# FDA's Active Assessment of Phthalates in Food Contact





Kevin Ott July 16, 2019

### **FVA** Functions Like a Trade Group: Website/Newsletter/Statistics/Advocacy/Messaging

#### **36 Editions**

#### www.flexvinylalliance.com





#### **FVA Parkalates Petition Open for Consumer** Through January 13, 2009.

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#### Flexible Vinyl Alliance

#### FLEXIBLE VINYL: BY THE NUMBERS

2011

Vinvl, also known as PVC, is derived from salt (one of the earth's most abundant resources) and natural gas. It is suitable for an almost limitless range of products since vinvl can be rigid and impact resistant enough for pipe o siding, and thin and flexible enough for wall covering, flooring, or upholstery. Vinyl is inherently recyclable and can be made weather and heat resistant, highly durable, and aesthetically pleasing The superior and proven performance characteristics of vinyl make it a critical material in health care products that are regulated for safety by the U.S. Food and Drug Administration. These products and procedures include intravenous blood bags, kidney dialysis and blood transfusions, cardiac catheters and

endotracheal (breathing) tubes.

The flexible vinyl industry is a significant contributor to the domestic economy with an estimated annual value that exceeds \$20B for the North American manufacturing and retail sectors.

\$20 Billion

#### 1000 Sites/47 States

Flexible vinvi related operations throughout the value-added supply chain include more than 1,000 manufacturing sites in 47 states

#### 275,000+ Workers

It is estimated that the flexible vinvl industry employs more than 275,000 domestic workers, and is part of the larger contingent of the plasticsproduction workforce that exceeds

Flovible vinvi has a long track record as a sale, affordable, durable & sustainable material. Vinyl additives have been studied closely by independent scientists, the federal government, and industry and used safely for more than 50 years

50 Years of safe use

1 million persons domestically.

50 Years of saving lives Wire and cables sheathed with PVC prevent potentially fatal electrical accidents In hospitals around the world PVC medical tubing that does not break or kink delivers fluids and medicines to the sick Vinvi flooring and wall coverings are easy

products are engineered to be long-lasting

with life cycles of 50 years and beyond

to clean and disinfect, helping prevent the spread of hospital-horne illnesses The survival of victims of war and natural disasters such as in Haiti and Irag is aided with vinyl products including flexible, flat-folding temporary shelters and field doninved surnical units. Cars are safer and last many years longer because of durable PVC components and coatings that protect from water and corrosion, PVC

EVA Copyright 2011, www.flagvinylalliance.com

"Getting Smart Around Phthalates & PVC: June 2019" @FVA Website



# **Flexible Vinyl By the Numbers**

- Significant impact on the domestic economy with an estimated annual value that exceeds \$<u>20 billion</u> for the North American manufacturing and retail sectors
- Flexible vinyl related operations within the supply chain include:
  - more than 1000 manufacturing sites in 47 states
  - estimated employment of <u>275,000 people</u>
- Flexible vinyl is part of the larger domestic <u>plastics industry</u> which employs 900,000 million American workers
- <u>28-31% of all PVC resins go into flexible PVC products</u>

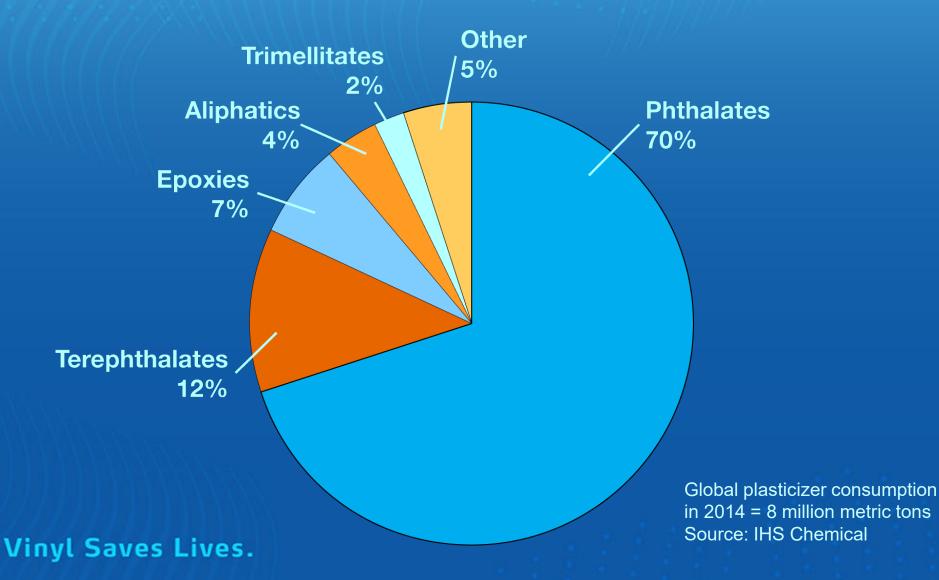
the flexible vinyl industry is large and is a major employer of American workers



