

WHAT'S IN THE PACKAGE?

Unveiling the Toxic Secrets of Food and Beverage Packaging



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LIST OF ABBREVIATIONS

BPA	Bisphenol A
BPB	Bisphenol B →
BPE	Bisphenol E →
BPB	Bisphenol B →
BPF	Bisphenol F →
BPS	Bisphenol S →
CAS	Chemical Abstract Service
CBI	Confidential Business Information
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CEDI	Cumulative Estimated Daily Intake
DBP	Dibutyl Phthalate
DEHA	Di (2-ethylhexyl) adipate
DEHP	Di (2-ethylhexyl) phthalate
DiNP	Diisononyl phthalate
EPA	United States Environmental Protection Agency
FCM	Food Contact Material
FCS	Food Contact Substance
FDA	United States Food and Drug Administration
FFDCA	Federal Food Drug and Cosmetics Act
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
FSMA	Food Safety Modernization Act
GRAS	Generally Recognized as Safe
HPP	4-cumylphenol → <i>Alternative to BPA</i>
MOU	Memorandum of Understanding
NHANES	National Health and Nutrition Examination Survey
NIAS	Non-Intentionally Added Substances
NTP	National Toxicology Program
OEHHA	California Office of Environmental Health Hazard Assessment
OPPT	EPA's Office of Pollution Prevention and Toxics
PBDE	Polybrominated diphenyl ether
PET	Polyethylene terephthalate
PFAAs	Perfluoroalkyl acids
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctane sulfonate
PMN	Pre-manufacture Notice
PVC	Polyvinyl chloride
TNPP	Tris (nonylphenol) phosphate
TOR	Threshold of Regulation
TSCA	Toxic Substances Control Act

EXECUTIVE SUMMARY

In 1906, Upton Sinclair's novel *The Jungle*¹ shocked the American public with its horrific exposé of the meat processing industry. Four months after the book was published, Congress passed the first restrictions on food processing. Congress took broader action in 1938 by passing the Federal Food Drug and Cosmetic Act (FFDCA), requiring ingredient labels, detailed information about when and where food is grown and processed, and regulation of how it is packaged. It led Americans to believe the U.S. had the highest standards for a safe food supply. But in recent years, American confidence in the safety of the U.S. food supply has been eroding, from 78% in 2012 to 61% in 2015, with concern about chemicals in food overtaking fear of food borne illness as Americans' top food safety concern. Americans care deeply about the safety of the foods they eat. When they receive information about potential health threats, U.S. consumers respond through purchasing decisions.

There are about 10,000 chemicals that are used as direct food additives (purposely added to food). For the most part, consumers have no idea what chemicals are added to the foods they eat or what potential health threats are associated with them because the identities and risks of these chemicals are shrouded in secrecy. Even less is known about the 4,000-6,000 chemicals used in food packaging as the safety of a majority of these "indirect food additives" has not been determined.

This report investigates the issue of chemicals in food packaging and their impact on the safety of what American consumers eat and drink. While the report focuses specifically on the packaging issue, its insight into systemic regulatory failure and recommendations about how to fix the problems are equally applicable to direct food additives.

Transparency not only ensures the public's right to know about toxic chemical ingredients to which they may be exposed, it drives changes in the marketplace. Examples of marketplace responses to ingredient transparency include manufacturing facilities that have reduced pollution emissions as a result of required public reporting on the Toxic Release

Inventory, or those that have eliminated chemical ingredients rather than list them on product labels under the requirements of Proposition 65 in California. Others have responded to requirements to list specific chemicals as in the flame retardant in furniture label required on California's recently enacted SB 1019 (Leno).

Packaging Chemicals Pose Significant Health Hazards

Very few of the thousands of food packaging chemicals in use have undergone rigorous health risk assessment, so a comprehensive analysis of health hazards is not possible. However, one recent analysis of known health risks indicates that at least one hundred and seventy-five (175) of the U.S. food packaging chemicals are either known or suspected endocrine disruptors, or exhibit carcinogenic, mutagenic, or reproductive toxicity.

Endocrine Disruption. Endocrine disruptors used in packaging include bisphenol-A (BPA), alternatives to BPA, phthalates, nonylphenol, styrene, fluorochemicals, and perchlorate. These chemicals are harmful at very low doses. The impacts include a wide range of reproductive effects — estrogenicity, inhibition of natural hormones, impaired fetal and sexual development, infertility, and diminished libido. Many food packaging endocrine disruptors are also associated with immunotoxicity, thyroid disturbance, diabetes, and obesity. Endocrine disruption can also lead to breast, prostate, and testicular cancer.

Cancer. Styrene is listed as a human carcinogen on California's Proposition 65 list, as are certain phthalates, including diisononyl phthalate (DiNP) and Di (2-ethylhexyl) phthalate (DEHP), and benzophenone, a chemical used in some packaging inks. Fluorochemicals and BPA are associated with breast, kidney, testicular, prostate, and other cancers.

Other Health Impacts. In addition to endocrine disruption and cancer, many chemicals used in food packaging are linked to other health impacts, such as: cardiac toxicity, liver damage, low birth weight,

pulmonary effects such as asthma, impairment of neurological development in the fetal and infant brain, and thyroid function.

Packaging Chemicals Contaminate Food and the Environment

Chemical Migration. A wide body of research demonstrates that chemicals migrate from packaging into food. That is why these chemicals are defined as food additives under the FFDCa. This paper highlights evidence of bisphenol-A in canned infant formula; di(2-ethylhexyl) adipate (DEHA) migrating from PVC film into cheese; fluorochemicals transferred from food packaging paper and fiberboard into foods; phthalates migrating from paperboard into infant food and exceptionally high levels found in school meals; formaldehyde, acetaldehyde, metal antimony, polybrominated diphenyl ethers leached into water from polyethylene terephthalate (PET) water bottles; and volatile organic chemicals migrating as gases from secondary packaging (for example, cereal boxes) through plastic or coated paper bags.

