution occurred (a retrospective analysis) and to understand why substitution is not occurring for specific chemical categories in specific product categories or sectors (a diagnostic analysis).

To develop the framework, the GC3 drew on its experience in green chemistry innovation and adoption, chemical substitution, prior research conducted by the GC3[1], and the expertise of the members of its Plasticizer Workgroup, comprised of experts from companies along the plasticizer value chain, service providers, and other stakeholder organizations.

This framework was first used in three case studies focused on product categories where plasticizer substitution has occurred widely. The researchers then applied the framework to two additional product categories to identify barriers and the lack of sufficiently strong drivers that are preventing substitution in those categories.

The case study information is based on interviews with industry knowledge experts and literature review.

The three product category case studies where substitution of plasticizers has occurred widely are: i) luxury vinyl tile (LVT), ii) screen printing on apparel, and iii) inflatable PVC toys. The two product category case studies for which substitution has largely not occurred are: i) garden hoses and ii) IV fluid delivery products (FDPs).

The Framework for Case Study Analysis

The GC3 framework elements to examine enablers and barriers to the adoption of plasticizer alternatives are:

Drivers – drivers are internal or external factors that push substitution action on the part of the company

- Brand culture or action captures actions taken by brands that helped to catalyze substitution in the wider product category. This driver addresses corporate culture and public commitments, risk and reputational considerations, stakeholder engagement,

[1] Tess Fennelly & Associates, https://greenchemistryandcommerce.org/documents/Advancing-Green-Chemistry-Report-June2015.pdf

management, and implementation of a Restricted Substances List (RSL) and/or chemical management policies.

- **NGO pressure** captures NGO campaigns that demand action from brands and retailers, such as the elimination of chemicals of concern from product manufacturing or products on store shelves.
- **Retailer culture or action** captures actions such as retailer commitments and policies to eliminate certain priority chemicals. This driver encompasses actions driven by corporate culture, NGO pressure, and other market factors.
- **Regulations** capture government policies that restrict particular substances or drive substitution actions. A brand or retailer may proactively restrict a chemical even if a particular chemicals policy does not apply to the product or product category that they market and sell, for reputational reasons or to minimize risk.
- **Consumer pressure** captures substitution actions driven by pressure from individual consumers or consumer communities that gather and express their views in blogs, in other online forums, or in purchasing decisions. This also distinguishes whether a product is consumer-facing to individual or institutional purchasers. Often consumer pressure is driven by NGO pressure or NGO pressure is presented as consumer pressure – though it may not always originate directly from consumer concerns – so these drivers frequently run in parallel.
- **Industry standards** captures actions that are driven by voluntary standards developed by companies and organizations in industry or product sectors.
- **Green standards and certifications** capture actions driven by third-party standards and product certifications that are designed to be consumer-facing, such as Cradle-to-Cradle Certified™ and others that apply to manufacturing and the supply chain, such as bluesign®.

Key enablers/barriers – enablers are factors that support the pull-through of alternatives; barriers are factors that hinder substitution

- **Chemical performance and track record** captures whether one or more alternatives are available that meet performance requirements and have a history of successful use in a product category. An alternative's effective performance in one product category can be an enabler for substitution in another product category. Successful engagement of chemical producers as key stakeholders in identifying and evaluating alternatives can support the pull-through of alternatives.
- **Safety and availability of safety data** captures whether available substitutes are considered safer compared to incumbents. This includes whether toxicity data and robust safety assessments are available to companies for their substitution decision-

making and are publicly available and convincing to NGOs and other stakeholders and influencers.

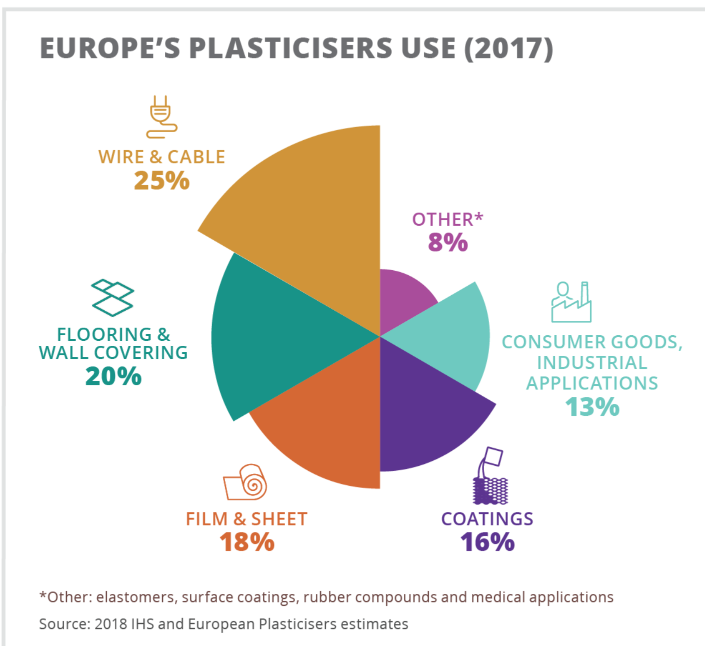
- **Cost** captures whether substitutes are available at a price that is acceptable or tolerable to companies making substitution decisions.
- **Scaling** captures whether there is and will continue to be a dependable and adequate supply of the desired alternative.
- **Multiple suppliers** relate to scaling and captures whether there is more than one supplier of alternatives, which gives product manufacturers greater confidence in supply and price.
- **Switching process, costs, and time** captures the relative complexity, time, effort, and resources required to switch manufacturing and supply chain over to a new alternative, including whether the alternative is a drop-in replacement or requires reformulation and new equipment.
- **Transparency** captures whether a brand or retailer sourcing materials, components, and products from its supply chain is given full, adequate ingredient information. Having this information enables substitution; not having it is considered a barrier.

AN OVERVIEW OF PLASTICIZERS

Plasticizers are relatively non-volatile organic substances (mainly liquids) defined by the International Union of Pure and Applied Chemistry (IUPAC) as "a substance or material incorporated in a material (usually a plastic or elastomer) to increase its flexibility, workability, or distensibility"[2].

They are used in many consumer products and product categories, but the dominant application is to soften plastic, mostly polyvinyl chloride (PVC). According to European Plasticisers, a sector group of the European Chemical Industry Council (CEFIC), over 85% of all plasticizers consumed in Europe are used in flexible PVC applications, largely for the construction, automotive, and wire and cable sectors. Plasticizers are also used in toys, apparel, and many other product categories (**Figure 1**).

FIGURE 1
European plasticizer use by product category



Plasticizers are usually classed based on their chemical structure. The most common plasticizers are shown in the table below (**Table 1**). Many plasticizers that are available today can be used for a wide array of different product categories.

Appendix 1 contains a list of plasticizers and their acronyms.

[2] C. E. Wilkes, J. W. Summers, C. A. Daniels, PVC Handbook, Akron, Ohio, 2005.