# **Seven Pillars of fPVC**



### THE WORLD OF PLASTICIZERS Globally, phthalates are still the dominant plasticizer.



# The "BIG FIVE" Targets: 2019

- Phthalates
- Bisphenol A
- PFAS
- Flame Retardants
- Insecticides

PHTHALATE FREE SAFE FOR YOUR KITTY & FAMILY



# Phthalates Are Now "Keeping Bad Company" per Activist Misinformation

- Phthalates
- Bisphenol A
- PFAS
- Flame Retardants
- Insecticides

#### **CHEMICALS** KNOWN TO DISRUPT BRAIN DEVELOPMENT have detectable levels of 62 chemicals in their bodies out of 163 screened Polybrominated \_ead diphenyl ethers (PBDEs) Mercury Polychlorinated biphenyls (PCBs) Organophosphate pesticides Polycyclic aromatic Phthalates hydrocarbons (PAHs) PROJECT **TENDR**

# Food as an Epidemic



# The July 12, 2017 NYT Mac and Cheese Click-Bait Story Based on Junk "Study"

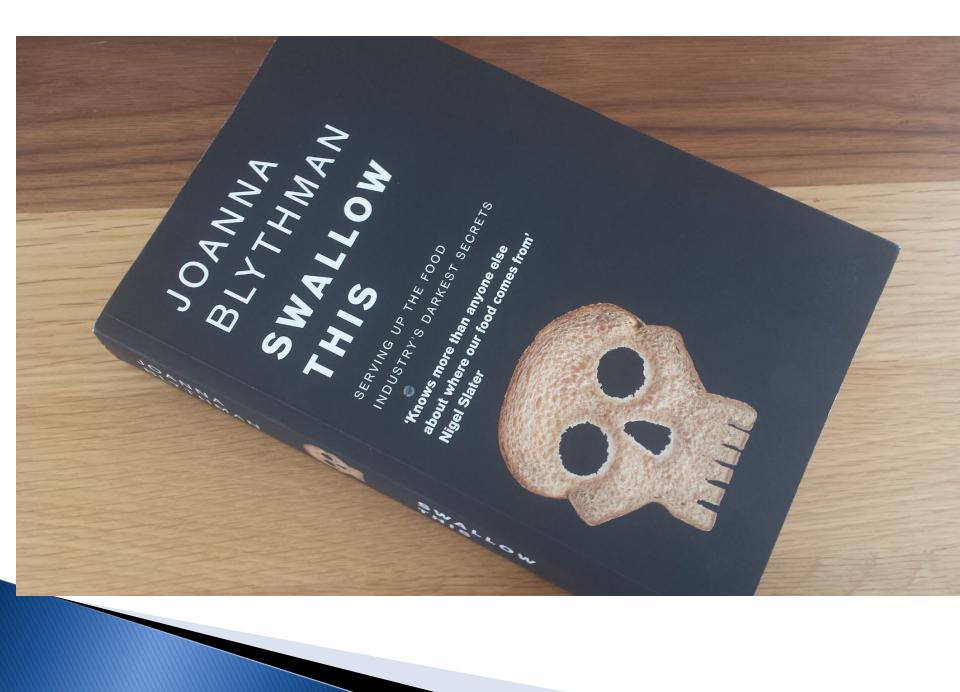


Table 1. Macaroni & Cheese Powder Had Highest Phthalates of Products Tested

Products Tested	Product Description	Number of Varieties Tested	Concentration of TOTAL Phthalates Average and Range, in µg/kg or parts per billion (ppb)					
			In FAT (measured)			In PRODUCT (calculated)		
			Avg.	Low	High	Avg.	Low	High
Cheese Powder	Macaroni and Cheese, dry mix	10	940	365	2,523	106	34	218
Processed Cheese	Slices	5	569	180	1,223	105	38	216
Natural Cheese	Hard, Shredded, String & Cottage	15	216	< 55 *	567	53	< 17 *	203