Significant Presence in Humans. Food packaging chemicals are widely present in the U.S. population, including BPA found in 92% of children (at least six years old) and adults in the United States. Ten of the 15 phthalates, as well as perfluorooctanoic acid (PFOA) and perchlorate, were detected in virtually all samples according to a recent national study.

Food Consumption as Chemical Exposure Pathway. While food is but one of many possible exposure sources for widely used chemicals, it is a significant one. EPA found that food appears to be the primary route of exposure to BPA, although its use in food accounts for less than 5% of the BPA used in this country. Several studies have also identified diet as an important contributor to exposure to phthalates and perfluorinated compounds, particularly PFOA and perfluorooctane sulfonate (PFOS).

Packaging chemical exposure is a social and environmental justice issue. Fresh, unpackaged food is often beyond the financial or physical reach of many populations in the U.S. Areas with less access to healthy foods are, on average, lower-income, and home to communities of color, when compared to areas with greater access.



Environmental Contamination and Wildlife Effects. Containers and packaging of all types (including food packaging) account for 30% of the nation's municipal solid waste stream. The presence of packaging chemicals in the aquatic environment is documented and known to contribute to environmental endocrine disruptor loads that are impairing sexual development and function in aquatic and amphibious wildlife, affecting reproduction and exerting estrogenic effects on both vertebrate and invertebrate wildlife species, and causing feminization of many fish and wildlife species.

Regulatory Failure

The federal Food and Drug Administration (FDA) is charged with regulating chemicals in food packaging. Under the 1958 Food Additives Amendment to the FFDCa, chemicals in food packaging are defined as indirect food additives, those likely to be consumed after migration out of the package or from other contact. Originally, the FDA reviewed applications or petitions, under the **Indirect Food Additive** program in which the FDA reviewed the safety of each chemical and the public had an opportunity to provide comment. But nearly 3,000 of the 4,000 chemicals approved through this means lacked any basic toxicological evaluation and those approvals are now decades old. The FDA considers carcinogens present in products at five parts per billion or less than one percent to be below the "Threshold of Regulation," although carcinogens can cause harm at much lower levels.

In 1997, the FDA eliminated the time-intensive indirect food additive petition process and developed **Food Contact Substance (FCS) Notifications**

whereby industry submits a notice, FDA has 120 days to respond, and posts a notice of the decision, leaving no opportunity for public comment or review. Approximately 701 substances have been allowed under this FCS notification program. These notices are confidential, making them more appealing to industry. But the primary regulatory option in use today is the **Generally Recognized as Safe (GRAS)** determination. Established by a 1958 amendment to the FFDCFA, the GRAS designation was created to exempt common food ingredients (spices, oils, vinegars, etc.) from regulation as additives. Three main categories of GRAS determinations include:

- common food ingredients in use before 1958 (commonly of biological origin),
- manufacturer self-determined GRAS substances (manufacturers make the safety determination on their own, without agency oversight or even notice), and
- those determined to be GRAS by an association expert panel (the panel is selected and convened by an association to evaluate safety of a substance) — no notice to the agency required.

By far the most popular methods manufacturers employ for getting a GRAS determination are the self-determination process (1,000 substances) and the associated expert panel route (2,700 substances). The GRAS program is one of the most egregious examples of meaningless federal regulation. Leaving it up to manufacturers to make safety determinations or to experts chosen by a manufacturer, and not requiring notice or oversight by the regulatory body, doesn't just cut the public out of the review process, it eliminates the regulators themselves.

What's in the Package is a Secret

Trade secret laws allow companies to keep various types of information confidential, largely as a protection from competition. While some of this is a legitimate need in a global marketplace where patents and copyrights cannot be relied on to protect a company's competitive advantage, trade secrets can clash with public safety and environmental protection, including the right to know what the ingredients are in the foods one purchases. A case in point is the

ability of companies to hide the list of chemicals in products, either completely or behind vague phrases such as inert or inactive ingredients, food coloring, fragrance, and flavoring, even if these substances pose a threat to health or the environment. Yet the lack of chemical ingredient disclosure has become indefensible over time, even from the business perspective. Modern technology often enables companies to back-engineer their competitors' products and identify chemical components.

The FDA's regulation of food packaging chemicals allows ample protection of corporate trade secrets, even with GRAS chemicals that are supposed to be well known and publicly recognized as safe. Some manufacturers maintain trade secrets on GRAS ingredients. Trade secret protections create a kind of "Catch-22." Although GRAS determinations are supposed to be based on publicly available safety information, manufacturers do not have to disclose either the identity of the chemical for which it has made a GRAS determination or the safety information upon which they based their decision.

California's Limited Framework for Reducing Chemical Hazards from Packaging

The foundational statute in California that grants regulatory authority over food and food packaging ingredients is the Sherman Food, Drug, and Cosmetic Law (Sherman Law). It adopts and incorporates all federal food additive regulations and uses these as a floor, not a ceiling, granting California's Department of Public Health the authority to be more stringent than the FDA, although it has not exercised this authority for packaging chemicals. California has a Toxics in Packaging Prevention Act that bans the heavy metals lead, mercury, cadmium, and hexavalent chromium from use in packaging. In addition, Proposition 65 requires that people be informed when they are exposed to chemicals that cause cancer, birth defects, or other reproductive harm. This is a landmark right-to-know program, but it places a heavy burden on the state to evaluate chemicals and make safety determinations, against significant challenges launched in almost every case by the industry. Despite such roadblocks, a handful of food packaging chemicals — including

BPA, styrene oxide, DEHP, DiNP, and benzophenone — are listed on Prop 65. None of these laws requires consumer notification of chemicals in food packaging as an ingredient in food.