TABLE 1
Composition of typical plasticizers

Plasticizer	Composition and Production Route
Ortho-phthalate esters (or simply ortho-phthalates)	Produced by esterification of phthalic anhydride or phthalic acid obtained by the oxidation of orthoxylene or naphthalene. Can be further broken down into low molecular weight (LMW) ortho-phthalates and high molecular weight (HMW) ortho-phthalates. **LMW –** 3-8 carbon atoms in their chemical backbone. Commonly used in medical devices, general-purpose PVC, adhesives, inks, and cosmetics. There is greater concern about the potential toxicity of LMW ortho-phthalates compared to their longer-chain counterparts (DEHP, DIBP, DBP). **HMW –** 9-13 carbon atoms in their chemical backbone. Commonly used in PVC products such as wire and cable, flooring, wall coverings, self-adhesive films, synthetic leather, coated fabrics and roofing, and automobile applications (DINP, DIDP).
Terephthalates	This family of plasticizers is isomeric with the ortho-phthalates, using terephthalic acid or dimethyl terephthalate as the starting material instead of phthalic anhydride. The main terephthalates are DEHT (also known as DOTP), used as an alternative to DEHP and DINP, and DBT, used as an alternative to DBP and DIBP.
Aliphatic dibasic acid esters	These include chemicals such as glutarates, adipates, azelates, and sebecates. They are made from aliphatic dibasic acids such as adipic acid and alcohols.
Cyclohexanoates	An esterification based on cyclohexanoic acid.
Benzoate esters	Esterification products of benzoic acid and selected alcohols or diols.
Trimellitate esters	Produced by esterification of trimellitic anhydride (TMA) and typically C_8-C_{10} alcohols.
Polyesters	Formed by reacting dicarboxylic acids and difunctional alcohols.
Citrates	Tetraesters, resulting from the reaction of one mole of citric acid with three moles of alcohol. Citric acid's lone hydroxyl group is acetylated.
Bio-based plasticizers	Based on epoxidized soybean oil (ESBO), epoxidized linseed oil (ELO), castor oil, palm oil, or other vegetable oils, starches, sugars, etc.
Others	Includes phosphates, chlorinated paraffins, succinates, alkylsulfonates, acetylated glycerides, sulfonamide, and polyol esters.

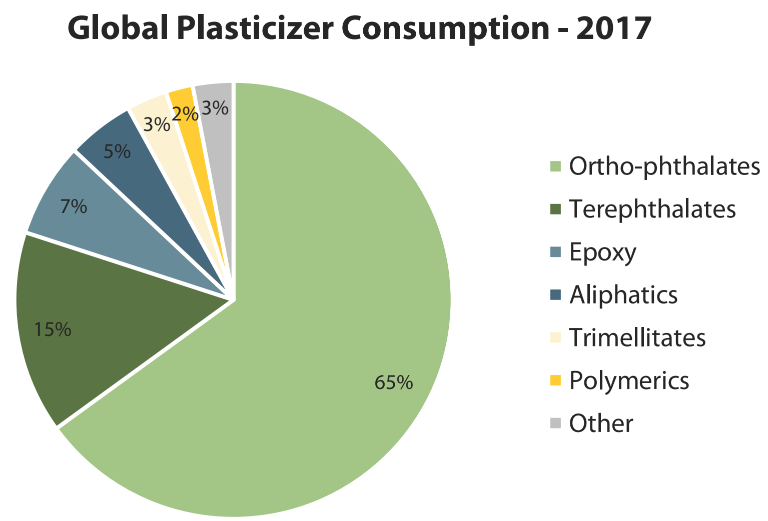
Sources: Special Chem – Polymer Additives; European Plasticisers (a sector group of CEFIC)

Trends in Plasticizer Production and Use

Figure 2 shows the world consumption of plasticizers by type in 2017 and **Figure 3** shows the predicted assortment in 2022. Ortho-phthalates are expected to decrease in market share by 5% between 2017 and 2022, possibly due to market pressures and regulations, and other plasticizers, such as terephthalate, trimellitates, and polymerics, are expected to see increased use.

FIGURE 2

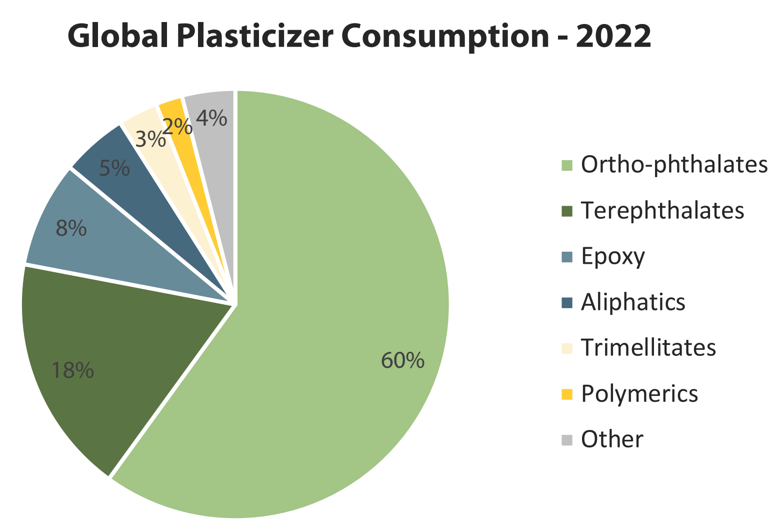
World consumption of plasticizers by type in 2017



Source: [2018 Chemical Economics Handbook Plasticizers report, IHS Markit]

FIGURE 3

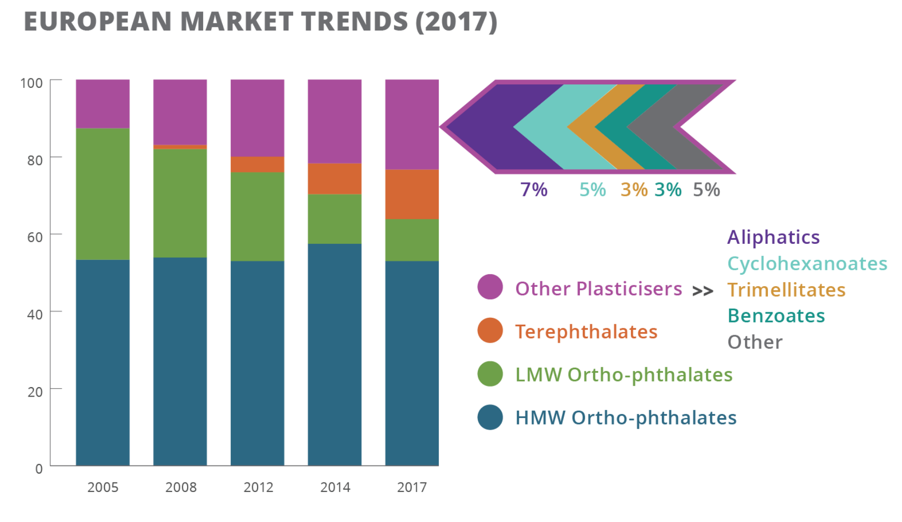
Predicted world plasticizer consumption by type in 2022



Source: [2018 Chemical Economics Handbook Plasticizers report, IHS Markit]

Figure 4 shows European trends in the types of plasticizers used. There has been a gradual decrease in the use of low molecular weight ortho-phthalates like DEHP and an increase in "other" plasticizers that include benzoates, cyclohexanoates, etc.

FIGURE 4
European market trends of plasticizers



Source: 2018 IHS and European Plasticisers estimates

Ortho-phthalates will continue to account for most global plasticizer consumption and remain at approximately 60–65% of the market. However, there is a slight downward trend in volume due to the following:

- Growth of the market for non-ortho-phthalate plasticizers and the ability of these to meet necessary performance requirements.
- Ongoing pressure from retailers and large purchasers to limit the use of ortho-phthalates, especially in developed regions.
- Increasing government regulations targeting specific phthalates or the entire class of ortho-phthalates in specific product categories. Non-ortho-phthalates are expected to continue to grow in the future because they can address some of the health concerns facing some ortho-phthalates and meet the necessary performance requirements.

World consumption of other plasticizers is forecasted to grow at an average annual rate of 5-8% during 2017–2022. Economic and technical performance will be an important indicator of future demand for specific plasticizers, which can be affected by raw material costs and access to low-cost feedstocks.