\* The highest limit of quantification (LOQ) in fat, and in a hard cheese product with a fat content of ~ 30%, for DEHP,













#### Patients, Consumers and Industry Agree... FDA's Essential Work Must be Funded



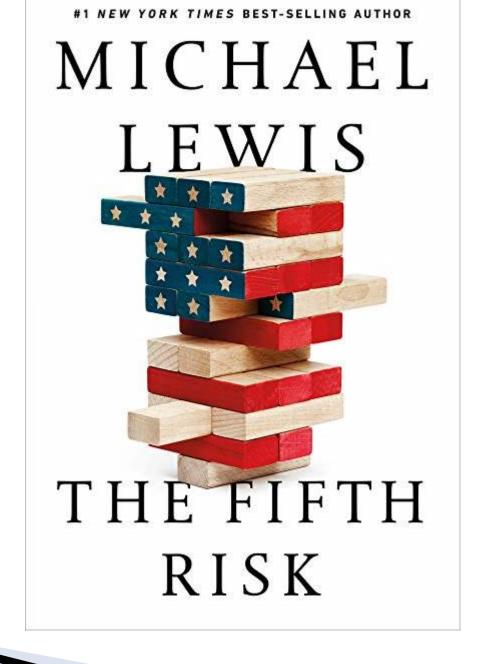
#### Department Of Health And Human Services Food And Drug Administration

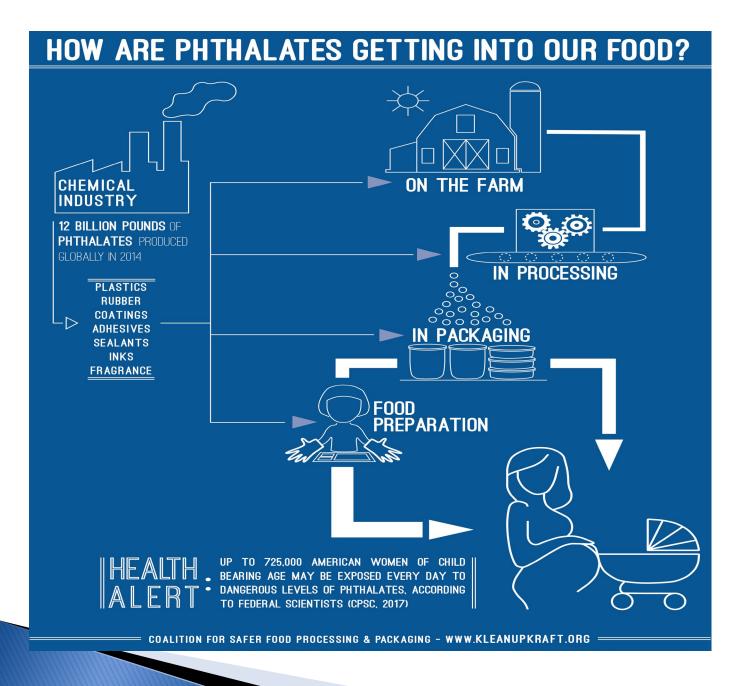
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the Executive Secretariat Office of Commissioner of Food & Drugs the Chief Counsel Director Norman E. Sharpless, MD (Acting) Marina H. Varnado Chief Counsel (DCAB) Stacy Cline Amin Principal Deputy Commissioner Amy Abernethy, MD, PhD Office of the Counselor to the Commissioner (DCAA) Chief of Staff Counselor to the Commissioner Lauren Silvis (DCA) Vacant (DCAC) Center for Center for Center for Center for Center for Center for Office of Oncology **Biologics Evaluation Devices & Radiological** Drug Evaluation & Food Safety & Tobacco Products Veterinary Medicine Center of Excellence **Regulatory Affairs** & Research Health Research **Applied Nutrition** Director Director Director Director Director Director Director Associate Commissioner Jeffrey Shuren, JD, MD Peter W. Marks, MD, PhD Janet Woodcock, MD Susan T. Mayne, PhD Mitchell Zeller, JD Steven M. Solomon, DVM Richard Pazdur, MD Melinda K. Plaisier (DCE) (DCF) (DCB) (DCC) (DCD) (DCG) (DCH) (DCI) Office of the Chief Scientist **Clinical Policy External Affairs Food Policy Minority Health** Operations Policy, Legislation, Women's Health & Programs & Response & Health Equity & International Affairs Chief Scientist **RADM Denise Hinton** Director Associate Commissioner Deputy Commissioner Assistant Commissioner Chief Operating Officer Deputy Commissioner Assistant Commissioner Vacant Keagan Lenihan Frank Yiannas CAPT Richardae Araojo, James M. Sigg Anna Abram Vacant National Center for PharmD Toxicological Research Director, William Slikker, PhD (DCJ) (DCK) (DCL) (DCM) (DCN) (DCO (DCP) (DCQ)