Recommendations

The first step in removing the shroud of secrecy regarding chemicals in food packaging is simply to make them known. Transparency allows government to set health protective regulations and consumers to make safer choices. In cases when companies don't want to list toxic chemicals in their products, they will avoid them, so transparency can drive companies to reduce the presence of known toxic chemicals in their products. Companies that move away from toxic chemical ingredients often achieve a competitive advantage in the marketplace:

1. Disclosure should be based on the presence of a chemical, not an estimate of exposure. Models that rely on risk estimates are inadequate. Many food packaging chemicals are harmful at very low doses, and numerous daily exposures may be more significant in the aggregate. Risk estimates do not usually account for synergistic effects or effects of mixtures of chemicals. Labeling requirements for pharmaceutical products, for example, are comprehensive. Individual ingredients in a pharmaceutical product must be disclosed to patients and consumers. No exceptions are made for the amount of the ingredient, or whether it is an active or inactive ingredient.

2. Trade secret claims on chemical ingredients should be prohibited. Industry uses the claim of trade secrets as a first line of defense to prevent disclosure. Although many statutes, such as TSCA, do not allow

trade secret claims to apply to health and safety information regarding chemicals that are the subject of the regulation, in practical terms, public agencies do not have the resources necessary to systematically challenge them. Trade secret claims should be categorically disallowed for food packaging chemicals that, like other food ingredients and pharmaceuticals, are directly consumed.

3. Disclosure should be directly on the label. Having to search for chemical ingredients on-line or through a secondary outlet is a significant hurdle for consumers making immediate decisions about food and beverage products for their families, especially for those who lack internet access. To be fully protective of public health and accessible to all, packaging ingredients should be displayed on the product label, with more comprehensive information available by phone or via a company website.

4. The Sherman Law should be updated to ensure the safety of food and indirect food additives. The shortcomings of the FDA regulatory program should be addressed in state regulations. The state should review all indirect food additives currently in use in packaged food products sold in California. Regulators should determine whether chemical safety has been established through sound scientific research. For chemicals that lack adequate scientific support, the state must require that the research be conducted within a narrow time frame if the chemical is to continue to be approved for use in California. The review process should include complete transparency regarding the data on which the decision is based, ample opportunity for public comment, and opportunities to appeal approvals for specific chemicals.

INTRODUCTION

In the 1980s and 1990s, consumers were fairly confident in the safety of the food supply, with the top safety concern related to food spoilage.² In recent years, Americans' confidence in the safety of the U.S. food supply has been eroding, from 78% in 2012 to 61% in 2015, with concern about chemicals in food overtaking fear of food borne illness as their top food safety concern. Forty-six percent (46%) of those who are not confident in the food supply rate chemicals in food and as their chief concern. Among those who chose chemicals, pesticide residues, or antibiotics in food as their top concern, 45% have made changes to their food purchases based on this concern. Yet few Americans (13%) have ever heard of the regulatory program that oversees chemicals in food or food packaging and even fewer (10%) know about the big loophole in consumer health protection built into that program — the Generally Recognized as Safe (GRAS) exemption for chemical ingredient review by



the federal government.³ This data suggests that many Americans care deeply about the safety of the foods they eat and when they receive information about potential health threats, consumers respond through purchasing decisions. However, they know very little about the real threat — the lack

of federal regulation to protect consumers from toxic chemicals in food and food packaging.

Food and beverage labels do not disclose the thousands of chemicals that are added directly to food or indirectly as a result of food packaging chemicals that migrate into food and beverage products. Chemicals are used in a wide array of packaging materials, including plastic films, bottles and containers, epoxy resins that line metal cans, paper and paperboard,

meat trays, bottle and jar lids, coatings, inks, sealants, and adhesives. Their range of purpose is equally broad. Some are inherent structural elements of the packaging material used, such as styrene, a monomer used to make polystyrene. Others are packaging additives used for a specific purpose, such as antimicrobials that prevent spoilage; coatings and constituent chemicals that keep paper and fiberboard from growing soggy from wet foods or developing static from dry foods; additives in gaskets that prevent leakage from bottles; and inks and pigments on the package that catch consumers' eyes.

Public health and environmental quality are threatened by the vast numbers of packaging chemicals flooding the marketplace, while the regulatory structures meant to protect against them fail to achieve any meaningful protections. Federal statutes and regulations are structurally inadequate to address the risk and the agencies charged with implementation are underfunded, understaffed, under-motivated, and lack the fundamental data needed to make informed decisions. Industry impedes what progress might be otherwise possible by threatening legal action in order to stop or delay regulation, and by endless engagement to influence regulatory outcomes and policy development. The porous border between government regulators and industry representatives ensures divided loyalties, conflicts of interest, and a ceding of authority to those whose bottom lines depend on preserving chemical use. All of these challenges exist and persist because of the general paralysis that plagues federal politics and lawmaking.

Faced with such an industry-friendly regulatory environment, the prospects for dramatic change at the federal level are dim. It thus falls to the states to protect the health of consumers and the environment. The challenges of ensuring that state or federal regulators are equipped to provide such protection, in the face of well-funded chemical industry lobbying and weak and ineffective toxics laws, make it unlikely that consumers can count on government regulators to protect them from exposure to toxic chemicals.

Given this lack of protection, and the fact that a free market relies on information to function, the best alternative is to provide the kind of transparency that will enable consumers to make informed choices about the food they purchase. Until there is a legal right to know what chemicals are present in food, either directly added or indirectly added, consumers lack the information to make educated purchasing decisions and there is no market pressure for manufacturers to abandon the use of toxic substances. States have led the way on chemical transparency and policy reform in general and the time is right for action at the state level on food packaging chemicals.