Government Regulations

Due to concerns about human exposure and toxicity, some ortho-phthalates, mostly lower molecular weight ortho-phthalates, have been under the regulatory spotlight for more than two decades. For example, the European Union (EU) regulated six ortho-phthalates in 1999 in childcare articles, with the United States (U.S.) issuing similar regulations in 2008. Within Europe, Denmark addressed all ortho-phthalates as a class rather than just a select few. Several U.S. states have regulated phthalates in children's articles and other products.

Toys and childcare articles[3] were initially the focus for restrictions due to concerns about children's exposure, although the actual products that fit within the definition of childcare articles is somewhat left for interpretation. For example, Nike® and many to some apparel companies interpreted that a childcare article should include printed pajamas because a child could suck on their pajama sleeves to lull them to sleep.

Table 2 provides a high-level overview of select government regulations on phthalates globally. The table shows that ortho-phthalates are increasingly being regulated in an expanding number of product categories.

TABLE 2

Phthalate regulations

Year	Regulation
1999	EU temporary restrictions on 6 ***ortho-phthalates*** plasticizers in toys and childcare items. These include: BBP: Butyl benzyl phthalate DBP: Dibutyl phthalate DOP/DEHP: Di-2-ethylhexyl phthalate DIDP: Diisodecyl phthalate DINP: Diisononyl phthalate DNOP: Di-n-octyl phthalate
2008	Several ortho-phthalates are listed as reprotoxic category 1B substances under EU Regulation (EC) 1272/2008 – Classification, Labeling and Packaging of Substances and Mixtures (CLP Regulation). These include: BBP, DEHP, DBP, DIBP, and Bis-(2-methoxyethyl) phthalate. U.S. Congress permanently prohibited children's toys or childcare articles containing concentrations of more than 0.1% of DEHP, DBP, or BBP though the Consumer Product Safety Improvement Act of 2008 (CPSIA), including restrictions on six ortho-phthalates in toys and childcare items. On October 27, 2017, the U.S. Consumer Product Safety Commission issued a final ortho-phthalates rule (16 CFR part 1307) making permanent the interim prohibition on children's toys that can be placed in a child's mouth and childcare articles that contain concentrations of more than 0.1% of DINP.

[3] A childcare article is a consumer product that is designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help children age 3 and younger with sucking or teething

	The first Substances of Very High Concern (SVHC) list under the EU's Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) regulation included DBP, BBP, and DEHP. Substances on the SVHC list are subject to the authorization process under REACH.
2010	DIBP added to EU SVHC candidate list–Diisobutyl phthalate
2011	C_6-C_8P added to EU SVHC candidate list–Diisoheptyl phthalate C_7-C_{11}P added to EU SVHC candidate list–Di C_7-C_{11} phthalate
2012	DPP added to EU SVHC candidate list–Dipentyl phthalate
2013	DHP added to EU SVHC list–Dihexyl phthalate (To date, nine ortho-phthalates have been identified as Substances of Very High Concern, and four are included in the EU Authorisation process (DEHP, DBP, BBP, DIPB) DINP added to CA Prop 65 –Diisononyl phthalate Korea restrictions on 6 ortho-phthalates
2014	China and Hong Kong restrictions on 6 ortho-phthalates
2015	DINP proposed classification by Denmark as a reproductive toxicant (Repro Cat 1B) according to CLP, the EU implementation of the Globally Harmonized System. In 2018, the ECHA's Risk Assessment Committee (RAC) concluded that the data on DINP do not warrant classification as toxic to reproduction. DEHP, DBP, BBP, and DiBP added to updated Restrictions on Hazardous Substances in electronics (RoHS) restrictions.

NGO Campaigns Targeting Plasticizers

Several nonprofit advocacy groups have established campaigns calling for the replacement of ortho-phthalates individually, or as a class, in a range of consumer products.

NGO campaigns often speak directly to consumers and may target specific brands or retailers, through testing or specific actions. As a response, targeted brands and/or retailers are motivated to address and respond to the campaigns to protect their brand reputation and minimize company risk. Some of these campaigns include:

Safer Chemicals, Healthy Families Mind the Store

Mind the Store, now in its fifth year, ranks retailers on how they address toxic chemical concerns. The campaign challenges the largest retailers to eliminate toxic chemicals in products and packaging and to develop comprehensive safer chemicals policies. Every year, a scorecard of retailers is published based on a set of criteria and scoring algorithms.

The campaign recently published an update of its 2015 report showing how home improvement retailers have followed through on commitments to remove ortho-phthalates from flooring. In

2015, 58% of 65 vinyl floor tiles tested contained phthalate plasticizers. This sparked action, initially by Home Depot, to eliminate ortho-phthalates, as a class of chemicals, from flooring by the end of 2015. By 2019, samples tested from Home Depot, Lowes, and Lumber Liquidator did not contain ortho-phthalates. This type of retailer leadership can successfully cascade across a whole product category.

Health Care Without Harm

Health Care Without Harm (HCWH) is an international coalition of advocates, health professionals, and health organizations focused on reducing the healthcare sector's environmental and health footprint. HCWH initially targeted mercury and phthalates for substitution in hospital settings, publishing or commissioning several reports on the health risks of phthalates in medical devices and potential alternatives.

Greenpeace Detox Fashion and ZDHC

Greenpeace began advocating for the replacement of phthalates in toys and other articles in the 1990s through its Toy Campaign. In 2011, its Detox Fashion campaign targeted large apparel brands and retailers to eliminate hazardous chemicals in textile and leather manufacturing by 2020, with all ortho-phthalates included as one of the 11 classes of chemicals identified for action. The campaign led to the formation of the Zero Discharge of Hazardous Chemicals (ZDHC), a group of apparel and footwear brands and retailers working together to lead the industry towards zero discharge of hazardous chemicals by 2020.

ZDHC manages "input chemistry" via a Manufacturing Restricted Substances List (MRSL) and tests wastewater to verify that MRSL-conformant chemical formulations are used in textile manufacturing. After eight years of data collection, ZDHC published an Impact Report in 2019 showing that for an 18-month monitoring period, over 98% of manufacturing facilities that followed the ZDHC approach and used ZDHC tools had no detection of MRSL analytes, including ortho-phthalates.

Ecology Center, Healthy Stuff

Healthy Stuff is a project of the Ecology Center, a Michigan-based nonprofit environmental organization that tests household items for toxic chemicals and reports on its findings. It is based on research conducted by environmental health organizations and other researchers. For example, in 2011, 2012, and 2013, the Ecology Center tested over 200 garden hoses from national retailers. The hoses were tested for heavy metals and bromine, and a subset was tested for ortho-phthalates.

In 2016, a follow-up report tested 32 hoses, of which 24 were PVC. The other eight were various types of polyurethane, synthetic rubber, and other polymers. The results showed that PVC garden hoses frequently contained ortho-phthalates in addition to other contaminants. These included DIBP, DBP, DEHP, DINP, DPHP, and DIDP. Hoses labeled as “drinking water safe” did not contain heavy metals and were less likely to contain ortho-phthalates. It should be noted that 63% of the PVC garden hoses contained dioctyl terephthalate (DEHT/DOTP), a non-phthalate alternative to DEHP. Some hoses contained multiple ortho-phthalates which suggests the hoses may have contained recycled PVC.

Retailer Initiatives Targeting Plasticizers

Many leading U.S. retailers are addressing plasticizers, due to both consumer and NGO pressures and emerging regulations. For example, Lowes stopped selling all flooring containing ortho-phthalates in 2015 and The Home Depot® safer chemicals policy commits to restricting flame retardants, PFAS, and ortho-phthalates in certain products, including paints, vinyl and laminate flooring, carpet, and insulation. In January 2019, Kingfisher plc pledged to restrict all ortho-phthalates in its own branded products by 2025 as part of their Chemicals Roadmap.