May 2019

















# Sustaining PVC Means Defending the Material: Which Means Understanding Risk!

### HAZARD

Anything that can cause harm (eg. a chemical, electricity, ladders, etc) How great the chance that someone will be harmed by the hazard,

RISK

# HAZARD

CHEMICAL

PRESENCE

• **HUMAN** 

HEALTH

### <u>Activist Petition: Published May 20, 2016:</u> 6B4815

- Environmental Defense Fund (EDF): \$
- Breast Cancer Fund
- Center for Environmental Health
- Center for Food Safety
- Center for Science in the Public Interest
- Clean Water Action
- Consumer Federation of America
- Earth Justice
- Learning Disabilities Association
- NRDC

 Seeks to <u>De-Authorize</u> Use of 30 FDA Approved Ortho-Phthalates, <u>including</u> DEHP, DIDP, DINP & DCHP



### THE FVA PETITION OF 2018: 8B4820

### DEHP, DIDP, DINP, DCHP: Remain Authorized for Food Contact

26 Other Abandoned for LACK OF USE in Food Contact Applications

KEY: Abandonment Request Based on <u>"Not Used" vs. "Not Safe"</u>



### **FVA Ortho-Phthalates Coalition Extensive Procedural Process Since 2016 Includes:**

- Petition Drafting & Filing (83 pp: June 22, 2018)
- Survey of Uses Collected from Industry
- Responses to FDA Technical Inquiries
- Food Additive Master File (Exposure Data)
- FOIA Defense (Successful)/ Affidavits
- Responses to NGO Critiques of our Petition
- Press Release
- Issue Briefs
- Coalition Building

Scrutiny of Phthalates in Food Contact: Now a Matter of FDA Process (and NGO-Driven Messaging) which has reached the States

• Activist Petition: De-Authorizes 30 PE's Contact

- FVA Petition: Retains 4 Phthalates; Abandons 26
  - JUNK SCIENCE: Orchestrated Attacks using Junk Science, with willing media/lawmaker "partners"
- Maine Bill LD 1433: Enacted June 2019:

**Precedent Setting** 



ACTIVISTS HAVE CIRCLED THE WAGONS AROUND FOOD SAFETY

The activist's latest tactics: "Instead of attacking vinyl itself, its crusaders (have) turned to the many substances that are added to PVC to give it its desired characteristics...."

Patrick Moore, Confessions of a Greenpeace Dropout

Vinyl Saves Lives.



#### **FDA Scientists Say:**

"There have been no studies to date which show any connection between human dietary exposure to phthalates and adverse health

#### effects."

Source: Investigation of the primary plasticizers present in polyvinyl chloride (pvc) products currently authorized as food contact materials. Article in "Food Additives and Contaminants" Part A: March 2018.

#### Vinyl Saves Lives.





### Attitudes Toward Phthalates Influence Customer Specifications of PVC



### Real Assessments at FDA <u>are</u> Being Conducted

# <u>WE EXPECT A GOOD OUTCOME ON THE</u> <u>FDA MATTER!</u>

### PLASTICS Supports the Ortho-Phthalates Coalition of the Flexible Vinyl Alliance

For Any Questions:

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