It should be noted that chemicals enter food, and are thus consumed, in a variety of ways. “Direct additives” refer to substances — including chemicals — that are intentionally added to a food or beverage item. While their *presence* is disclosed on ingredient labels, the information can be vague. Ingredients such as sugar, salt, wheat, etc. are clear but the food industry and regulatory agencies leave consumers in the dark about specific chemical additives by grouping them in a cloak of secrecy with terms like “artificial flavors,” “color,” and “preservatives.” These terms fail to identify the ingredient; rather they refer to the function in the manufacturing process. The public has a right to know the potential effects of direct additives. Labels should require greater transparency

INGREDIENTS: SUGAR, CORN SYRUP, WATER, ENRICHED BLEACHED FLOUR (WHEAT FLOUR, NIACIN, REDUCED IRON, THIAMIN MONONITRATE [VITAMIN B1], RIBOFLAVIN [VITAMIN B2], FOLIC ACID), PARTIALLY HYDROGENATED SOYBEAN AND COTTONSEED OIL WITH TBHQ TO PRESERVE FLAVOR, DEXTROSE, PALM AND PALM KERNEL OIL, COCOA, SOYBEAN OIL, EGGS, WHEY (MILK), LEAVENING (BAKING SODA, SODIUM ALUMINUM PHOSPHATE), EMULSIFIERS (SORBITAN MONOSTEARATE, POLYSORBATE 60, SOY LECITHIN, MONO- AND DIGLYCERIDES), SALT, CORN STARCH, COLORS (YELLOW 5, RED 40, BLUE 1), SORBIC ACID (TO RETAIN FRESHNESS), EGG WHITES, NATURAL AND ARTIFICIAL FLAVORS.

Given the array of sources of indirect additives, the issue is both broad and complex. For that reason, this paper focuses specifically on those chemicals intentionally added in packaging that can leach into food or beverages and are ultimately consumed by the unknowing public.

regarding the specific chemicals used in artificial flavors, color, and preservatives.

Indirect additives are those that come into contact with food or beverages through packaging, processing, or holding. These “food contact substances” are known to or are “reasonably expected to” migrate into the product, ultimately becoming a component of, or having a technical effect on the food. Sources of indirect food additives include intentionally added additives in food packaging and non-intentionally added chemicals in cooking receptacles, conveyor belts, trays, container liners — i.e. the production chain.⁴

Given the array of sources of indirect additives, the issue is both broad and complex. For that reason, this paper focuses specifically on those chemicals intentionally added in packaging that can leach into food or beverages and are ultimately consumed by the unknowing public. In providing a context in which to understand the need for public disclosure of food packaging chemicals, this report summarizes what is known about potentially negative health effects and the exposure potential of indirect food additives; describes the current regulatory failures that allow such hazards to persist; and highlights how disclosure will both allow for individual choice and spur safer packaging options on a broader scale.

I. Food Packaging Chemicals Pose Significant Health Hazards

While thousands of food packaging chemicals are regulated by the federal government,⁵ countless others slip through the regulatory net, including breakdown products not yet identified or characterized, and contaminants in both virgin and recycled feedstocks.⁶

Regulatory testing requirements have failed to characterize food packaging chemical hazards adequately, or even to examine them at all in many cases (as described in Section III). The hazards of a few high profile substances have captured headlines and spawned hundreds of research papers in the open scientific literature. At the top of this list are the following:

- Bisphenol A (BPA), found in polycarbonate plastics, the epoxy resin linings of metal cans, and in other non-food related products such as paper receipts;
- Phthalates, a family of plasticizing chemicals that includes Diisononyl phthalate (DiNP) and Di (2-ethylhexyl) phthalate (DEHP), a high-production-volume phthalate plasticizer that has been associated with endocrine disruption;⁷
- Di (2-ethylhexyl) adipate (DEHA), a non-phthalate plasticizer and potential carcinogen used in meat wrapping operations;⁸
- 4-nonylphenol, a breakdown product of the antioxidant and thermal stabilizer tris (nonylphenol) phosphite (TNPP) found in some rubber products and polyvinylchloride food wraps;⁹
- Styrene, a building block and breakdown product of polystyrene and polystyrene foam (commonly known as Styrofoam™);¹⁰
- Fluorochemicals such as perfluorooctanoic acid (PFOA), perfluorooctane sulfonate (PFOS), and perfluoroalkyl acids (PFAAs),¹¹ pervasive chemicals used, among many things, to coat greaseproof paper¹² and treat paper and fiber containers;¹³
- Perchlorate, used in various formulations for food packaging gasket closures and as an anti-static agent in dry food packaging.

A handful of others have garnered less public attention, while the vast majority remains largely uncharacterized outside the thin-to-nonexistent regulatory record. Research on high profile chemicals, however, serves as both an example and a red flag, signaling the potential risks lurking in chemicals not yet scrutinized to the same degree.

The record on health hazards of packaging chemicals is so large that a complete review is beyond the scope of this paper. One recent analysis,¹⁴ for example, compared regulatory lists of approved packaging chemicals from the U.S. and the European Union, to lists of identified “chemicals of concern.”¹⁵ One hundred and seventy-five (175) of the U.S. food packaging chemicals were flagged as known or suspected endocrine disruptors, or as exhibiting characteristics of carcinogenic, mutagenic, or reproductive toxicity. Another analysis found that 44 of the food packaging chemicals approved for use in the United States are cited as known or potential endocrine disruptors in the scientific literature.¹⁶ Since there are thousands of food packaging chemicals in use and few have undergone rigorous health risk assessment, these numbers do not provide an accurate understanding of the full range of food packaging additives that present a threat to public health and the environment. Instead of a full review of health hazards posed by food packaging chemicals, this paper offers examples that shed light on this broad and complex policy issue and its health and environmental implications.