SUMMARY OF CASE STUDIES WHERE SIGNIFICANT SUBSTITUTION HAS OCCURRED

In all cases, the GC3 framework for examining enablers and barriers to adoption was completed via online research and through individual interviews. Below is a summary of each case study, while full case studies can be found separately on the GC3 website.

Luxury Vinyl Tile

Product overview

Luxury vinyl tile flooring (LVT) is made as either glue-down or floating tiles and/or planks. Four distinct layers are fused: a resilient vinyl backing, a vinyl photographic film layer, a performance wear layer, and a urethane or aluminum oxide top layer for wear/scratch resistance.

Consumers favor LVT because it is easy to install and has attractive visuals. LVT has photo-realistic 3-D graphics that simulate natural wood or stone. It is highly durable and provides the promise of no/low maintenance.

LVT experienced rapid market penetration and growth in the U.S. starting in 2012, when big box stores began to carry the product. From 2012 to 2015, the market grew from nothing to become the number one flooring material sold.

Early LVT products were developed with DEHP and DINP. DEHP was dominant in products manufactured in Asia because it was significantly cheaper and a more efficient plasticizer than DINP. Less DEHP is needed to provide the same performance. The substitution factor for DINP vs. DEHP is 1.06, meaning that DINP is 6% less efficient in its plasticizing capability than DEHP.

Tarkett, a large flooring company, was the first company to manufacture LVT in the U.S. in 2011, and the company developed their first product with DEHT/DOTP, an ortho-phthalate-free plasticizer. This means that switching to an alternative was not an issue given that they did not use an ortho-phthalate in the first place. The company was able to design its production processes from the ground up for use with alternative plasticizers.

Summary of drivers

Three main drivers led Tarkett, and eventually the category, to non-ortho-phthalate plasticizers: brand action and culture, NGO pressure, and retailer action. Regulations were an indirect factor.

Brand action and culture. In 2010/2011 Tarkett selected DEHT/DOTP and DINCH in their LVT when customers asked them to avoid ortho-phthalates. Tarkett applied the precautionary principle and selected alternative plasticizers that were already used for toys. Toxicological studies existed and showed no risk for applications of the alternatives in LVT. Other manufacturers followed suit and by 2014, most U.S. LVT producers used non-phthalate plasticizers.

NGO pressure. Many NGOs have actively addressed ortho-phthalates in flooring. In 2014, the Healthy Building Network (HBN) released its research brief *Phthalate-free Plasticizers in PVC*. In 2015, NGOs released testing results of vinyl floor tiles sold at U.S. home improvement retailers. 58% of tested vinyl floor tiles contained ortho-phthalates. Most were lower-cost LVT flooring that contained DEHP and were manufactured and supplied by Asian companies. Between 2014 and 2016, NGOs met with large U.S. retailers and challenged them to eliminate ortho-phthalates.

Retailer action. In April 2015, Home Depot announced that it would discontinue the use of phthalates in vinyl flooring by the end of the year and very quickly, Lowe's, Lumber Liquidators, Menards, and Ace Hardware followed suit. In 2019, Kingfisher plc released their Sustainable Chemicals Roadmap, which committed to the phase-out of ortho-phthalates from their own-brand products by 2025.

Regulations. Although not a key driver, the CSPC's 2008 restrictions on phthalates in children's toys was a factor in Tarkett's decision to formulate their new LVT products without phthalates.

Summary of enablers

Performance. There was a track record of the acceptable performance of DEHT/DOTP and DINCH in the toy industry. For Tarkett, the performance of DEHT/DOTP was acceptable for investment but required significant resources to develop an LVT product with sufficiently good performance characteristics.

Safety. Given that DEHT/DOTP and DINCH were used in the toy industry and not regulated and based on analysis of the available data and comparative assessments, the general consensus by authorities and other organizations was that they were safe for use in LVT.

Cost. In 2011, the costs of DEHT/DOTP and DINCH were similar to DINP, the plasticizer that was used in the U.S. DEHP was more widely available in Asia, and the manufacturing cost in Asia was lower.

Quantity/Scale/Suppliers. There was already a supply of DEHT/DOTP and DINCH. In 2010, when Tarkett switched to DEHT/DOTP for the U.S. market and DINCH for the EU, there was only one supplier for each. This created some risk for early adopters; however, supply grew in 2014/2015 along with the market for LVT.

Switching process, costs, & time. Reformulation was required in some cases. For example, LVT manufacturers that switched to DEHT/DOTP reformulated some products to include non-phthalate fast-fusing plasticizers like dibenzoate, which took time and money to test but ultimately lowered the processing temperatures and press pressures required[4].

Conclusions

For the U.S. market, the switch to alternatives is essentially complete. NGO actions were a key driver. All segments of the vinyl flooring industry have switched to non-phthalate plasticizers or to different resins where plasticizers are not needed.

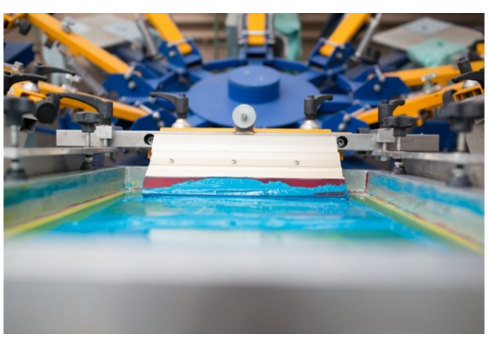
In addition to the drivers above and the availability of alternatives, there was cooperation along the value chain between LVT producers and the chemical suppliers of DEHT/DOTP and DINCH.

The barriers to substitution were minimal, mainly technical in nature (processing challenges), and were addressed through significant in-house research and collaboration with suppliers.

Screen Printing with Plastisol Inks on Apparel

The elimination of plasticizers in screen printing inks was achieved by either eliminating PVC entirely or by replacing the plasticizer in plastisol inks.

Product overview



Screen printed textiles are commonly printed with plastisol ink, a suspension of polyvinyl chloride (PVC) or other polymer particles in a liquid plasticizer. The PVC is mixed with approximately 40% plasticizer to make it resemble and flow like a thick viscous liquid.

The invention of plastisol ink in the 1970s enabled screen printers to run more complex designs, print on any type of garment, and run mass production effectively. Plastisol inks will not dry at room temperature and require curing at 180 °C. When

[4] "Dibenzoate Plasticizers Offer a Safer, Viable Solution to Phthalates", Shamsi P. Gravel and Emily McBride (2010), Adhesivess and Sealants Industry Magazine, https://www.adhesivesmag.com/articles/88751-dibenzoate-plasticizers-offer-a-safer-viable-solution-to-phthalates

the curing temperature is reached, the PVC dissolves, and the mixture turns into a viscous gel that forms a flexible, permanently plasticized solid product when cooled to 60°C.

Plastisol inks offer many advantages to the printer, the brand, and the consumer. They are not water-soluble and will not dry if left on the screen for extended periods. Ink can be quickly flashed and stacked on top of itself, thus producing complex designs. Printed garments do not need to be washed after printing, and plastisol inks are often used to print on colored fabric due to the high-quality resulting print.

The most common plasticizers that were used historically were DEHP and DINP due to their low cost and effective plasticizer function.

Summary of drivers

Three main drivers led to the phase-out of plastisol inks in screen printing: brand culture and action, NGO pressure, and regulations. In this case, brand action – through restricted substances lists – was a key factor.