Endocrine Disruption

Endocrine disruption is a global term that refers to the myriad ways chemicals interfere with finely-tuned hormonal signals — mimicking natural hormones, competing with them for binding sites on cells, and scrambling the homeostatic processes by which normal hormonal levels are maintained in the body. Because hormones play a central and basic role in every aspect of reproduction, development, and daily functioning, endocrine disruption leads to numerous pathologies in both human and wildlife populations.



Most sobering of the revelations about chemical endocrine disruption is that it can occur at extremely low doses — far lower than are accounted for by standard toxicology studies.¹⁷ The importance of low dose effects cannot be overstated. It means that for many endocrine disruptors, packaging chemicals among them, effects have been observed at the levels people are, in fact, being exposed to.¹⁸ For example, low dose effects of BPA have been observed below the acceptable daily intake level set by the United States Food and Drug Administration (FDA) in animal studies and humans.¹⁹ Estimates of current dietary phthalate exposures also exceed the United States Environmental Protection Agency's (EPA) reference dose and the United States Consumer Product Safety Commission's acceptable daily intake for certain subpopulations, including infants.²⁰

The literature contains a large body of research on the endocrine activity of BPA,²¹ (it was once considered for pharmaceutical use as a synthetic

estrogen),²² phthalates,²³ 4-nonylphenol,²⁴ styrene,²⁵ fluorochemicals,²⁶ and other food packaging chemicals.²⁷ While BPA is listed as causing female reproductive harm on California's Proposition 65 lists by decision of the state's Developmental and Reproductive Toxicant Identification Committee,²⁸ alternatives, including bisphenol B (BPB), bisphenol E (BPE), bisphenol F (BPF), bisphenol S (BPS) and 4-cumylphenol (HPP) have also been shown to pose potentially serious endocrine risks.²⁹

Endocrine disruption caused by chemicals commonly used in food and beverage packaging is associated with a wide range of reproductive effects — estrogenicity,³⁰ inhibition of natural hormones,³¹ impaired fetal and sexual development,³² infertility,³³ and diminished libido.³⁴ Food packaging chemicals are also associated with non-reproductive endocrine pathologies, such as immunotoxicity,³⁵ thyroid disturbance,³⁶ diabetes,³⁷ and obesity.³⁸

Hormonal chaos does not just affect current consumers. It extends to the next generation and possibly beyond by altering cell development in ways that can be passed along to offspring, potentially leading to what one set of authors call a “transgenerational cascade” of deleterious effects.³⁹ Prenatal exposure to BPA, for example, has been shown to damage egg formation and future female fertility,⁴⁰ and both BPA and phthalates adversely affect multiple endpoints of sexual development in male fetuses.⁴¹

Cancer

Numerous food packaging chemicals are suspected carcinogens. Depending on the type of cancer, this effect may be attributable to endocrine disruption (e.g. endocrine-mediated cancers such as breast, prostate, and testicular), genotoxicity, or other carcinogenic mechanisms.

- Styrene and styrene oxide⁴² are both classified by the National Toxicology Program (NTP) as “reasonably anticipated to be” human carcinogens.⁴³ Styrene is chiefly linked to leukemia, lymphoma, and related (lymphohematopoietic) cancers.⁴⁴ California’s Office of Environmental Health Hazard Assessment (OEHHA) lists styrene oxide as a chemical “known to the state to cause cancer” on California’s Proposition 65 list.⁴⁵
- Fluorochemicals have been associated with an array of cancers — breast,⁴⁶ kidney,⁴⁷ testicular,⁴⁸ prostate, and others.⁴⁹ The EPA’s Office of Pollution Prevention and Toxics (OPPT) concluded that PFOA showed “suggestive evidence of carcinogenicity.”⁵⁰ A majority of the EPA’s Science Advisory Board disagreed with this designation, however, recommending instead that it be classified as a “likely” carcinogen.⁵¹ Internal reports from the FDA indicate that they too believe PFOA is a likely carcinogen.⁵² The EPA’s factsheet on PFOS and PFOA indicate these two chemicals are the two perfluorinated chemicals that have been produced in the largest amounts within the U.S. In May 2006, the EPA’s Science Advisory Board suggested that PFOA is “likely to be carcinogenic to humans” while in 2002 the American Conference of Governmental Industrial Hygienists classified PFOA as a Group

A3 Carcinogen,⁵³ i.e. one that is a confirmed animal carcinogen with unknown relevance to humans.⁵⁴

- DEHP is classified by the NTP as “reasonably anticipated to be a human carcinogen.”⁵⁵ The NTP cites liver tumors as the major site of concern, but also notes evidence linking DEHP to testicular and pancreatic tumors. Recent research has highlighted the possibility of a further link to glioblastoma.⁵⁶ DEHP, DiNP, as well as benzophenone, a chemical used in some packaging inks, are included in OEHHA’s list of “Chemicals Known To The State To Cause Cancer Or Reproductive Toxicity.”⁵⁷
- BPA has been associated with breast tumors⁵⁸ and other cancers,⁵⁹ possibly as a result of developmental abnormalities caused by its endocrine effects.⁶⁰

Cardiac Toxicity

Several packaging chemicals have been shown to disrupt cardiac health and electrical signals, with the bulk of evidence focused on BPA. Chronic BPA exposure is associated with morphological changes to the heart, atherosclerosis, and blood pressure effects.⁶¹ Acute BPA exposure may cause arrhythmia,⁶² hypertension,⁶³ and other electrical disruptions.⁶⁴ Fetal exposure to BPA can alter the gene transcription necessary for normal cardiac development.⁶⁵

Other packaging chemicals implicated in cardiac disease include PFOA, linked to high cholesterol,⁶⁶ and DEHP, linked to alterations that mimic diabetic cardiomyopathy⁶⁷ and disrupted electrical signaling between cardiac cells.⁶⁸