Brand culture and action. Many of the most recognized global brands are apparel brands. These brands are part of a very large product sector where consumer purchasing decisions may partly depend on brand reputation; therefore, protecting brand reputation and minimizing company risk is very important. A complete shift away from regulated ortho-phthalates and PVC was one way to ensure brand reputation remained intact, given increasing consumer and regulatory pressures. Additionally, at the time substitution was occurring, some brands were facing negative press from a variety of other issues such as worker safety and fair pay, and hence sensitivity was high.

NGO pressure. NGO pressure and regulations created the tipping point for many brands to phase out PVC and plastisol inks. In the 1990s, Greenpeace USA started its PVC: The Poison Plastic campaign that impacted the fashion industry. In Europe, the 1999 ortho-phthalate regulations in toys caused several brands to be cautious and apply these regulations to apparel, especially as apparel could be interpreted to fall under the regulation. In 2011, the Greenpeace Detox Fashion Campaign pressured brands to meet ZDHC by 2020 for eleven classes of chemicals, including all ortho-phthalates.

Regulations. Regulations provided an additional impetus for the gradual, but decisive move away from a plastisol-dominant market. In 1986, California passed Proposition 65, which requires the state to publish a list of chemicals known or suspected to cause cancer or reproductive impacts. Some ortho-phthalates are on that list.

In 1999, the EU restricted 6 ortho-phthalate plasticizers in toys and childcare items. Screen printed apparel could potentially fit into these regulations, although apparel was not called out specifically. In 2008, some plasticizers were added to the SVHC list under REACH.

The 2008 U.S. Consumer Product Safety Improvement Act (CPSIA) was an important regulatory driver affecting the use of ortho-phthalates in textile inks for products made and sold domestically. However, this law does not ban or restrict the use of PVC or plastisol inks.

Summary of enablers

Performance. For alternative plasticizers**,** DEHT/DOTP replaced DEHP, although it is approximately 7% less efficient (i.e., more plasticizer is required, and some reformulation may be necessary).

Alternatives to plastisol inks. High solid acrylic (HSA) inks and polyurethanes are considered acceptable substitutes. Benzylcyclohexanones, Dibenzoates and DINCH are used as plasticizers in these inks. Initially, they were difficult to work with, but today, most of the common printing techniques can be accomplished with these materials. Significant development by printers was necessary and it was not a straightforward switch.

Safety data. If a replacement chemical is not on an RSL, it is generally considered by the industry as acceptable for use. Brands typically do not specify to their suppliers what chemicals to use, but rather what not to use. Eco-standards in the textile industry, such as bluesign® or OEKO-TEX®, have helped facilitate substitution. These programs are used by many brands, and they include assessments that guide the supply chain toward safer materials.

Cost. Alternative plasticizers are slightly more expensive than DEHP. HSA inks and polyurethanes are more costly than standard PVC plastisol and are substantially more expensive than other water-based inks, but they mimic plastisol inks better than other water-based inks. Substitution occurred in this product category despite slightly more expensive plasticizers.

Scale. No issues were identified with either type of replacement.

Switching process, costs, and time. The same equipment can be used with either replacement; however, for alternatives to plastisol inks, extra effort is required by the screen printer. These inks do not offer the same wet-on-wet print and bleed-blocking capabilities as PVC inks and because water-based inks eventually dry on the screen, many printers have two sets of screens that are rotated. As one set is used, the other is washed to remove drying ink.

Another challenge is color variation on fine mesh screens due to the drying effects of the inks and the clogging of meshes. This is largely overcome by rotating the two sets of screens.

Conclusions

For the U.S. and European markets, the switch to alternative plasticizers or non-plastisol inks is considered to be fairly complete, especially in the EU where the softer feel of water-based inks is preferable to plastisol. Today, approximately 90% of the production and goods sold in Europe are printed with water-based prints. Many inks meet eco-standards that do not allow ortho-phthalates, and ink manufacturers test for the presence of phthalates.

This is a collaborative industry that has tools such as RSLs and industry support such as collaborations between the Apparel and Footwear International RSL Management Group (AFIRM Group®), the American Association of Footwear and Apparel (AAFA), and ZDHC. Concerted sectoral and supply chain collaboration has helped accelerate the transition towards alternatives. However, plastisol ink is still used in screen printing and there is a chance that the switch to alternative inks is not exhaustive, especially in Asian production. Screen printing is a highly fragmented sector, and it is not possible to determine if all screen printing occurs with alternatives.

A significant amount of reformulation and testing was required, and the change did not occur overnight. Initial prints yielded poor results but the message to the chemical industry was clear. PVC and regulated ortho-phthalates were not an option for many major apparel brands.

Inflatable PVC Toys

Brand image is critical in the toy industry, with iconic products, such as Barbie, often representing the company and its image (the brand). This is less true in inflatable PVC toys, where no brand dominates the market. In the inflatables category, consumers look for a specific product type rather than a particular brand, though company image remains very important, and consumers can recognize certain brands when given visual clues.

Product overview

Inflatable PVC products are manufactured through the calendaring of PVC resin in combination with plasticizers and dyes. Thin, PVC sheets are cut, and radio frequency welded together to form airtight seals that allow toys and other merchandise to take form through inflation. These products are intended to be used in a wide variety of applications, including airbeds, boats, pool floats, children's ball pits, and so forth.

Scalability and consistency are very important to manufacturers because often the same PVC sheet is used for an adult airbed as a child's inflatable toy, meaning that the same plasticizer is used regardless of the product application.

DEHP was used historically and was replaced as early as 2005 with DEHT/DOTP because the two plasticizers are similar in cost and performance for this application, and DEHT/DOTP was readily available.

Summary of drivers

Regulation was the main driver for substitution in this product category, however, the transition happened before the 2008 U.S. law went into effect, most likely due to European and U.S. state-level regulatory actions, increasing NGO pressures on phthalates in toys, and increasing consumer awareness through media attention.

Brand action. Removing phthalates was a way to reduce company risk and perhaps simplify supply chains. It can take up to 18 months to transition towards new formulations, and getting a head start on "watch" chemicals is a strategy adopted by many companies to proactively manage company risk. Increasing pressure on PVC and phthalates from NGOs, particularly Greenpeace, led some toy manufacturers, such as LEGO®, to phase out ortho-phthalates in some or all uses as early as the late-1990s. Some toy manufacturers had significant challenges in finding alternative plasticizers and materials for some applications, such as roto-molded doll heads for iconic brands, as alternatives did not initially perform well and hence substitution took some time.

Regulations. Regulations in the EU and the U.S. catalyzed the substitution of DEHP and DINP with DINCH and DEHT/DOTP in PVC inflatables. In 2005, the EU introduced a phthalate restriction 2005/84/EC. This Directive prohibits the use of certain phthalates in the manufacturing of toys and childcare articles intended for children. The 2008 U.S. CPSIA also restricted phthalates in children's toys and childcare articles.

Summary of enablers

Performance. From a manufacturing standpoint, the switch to DEHT/DOTP was fairly seamless, offering no particular challenges. It met quality requirements and had similar performance to DEHP.

Safety data. Toy manufacturers relied on their chemical suppliers to conduct the necessary risk assessments and obtain the required toxicity data. DINCH and DEHT/DOTP are not restricted plasticizers under the laws mentioned above, and this was one reason that toy manufacturers switched to them.

Cost. Product cost initially increased because the costs of DINCH and DEHT/DOTP were slightly higher and new supply networks for the plasticizers had to be established.

Scale. DEHT/DOTP has been on the market for 40 years and therefore scale for this product category was not an issue when toy makers were making the switch. Additionally, the quantities used were relatively small.

Switching process. There were significant resources dedicated to trial production and testing to ensure that the required performance attributes were met, as the product must hold air without breaking. The manufacturers whose markets were primarily European tended to substitute with DINCH and DEHT/DOTP earlier and quicker (by 2005) given the previous implementation of European regulations, and a desire to minimize cross-contamination and avoid mistakes. Those whose markets were primarily in the U.S. tended to be slower to switch. In time, scale and increased efficiencies have improved and thus stabilized cost.