Other Health Effects

Food packaging chemicals are also known or suspected to cause assorted other adverse health effects. Liver damage is associated with increasing urinary levels of BPA,⁶⁹ and with serum levels of PFOA and PFOS.⁷⁰ Fluorochemicals can lead to low birth weight.⁷¹ Phthalates and BPA are linked to pulmonary effects, including asthma.⁷² Styrene is a well-known neurotoxicant in occupational settings.⁷³ Both pre- and postnatal BPA exposures alter neural cell growth and morphology.⁷⁴ The common

BPA substitute, BPS, has also been shown to disrupt normal neurological development.⁷⁵ Perchlorate can affect fetal and infant brain development by interfering with normal production of thyroid hormone in the pregnant woman and the child.⁷⁶

As with carcinogenicity, some of these other adverse outcomes are posited to stem from endocrine

disruption, while others may result from different mechanisms. All, however, are confirmation of the overarching truth that the greater scrutiny high profile chemicals receive, the more detailed the evidence against them becomes. There is no reason to think the same would not be true if lower-profile food packaging chemicals, not yet in the spotlight, garnered the same attention.

II. Packaging Chemicals Contaminate Food and the Environment

Chemical Migration

The seriousness of the health effects described above is not an abstract concern. Chemical migration from the package into the food⁷⁷ is neither unexpected nor unusual. It is a characteristic of most types of packaging and the very reason food packaging chemicals are defined as food additives under the Federal Food Drug and Cosmetics Act (FFDCA).⁷⁸ It is also why industry must generally submit test data estimating migration rates when seeking regulatory approval for food packaging chemicals.⁷⁹

Some food packaging chemicals (known as “active packaging”) are specifically designed to migrate, in order to slow food degradation and spoilage of various types.⁸⁰ Some non-intentionally added substances (NIAS) can contribute to overall leaching, which is also defined as migration. However, some polymers used for packaging also degrade when in contact with acidic or alkaline foods, UV light, and heat, leaching out monomers, like styrene from polystyrene. This process is considered a “release” and is not considered migration and therefore not assessed as part of any regulatory process.⁸¹

The pressing question is not whether food packaging chemicals migrate, but how much, and how that affects estimates of cumulative exposure from multiple sources. Estimating migration (whether through modeling or direct testing) is the subject of continuous debate and challenges, as science reveals analytical deficiencies and complexities in testing



protocols.⁸² While the technical disputes wear on, however, a steady stream of research repeatedly demonstrates that movement out of packaging can and does occur. The volume of this research is large enough to warrant fuller review of the literature,⁸³ but the specific examples below give a sense of the evidence:

- A 2010 study found detectable BPA in a majority of sampled foods in the United States, including canned infant formula.⁸⁴
- In 1998, cheese samples were found to contain high levels of DEHA, which researchers stated, “clearly had leached from the polyvinyl chloride (PVC) film.”⁸⁵ In 2014, DEHA migration from cling film to cheese was still found to be high.⁸⁶

- BPA from epoxy resins lining food cans migrates into the food at levels shown to pose health hazards.⁸⁷
- Several studies show that chemicals migrate from food packaging into dry foods. Fluorochemicals from treated food packaging paper transfer to food “during actual package use.”⁸⁸ Phthalates and mineral oils have been shown to migrate from recycled paperboard packaging into infant food,⁸⁹ while DiNP, disobutylphthalate, and benzophenone were found to migrate from recycled food packaging into rice and breadcrumbs used for battering and also into breakfast cereals.⁹⁰ Mineral oil consists of saturated hydrocarbons (like paraffins) and highly alkylated aromatic hydrocarbons. High levels of food contamination have been observed from mineral oil that leached from recycled and/or printed paper board packaging, with up to 70% (19ppm) found to migrate into dry rice and up to 33 ppm found in dry baby foods.⁹¹
- The breakdown product 4-nonylphenol was found at high levels in samples of polystyrene and PVC food packaging.⁹²
- A study that compared levels of DEHP and DiNP in school meals before and after the food was packaged found that packaging increased phthalate concentrations by more than 100%.⁹³
- Phthalates can migrate into infant food from recycled paperboard packaging⁹⁴ and have been shown to have a widespread presence in foods in the U.S.⁹⁵
- BPA migrates into water contained in polycarbonate bottles, increasing with rising temperatures, and is found at particularly high levels in water from reusable aluminum bottles with epoxy-based liners.⁹⁶
- PET bottles (made from polyethylene terephthalate) can leach formaldehyde and acetaldehyde,⁹⁷ as well as the metal antimony⁹⁸ into bottled water. PET and other types of plastic water bottles can also leach polybrominated



diphenyl ethers (PBDE)⁹⁹ and antimony together.¹⁰⁰ Mineral water from plastic bottles has been found to be estrogenic, while that from glass bottles is not.¹⁰¹

- Volatile chemicals can migrate as gases into food from secondary packaging that does not directly contact it (for example, boxes that contain crackers, cereal, or snack food in plastic or coated paper bags).¹⁰²

Significant Presence in Humans

Documenting the presence of packaging chemicals in food, as these and other studies do, demonstrates the potential for human exposure. Documenting the presence of packaging chemicals in human beings themselves confirms the reality. Nationwide surveillance data from the federal Centers for Disease Control and Prevention’s (CDC) 2009-2010 National Health and Nutrition Examination Survey (NHANES), found BPA in 92% of the urine samples from children (at least six years old) and adults in the United States.¹⁰³ Ten of the 15 phthalates analyzed in recent NHANES reports were detected in virtually all of the samples,¹⁰⁴ as were PFOA¹⁰⁵ and perchlorate.¹⁰⁶ Analysis of NHANES samples from earlier years found 4-nonylphenol in 51%, a level researchers speculated to be an underestimate due to possible analytic limitations.¹⁰⁷

In addition to NHANES reports, other studies have also found widespread BPA detection in blood and other tissues,¹⁰⁸ and as newer chemicals are substituted for older chemicals with documented hazards (whether for packaging or other industrial uses), body burdens of these new chemicals have also been found to increase.¹⁰⁹ Surveillance data do not exist for most of the thousands of other food packaging chemicals and mixtures to which people are exposed.

Food Consumption as Chemical Exposure Pathway

While food is but one of many possible exposure sources for widely used chemicals, it is a significant one. In its BPA Action Plan, the EPA states that, “Humans appear to be exposed primarily through food packaging uses of products manufactured using BPA, although those products account for less

than 5% of the BPA used in this country.”¹¹⁰ Several studies have also identified diet as an important contributor to overall phthalate exposure.¹¹¹ Specifically, diet was found to be the chief source of DEHP exposure for infants and adults in Germany, though other exposure sources had a greater effect for other phthalates tested.¹¹² A review of the literature on exposure to perfluorinated chemicals concluded that “dietary intake may be the most important source of exposure to PFCs, particularly PFOS and PFOA.”¹¹³ Another found that breakdown products from fluorochemical-coated food packaging were an important source of indirect exposure.¹¹⁴

The contribution of packaging to body burdens of packaging chemicals is further reinforced by studies that show the effect of targeted changes in diet (known as dietary interventions). One week of drinking liquids primarily from polycarbonate bottles significantly increased urinary BPA levels,¹¹⁵ and five days of consuming one serving of canned soup a day increased urinary BPA levels by 1000% when compared to levels in a control population consuming soup made with fresh ingredients.¹¹⁶ A reverse intervention showed the corresponding effect: substituting fresh food for canned reduced urinary levels of BPA and DEHP metabolites.¹¹⁷ In an elderly population, urinary BPA levels and blood pressure both spiked within two hours of consuming canned beverages that leached BPA, while no such changes were seen when beverages from glass bottles were consumed.¹¹⁸

These short-term fluctuations, and other studies linking biological levels of BPA to canned food consumption,¹¹⁹ confirm the relevance of food packaging chemicals for daily human exposure. Furthermore, as noted above, epidemiological and surveillance data both point to possible adverse effects at these current levels of exposure.

Non-Intentionally Added Substances

Food and food packaging manufacturers are often not aware of all the chemicals in their products because many fall into the category of Non-Intentionally Added Substances (NIAS); that is, they are present in food contact materials (FCMs) and can migrate into food, but were not added for a technical

reason. FCMs include more than just packaging, such as conveyor belts, baking trays, food processors, milking machines, tubing, etc., all of which may include NIAS. The unintended additives also originate from different sources and include break-down products of FCMs, impurities of starting materials, unwanted side-products, and various contaminants from recycling processes. In addition, NIAS can enter FCMs at any part of the production process, e.g. during the chemical synthesis of raw materials and the production of the final containers and materials. The properties of certain food types can also initiate the formation of NIAS from the respective FCMs.¹²⁰ This creates a complex challenge, especially for the food manufacturers who are legally responsible for the quality of their food.



A Social Justice Issue

Fresh, unpackaged food is often beyond the financial or physical reach of many populations in the United States. Some neighborhoods are so underserved by supermarkets and farmer’s markets that they have earned the moniker “food deserts,” and been subjected to considerable scrutiny in recent years for their effect on public health.¹²¹ Such areas are dominated by smaller stores with a smaller selection of food in general, and fresh food in particular.¹²² Areas with less access to healthy foods are, on average, lower-income, and home to communities of color when compared to areas with greater access.¹²³ Even in lower-income areas that have supermarkets (and thus do not strictly meet the definition of food desert), healthier food may be less available for purchase than in the supermarkets that serve higher income neighborhoods.¹²⁴

Greater reliance on packaged food — whether for financial reasons, limited accessibility, or both — would be expected to lead to higher body burdens of food packaging chemicals.

Availability is not the only impediment to a healthier diet. Fresh foods are often more expensive than processed and packaged foods.¹²⁵ Where they are comparably or lower-priced, however, at least one study of four Minnesota communities found that this was due to the poor quality of the produce, which had been priced to sell as it deteriorated.¹²⁶ According to the authors, “almost none of the stores in the urban areas stocked fresh fruits or vegetables that could be classified as “fresh/edible.”¹²⁷

Based on the dietary intervention data discussed above, greater reliance on packaged food — whether for financial reasons, limited accessibility, or both — would be expected to lead to higher body burdens of food packaging chemicals. This, in fact, appears to be the case. Two separate studies of NHANES populations found that lower-income participants had significantly higher urinary levels of BPA than did those with higher incomes.¹²⁸ One of these studies also found that higher BPA levels were associated with lower levels of food security (unreliable food supply), and with having received emergency food.¹²⁹

Packaging chemicals may thus pose a disproportionate health risk to already vulnerable and health-stressed populations.

Environmental Contamination and Wildlife Effects

All food packaging is ultimately discarded, entering the waste stream where it contaminates the environment and creates new exposure pathways for human beings and wildlife alike. As a result, many food packaging chemicals are widely detected in the environment.¹³⁰

The simple volume of food packaging waste ensures its significance. The EPA estimates that 14 million tons of plastic waste from containers and packaging were generated in the United States in 2012, along with 7 million tons of disposable plastic plates and cups.¹³¹ Containers and packaging of all types (including food packaging) account for 30 percent of the nation’s municipal solid waste stream,¹³² with BPA among the top organic contaminants detected in landfill leachate.¹³³ Newer, biodegradable and compostable packaging does not fully degrade under landfill conditions (though it may degrade more fully via industrial composting), and may thus fail to lessen the overall load of plastics in municipal waste.¹³⁴ Plastic waste is also an important source of pollution in the world’s oceans,¹³⁵ and food packaging and containers account for a substantial portion, as measured by the Ocean Conservancy’s Ocean Trash Index, which catalogs worldwide beach cleanup efforts and data.¹³⁶ Nonylphenol, BPA, phthalates, and other chemicals leach from plastic marine debris, contaminating seawater and exposing aquatic organisms.¹³⁷