Conclusions

The EU and then the CPSIA ortho-phthalate regulations, which targeted children's toys, were the main drivers for substitution. The EU market took the first step and other regions soon followed. Global manufacturers adapted global production to meet these standards to remain competitive and protect company image. In the U.S., substitution is almost complete because the CPSIA regulation banned several ortho-phthalates in children's toys. In addition, brand action for some companies helped catalyze the substitution process for the whole inflatable PVC toy product category.

SUMMARY OF CASE STUDIES WHERE SUBSTITUTION IS STILL IN PROGRESS

Garden Hoses

Product overview

Garden hoses are typically made from rubber or soft plastic, usually PVC. The hose interior is often reinforced with an internal network of fibers to provide toughness, reinforcement, and strength.

PVC garden hoses are made with multiple layers of PVC. The PVC pellets, which contain a plasticizer and other additives, are mixed with pigments and then homogenized, melted, and extruded to form a tube that is cooled in a water bath. It is then cut to the correct length.

Garden hoses are designed to be flexible and smooth to facilitate pulling them past obstacles such as trees, posts, and steps. They must also be tough enough to withstand being stepped on, run over with a vehicle, or scraped against outside obstacles without causing leakage and damage. Also, they must be able to survive a range of temperatures from -30F to 120F and resist sunlight and biodegradation.

Some garden hoses are designed to carry potable water, and these are typically made from materials that have been tested and shown not to leach harmful chemicals into the drinking water. If a garden hose is NSF/ANSI 61 or NSF/ANSI 372 certified, it means the product meets certain safety standards to be used for drinking water.

The type of plasticizer used in garden hoses depends on the product manufacturer, and it may also depend on the region in which the product is made. Approximately 20 years ago, almost all PVC garden hoses were made with PVC/DEHP, given its excellent plasticizer performance and acceptable cost. Today, many U.S. manufacturers have transitioned away from DEHP to either DEHT/DOTP or DPHP, due to the similar cost and plasticizer performance when compared to DEHP.

The garden hose market is not dominated by one brand, and brand recognition is not required to drive volume.

Summary of drivers

Where plasticizer substitution in garden hoses has occurred, there do not seem to be specific key drivers that have catalyzed the process. Where U.S. manufacturers have decided to switch, it was likely due to general consumer awareness around plasticizers and possibly brand action to reduce company risk.

The Ecology Center published three reports in 2012, 2013, and 2016 with rules for testing the presence of chemicals of concern, including phthalates. In each report, some garden hoses tested positive for phthalates. However, unlike NGO activity on luxury vinyl tile, the report was not part of a concerted NGO campaign to pressure manufacturers or retailers to eliminate ortho-phthalates. It is unclear whether the report changed consumer, or even retail purchaser, buying habits.

Purchasing decisions for garden hoses are driven by performance and cost rather than brand loyalty and concerns over chemical safety. It is unlikely that consumers know that garden hoses are made from PVC, and this lack of awareness could be a potential reason why the whole category has not switched.

Campaigns like Mind the Store have not specifically targeted garden hoses (as compared to vinyl flooring), and many big-box retailers have not focused on phthalates in garden hoses.

It is unclear whether home and garden retailer policies, such as that of Lowe's, have impacted the market for phthaltes in garden hoses.

Regulation on phthalates does not appear to be an important driver of change for this product category.

Summary of enablers

For manufacturers that transitioned away from DEHP to DEHT/DOTP and DPHP, the performance, cost, and safety data were not a barrier. Plasticizers were chosen that were used in other product categories where toxicological studies indicating lower risk existed.

There are several alternative plasticizers available for use, and hence supply was not an issue, and the switching process did not involve significant cost.

Conclusions

Based on the 2016 report by The Ecology Center, a little more than 25% of the market switched to alternative plasticizers. However, this number may be higher because "drinking water safe" hoses do not contain DEHP or other regulated phthalates and many garden hoses are made from polymers other than PVC.

Notwithstanding the Ecology Center reports, there is no direct NGO pressure on garden hose manufacturers or retailers selling them and no targeted regulations to accelerate substitution. Therefore, there is little need for manufacturers and even retailers to pursue substitution to protect their reputation.

There is no strong driver for substitution but there are some important barriers, including:

- **Incumbency**. Much of the garden hose production is in Asia, where there is a long history of DEHP use, given its cost and effectiveness. Since DEHP-plasticized PVC garden hoses are not under significant consumer pressure or regulation, there is little incentive to substitute either plasticizers or material. Additionally, manufacturers may not have much power over reformulation as they are often not manufacturing the hose material but rather purchasing long lengths of spool from China that is cut to length and fitted with special fittings and sold as consumer garden hoses.
- **Safety**. There is a limited concern for safety and some manufacturers believe that DEHP is safe to use in garden hoses given that it is not regulated in this product category.
- **Lack of brand reputation challenges**. Since there is no clear brand recognition pressure in this product category, there has been less incentive to switch given limited pressure.

IV Fluid Delivery Products (FDPs)

Product overview

With more than 40 million intravenous (IV) infusions administered in the U.S. every month, IV FDPs are one of the most common medical products used in healthcare[5]. According to Global Healthcare Exchange data[6], approximately 35% of this product category has moved away from PVC and/or DEHP. There are some successful drivers, but the adoption rate is slow.

Intravenous delivery products deliver fluids (such as electrolytes and colloids) to the body. They consist of a bag, tubing, and other accessories. The fluid must be kept safe, clean, and sterile. IV blood bags are a separate category and represent a significant substitution challenge as the leaching DEHP plasticizer binds with red blood cells, significantly increasing the shelf life of the blood. However, the recently updated PVC chapters of the European Pharmacopoeia now list 4 alternative plasticizers (DINCH, DEHT/DOTP, TEHTM, and BTHC)[7].

IV FDPs are usually made from PVC. The plastic resin is blended, melted, and extruded into sheets that are fabricated into the IV FDP. Fluid is added, and the bag is sealed. It is sterilized, packed, distributed, and stored. Many quality assurance checks are completed before shipment.

[5] Saline Shortages – Many Causes, No Simple Solution, NEJM, April 19, 2018 - https://www.nejm.org/doi/full/10.1056/NEJMp1800347
[6] GHX is a global healthcare exchange and data automation company. It maximizes industry savings using cloud-based supply chain technology exchange platform, solutions, analytics and services
[7] Council of Europe, European Directorate for the Quality of Medicines, https://www.edqm.eu/en/news/ph-eur-revised-its-general-chapters-plasticised-pvc-materials

IV FDPs should be visually clear, transparent, soft, and flexible to prevent kinking. They are sterilized with steam and radiation, are biocompatible, and are appropriate for the application in question. Because FDPs may be stored for many weeks before use, they must withstand storage conditions, prevent leaching, and ensure the solution remains safe for administration. However, multiple studies have concluded that some patients are likely to be exposed to potentially unsafe amounts of DEHP from IV FDPs while receiving medical care.[8]

FDPs are purchased by large hospitals and outpatient centers, often under contracts through Group Purchasing Organizations (GPOs), large purchasers for multiple hospitals that effectively negotiate prices based on scale. They are inexpensive and used only once before disposal. Doctors, nurses, and other medical personnel use them, sometimes in life and death situations, where ease of use is a critical factor.

Very early FDPs were made from glass with a rubber stopper, tubing, and a steel cannula. In the early 1970s, glass was replaced with an FDA-approved bag made from PVC and DEHP.

Summary of drivers

There are some drivers and enablers that have had some impact on substitution. NGO pressure, GPOs, and "hospital action" (loosely paralleled with retailer action) has resulted in some substitution. Note that "brand action" is not an important consideration as IV FDPs are not associated with a brand and this is not a consumer-facing category (a consumer does not choose what brand IV FDP to use, hence there is little awareness or consumer pressure to change). One exception is in California where, under Proposition 65, the state recommends that consumers limit their exposure to DEHP by requesting medical devices that do not contain DEHP. Prop 65 also requires hospitals and other businesses to post warning signs about potential exposure to certain toxic chemicals including DEHP.

NGO pressure. Health Care Without Harm (HCWH), started a campaign in the late 1990s that targeted medical products, including IV FDPs made from PVC and DEHP. They met with manufacturers to identify alternatives and encouraged hospitals to use alternatives to lower the risk of DEHP exposure, especially for vulnerable populations such as babies in the neonatal intensive care unit (NICU). The HCWH efforts led to significant attention to concerns about PVC and DEHP in medical devices, and led to FDA discussions and some healthcare sector actions, though that pressure has receded in recent years. HCWH helped create two initiatives, the Healthier Hospital Initiative and Practice Greenhealth, which target hospitals to provide resources such as a list of safer alternatives for particular applications.

Hospital/Healthcare provider action. By 2006, Dignity Health completed the phase-out of PVC and DEHP IV FDPs and replaced them with IV FDPs manufactured by B. Braun, a manufacturer of non-PVC alternative devices. In 2012, Kaiser Permanente agreed to phase out

---

[8] Tickner, Joel, Ted Schettler, Michael McCally, Tee Guidotti, and Mark Rossi. 2001. Patient health risks posed by the use of di-2-ethylhexyl phthalate (DEHP) in PVC medical devices: A review of the literature. *American Journal of Industrial Medicine* 39: 100-111.

PVC/DEHP IV medical equipment. There is some additional movement towards PVC and DEHP alternatives for IV FDPs, but it is often a hospital-by-hospital effort rather than by large healthcare providers who oversee numerous hospitals. Nonetheless, GPOs (which often supply multiple hospitals) have initiated programs to preferentially procure safer options for specific chemicals and materials of concern. For example, Vizient, which represents more than $100 billion in purchases, has instituted an environmentally preferred sourcing program that gives credit to PVC and DEHP alternatives.

Summary of enablers/barriers

Performance/track record. There are alternatives to PVC and DEHP IV FDPs, and the four large medical device manufacturers are currently making them[9]. Two avenues of alternatives exist: replace PVC with a polymer that does not require a plasticizer or use PVC with an alternative plasticizer. Alternative plasticizers include DEHT/DOTP, DINCH, DEHA, ATBC, TEHTM, and polyesters (polyadipate). Initial challenges with compatibility between the different sections of the IV FDP occurred but this was resolved. Initially, these alternatives caused the IV FDP tubing to kink, preventing smooth fluid flow. However, this issue has now been resolved.

Safety/availability of safety data. There is significantly more toxicology data on DEHP than on some alternatives, and some organizations may feel that not enough data exists on alternative plasticizers to support a change; however, the relevant endpoints and routes of exposure are well-covered by existing data for DEHA, DINCH, and DOTP. In addition, devices made with the available alternatives are FDA-approved. Some have been on the market for over 30 years, and some hospitals have transitioned to them.

Cost. Alternative IV FDPs (consisting of both alternative polymers and alternative plasticizers) tend to be more expensive than their PVC counterparts. However, the manufacturers have reduced their margins so that costs remain competitive.

Quantity/Scale/Multiple Suppliers. If all hospital systems and other purchasers decided to switch to PVC and DEHP-free IV FDPs today, the capacity would not exist to meet this need. But, based on the slow adoption rate, there is currently sufficient capacity. In addition, some manufacturers are increasing their capacity.

Switching process, costs, & time. For a manufacturer to switch to a non-PVC material, significant investment of time and money is required to achieve adequate performance, qualifications, and approvals. However, at least two companies already exclusively produce PVC and DEHP-free IV FDPs so these challenges can be overcome.

[9] Baxter, ICU Medical, Fresenius Kabi and B. Braun

Conclusions

Widespread substitution has not happened, and this could be due to many reasons. IV FDPs are a complicated product category and have different medical uses. This includes wound flushing, fluid replacement, dialysis, and blood transfusions. The product is not consumer-facing and is often used under high-stress situations by medical staff who are monitoring the health of their patients, while "consumers" are more worried about the immediate medical procedure than the safety of the devices being used. There could be a sense of comfort with the incumbent technology and resistance to change – medical professionals who currently use PVC IV FDPs have been using them for many years, know they are FDA-approved, perform well, and are easy to use. As such, health care providers have little incentive to switch and have little policy pressure to do so.

Other possible reasons for a low rate of substitution include:

1. NGO pressure, such as that from HCWH, on medical device manufacturers, hospitals, and GPOs to switch is less aggressive now than previously, resulting in less policy and market attention. However, there is some increasing effort from the environmental health community to pressure health care providers to substitute DEHP in medical devices.
2. Hospital purchasing is complex and substituting equipment can be complicated. Clinical staff are hard to please and have some influence in purchasing decisions. They may demand that performance be identical between the incumbent and its replacement and may be resistant to the training needed to adapt to an alternative. Additionally, switching behaviors of large purchasing organizations – focused on cost pressures – can be challenging.
3. There could be a lack of awareness among purchasers (or conflicting information) regarding concerns over the safety of PVC IV FDPs. Further, non-PVC IV FDPs may not be offered as an alternative.
4. Hospitals may not feel pressure to switch to alternatives, given that these products are not regulated or restricted and are FDA-approved. There is little incentive for a hospital to change.

DISCUSSION

The following discussion is based on the case studies along with GC3's supply chain engagement experience. It is intended to provide insights on factors that can facilitate substitution or impede substitution, as well as to support discussions on strategies that GC3 and other stakeholders can pursue to accelerate the substitution and green chemistry adoption processes. The information collected in each case study is not exhaustive, but an attempt has been made to involve the entire value chain and other stakeholders in understanding the barriers and enablers.

What leads to successful substitution?

Strong drivers are needed for chemical or material substitution. In each of the successful case studies, there was a primary driver (or multiple ones) that triggered activity in the supply chain or at a specific brand. The three key drivers that tend to surface across successful substitution cases are brand/retailer action, NGO action, and regulations.

Every product category is different. Some have strong brand awareness (toys and apparel) where consumer purchasing decisions may be linked closely to a brand. Other product categories without strong brand awareness may have purchasing decisions largely linked to performance and cost. Some product categories such as IV FDPs are not consumer-facing at all, which may be part of the reason for the lack of substitution.

Brand Action

For product categories that have strong brand awareness with consumers (apparel, toys, and to a certain extent, luxury vinyl tile), "brand action" may be the leading driver because protecting brand reputation is essential. Consumers make choices when they purchase products and a brand does not want to disappoint a consumer, or worse yet, lose a consumer to a competitor.

NGO Campaigns

NGO campaigns, usually targeted at either retailers or brands, have been enormously successful in catalyzing substitution because they can erode brand reputation very quickly and raise concerns at the C-suite level. As an example, Mind the Store (MTS) specifically targets retailers to eliminate certain chemicals from products on their shelves. MTS put pressure on retailers to stop selling flooring materials that contain phthalates. Retailers immediately challenged their suppliers (often brands) to eliminate ortho-phthalates – or they acted like brands if they were addressing their own "branded products." Some may say that flooring brands made the switch before NGO pressure or perhaps it was the retailers who applied pressure. Either way, NGOs are key drivers for substitution. In general, NGOs can exert pressure through media campaigns, raising public awareness, pressuring shareholders, and through public policy work.

Regulations

Regulation or threat of regulation is a critical driver for substitution. Ortho-phthalate use in toys, and to a lesser degree in apparel, is restricted under REACH and the U.S. CPSIA. If a product is regulated, then the brand or manufacturer has to act and often will act even if the regulation is not required for their product category is peripherally related (the perception that the brand should act). Some toy brands switched to alternatives before the regulations came into force to minimize company risk given increasing concerns about ortho-phthalates.

What about alternatives?

There are several acceptable alternative plasticizers available in the market today for most applications. With regard to the three product categories where significant substitution has occurred, alternatives were available that performed adequately, had similar costs to the incumbent plasticizer, were readily available, and assessments for these applications could demonstrate they were safer based on the available toxicological data.

Of course, with any change, there is a cost associated with running trials and changing formulations, but this did not seem to be a deterrent in the cases examined. For apparel, the move away from plastisol ink did result in a lower quality product initially, but the chemical industry and ink manufacturers provided support, and alternatives eventually reached similar performance. In all of the cases, collaboration with others in the sector or the value chain provided opportunities to share the knowledge that would help address technical challenges.

What are the barriers to substitution?

The barriers to substitution tend to be product category-specific. However, a few key barriers emerged:

- The lack of strong drivers for substitution such as regulations or a specific NGO campaign or retailer initiative.
- Incumbency of existing plasticizers, such as DEHP (and PVC itself), that are cheap, effective, and highly integrated into existing manufacturing processes.
- Lack of consumer/purchaser awareness such as when a product is not consumer-facing (e.g., IV bags) or when large purchasers are focused on cost and not on sustainability.

Garden Hoses

In specific cases, there has been substitution away from ortho-phthalates in garden hoses, especially in the North American and European markets, but this is far from complete. It is important to consider what makes consumers purchase a garden hose. Are they driven by price, performance, or brand? Given the safety concern raised by some NGOs about the content of hoses, is exposure a concern on the part of consumers, manufacturers, and retailers, given that the product is used outside?

It is unclear whether the few published reports about chemicals found in garden hoses catalyzed manufacturers to seek out alternatives. Garden hoses labeled “safe to drink” do NOT contain phthalates, showing that substitution is feasible and not cost-prohibitive. The Ecology Center reports have not been connected to a broader campaign pushing retailers to adopt alternatives, which could create concerns about brand image.

Finally, the specific regulations that target phthalates do not specifically address garden hoses. Overall, the lack of strong drivers, combined with incumbent manufacturing processes (mainly in Asia) are likely the reason for low phthalate substitution in this product category.

IV FDPs

For IV FDPs, low substitution rates may be due to an entirely different set of factors. IV FDPs are not consumer-facing products - a consumer does not choose or purchase these articles. However, there was a successful NGO campaign in the 1990s/early-2000s that targeted hospitals, GPOs, and IV FDP manufacturers, which drove awareness about PVC and exposure to DEHP. In response to the campaign, a small number of large healthcare organizations, notably Dignity Health and Kaiser Permanente, publicly committed to eliminating PVC medical devices containing DEHP.

It is difficult to gauge why substitution remains at 30-40%. While many factors could be at play, one compelling reason is that it is a challenging undertaking to transition away from incumbent medical devices in hospitals and move to alternatives. This was the case with mercury substitution in hospitals, where significant (often unfounded) concerns were raised about the performance of alternatives. PVC and DEHP IV FDPs have been used for decades. The safety of these devices is well-studied, they are cost-effective, medical personnel are comfortable using these products, and they perform well. Although in 2002 the FDA advised health care professionals to switch to devices made of alternative materials or PVC that does not contain DEHP, IV FDPs that are made from PVC and DEHP are FDA-approved and remain in use.

MOVING FORWARD

By understanding the enablers and barriers to substitution, a more nuanced picture of levers and opportunities to accelerate the adoption of green and sustainable chemistry options for specific applications emerges. This analysis demonstrates that the substitution process is complex (beyond simply identifying an alternative) and that the enablers and barriers are often context dependent. In the case of plasticizer substitution, more sustainable, technically feasible, and cost-effective options appear to exist in most cases. In other cases, new options may need to be developed, which creates additional challenges, including cost and the time related to testing and approvals/certifications.

Several key lessons have emerged from the cases:

- The need for strong drivers to motivate action. Regulations and NGO campaigns, combined with concerns over brand image, create a "pressurized system" that forces action, when it may not happen otherwise. Incumbent chemistries are often cost-effective, perform well, and are highly integrated into complex supply chains, creating inertia against substitution.
- The need to clearly identify and address barriers. A strong driver may not be enough to motivate substitution if barriers are significant. A detailed understanding of barriers to change serves to identify the strategies and interventions that may be needed to facilitate action on adoption. For example, training purchasers or clinical staff in hospitals may be sufficient to address resistance to the substitution of plasticizers in IV FDPs. These levers are context-dependent.
- Sectoral and supply chain collaboration can overcome barriers to change. Sectoral collaboration can help provide a stronger demand signal for substitution as well as provide a forum for sharing experience and knowledge. Collaboration along the value chain – particularly between chemical suppliers and brands – can help address technical barriers to substitution and allow greater understanding of drivers and barriers.

A key conclusion based on the case examples presented in this report is that a clear, nuanced understanding of enablers and barriers can support the design, the business cases/plans, and executive-level commitments across the value chain to pull through green and sustainable chemistry options. The GC3 will continue to improve the utility of the framework to establish critical background knowledge that will enable the development of strategies to accelerate the commercialization and adoption of green chemistry solutions for other chemical functions and applications.

APPENDICES

APPENDIX 1

List of plasticizers and their acronyms

Name	Acronym
Alkyl sulfonic acid esters	ASAE
Acetyl tributyl citrate	ATBC
Bis(2-ethylhexyl) adipate, di-2-ethylhexyl adipate, or dioctyl adipate	DEHA/DOA[10]
Butyl benzyl phthalate	BBP/BBzP
Benzyl cyclohexanoates[11]	BBzCh/ TxBzCh
Dibutyl terephthalate	DBT
Dibutyl phthalate	DBP/DnBP
Diethylene glycol dibenzoate	DEGDB
Diisobutyl phthalate	DIBP
Diisononyl cyclohexanedicarboxylate	DINCH
Diisodecyl phthalate	DIDP
Diisononyl adipate	DINA
Diisononyl phthalate	DINP
Diundecyl phthalate	DIUP
Di-2-ethylhexyl phthalate	DOP/DEHP
Di-2-ethylhexyl terephthalate	DEHT/DOTP
Dipropylene glycol dibenzoate	DPGDB
Dipropylheptyl phthalate or bis(2-propylheptyl)phthalate	DPHP
Epoxidized soybean oil	ESBO/ESO
Isodecyl benzoate	IDB
Isononyl benzoate	INB
Propylene glycol dibenzoate	PGDB
Triethylene glycol di-2-ethylhexanoate	TEGDO/TEGEH
2,2,4-Trimethyl-1,3-pentanediol diisobutyrate	TMPDDIB
Tri-2-ethylhexyl-trimellitate	TOTM/TEHTM
Triphenyl phosphate	TPP

Adapted from Emerald Performance Materials

[10] In industry di-2-ethylhexyl adipate (DEHA) is often referred to as dioctyl adipate (DOA). While dioctyl adipate (DOA) could also refer to a product with the straight chain octyl alcohol group (CAS# 123-79-5) no such plasticizer is offered commercially.
[11] Products on the market include butyl benzyl cyclohexanoate and texanol benzyl cyclohexanoate

GREEN CHEMISTRY &
COMMERCE COUNCIL