The presence of such chemicals in the waste stream and aquatic environment is known to contribute to environmental endocrine disruptor loads, which are an increasing concern for wildlife.¹³⁸ Several reviews have summarized the literature on endocrine disruption in aquatic species. One documented impaired male sexual development and function in aquatic and amphibious wildlife with exposure to 4-nonylphenol and BPA.¹³⁹ According to a second that reviewed a wide range of plasticizers and their impacts on both aquatic and terrestrial mollusks, crustaceans, insects, fish, and amphibians, “phthalates and BPA have been shown to affect reproduction in all studied animal groups,” with mollusks,



Phthalates and BPA have been shown to affect reproduction in all studied animal groups.

crustaceans, and amphibians exhibiting particular sensitivity.¹⁴⁰ A third determined that BPA exerts its estrogenic effects on both vertebrate and invertebrate wildlife species at environmentally relevant levels of exposure.¹⁴¹ Its authors concluded that a “comparison of measured BPA environmental concentrations with chronic values suggests that no significant margin of safety exists for the protection of aquatic communities against the toxicity of BPA.”¹⁴² A fourth also found reproductive effects in aquatic species at environmentally relevant levels.¹⁴³

A recent study conducted by the U.S. Fish and Wildlife Service and the U.S. Geological Survey found evidence that EDCs are causing feminization of smallmouth bass. In samples collected from rivers, lakes, ponds, and reservoirs in 19 National Wildlife Refuges in the northeast, between 60 and 100% of the male bass had female egg cells growing in their testes.¹⁴⁴ This study is one of many that are part of a widely recognized trend of feminization of fish and wildlife species that have been linked to EDCs ever since the publication of *Our Stolen Future* by Theo Colborn, Dianne Dumanoski, and John Peterson Myers.¹⁴⁵

The effects of food packaging chemicals on terrestrial wildlife have been less well studied than for aquatic life — a glaring gap for such ubiquitous contaminants. The data that do exist, however, point to the same concerns. One study examined how seawater polluted by endocrine disruptors affects food

sources for land-based species. Abnormal testicular development, impaired spermatogenesis, and early indications of incipient testicular cancers in Sitka black-tailed deer in Alaska, for example, were attributed in part to environmental estrogens from ocean matter washing over plants eaten by the deer.¹⁴⁶ Another study on voles one generation removed from the wild, found that BPA raised testosterone levels.¹⁴⁷ The dearth of data on terrestrial wildlife represents a significant deficit in our understanding of the full impact of packaging chemical hazards.

In sum, many food packaging chemicals are known to pose serious adverse health effects, and they are also known to migrate into food and beverages. People consume these chemicals along with their food, and then discard the packaging. Packaging chemicals then turn up in human biomonitoring surveillance as human contaminants, and in the environment as contaminants from waste. The continuous exposure that characterizes food packaging’s place in modern life — as a daily part of meals, drinks, and snacks — constitutes a vast real world experiment with no control and comparatively little data, except for a handful of the most studied chemicals.

Comparison of measured BPA environmental concentrations with chronic values suggests that no significant margin of safety exists for the protection of aquatic communities against the toxicity of BPA.

III. Regulations Fail to Protect Humans or the Environment

Food packaging chemicals are subject to an array of federal regulatory programs that fail to protect against the hazards described above. In addition to flawed foundational statutes and their corresponding regulations, the regulating agencies are themselves chronically stretched for resources and frequently lack the political will to address the problems. As evidence of hazard and exposure accumulates, and as industry adds a steady stream of new chemicals into the market, the programs consumers rely on to address these risks fall further behind.

The FDA, under the FFDCFA, has specific regulatory authority over food packaging, while the EPA, under the Toxic Substances Control Act (TSCA), has broad oversight authority for industrial chemicals. Both agencies and statutes are relevant to food packaging use and regulation. The FDA's role is direct, while the EPA influences food packaging decisions in the following indirect but important ways:

- Because many food packaging chemicals also have wide industrial uses, any EPA actions or findings regarding such chemicals in the industrial arena are relevant to the understanding of their hazards in food packaging as well, and could affect cumulative exposure and packaging use assessments and influence FDA decisions. The EPA, for example, recently weighed in on BPA and phthalates in non food packaging applications.
- The EPA and FDA recently entered into a data sharing Memorandum of Understanding (MOU) that allows the FDA access to all the confidential business information submitted to the EPA under TSCA and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).¹⁴⁸ While profound data gaps plague both agencies, this additional sharing is a step toward improvement.

Before describing the specific programs that govern food packaging, it is important to note a few overarching deficiencies that apply to them — and to virtually all federal environmental health statutes

and regulations — that lead to a systemic mischaracterization of risk:

- **Low-Dose Effects and Non-Linear Dose-Response Curves.** Toxicology protocols and safety assessments adhere to the doctrine that the “dose makes the poison.” They assume that hazards increase linearly from lower to higher doses, and they extrapolate low-dose effects from high-dose studies.¹⁴⁹ For endocrine disruptors, this assumption is patently inaccurate. As noted above, hormonally active agents can exert their effects at very low doses — often in ways that are functionally different from their effects at high doses — and they can display non-linear dose-response curves.¹⁵⁰ The inaccurate dose-response curves compromise both exposure assessments, which set the floors for regulatory action, and safety assessments, which are predicated on high-dose studies. Regulators routinely establish default levels of exposure to chemicals below which no, or minimal effects are expected (see FDA discussion below), but these are regulatory conveniences that do not necessarily correspond to actual risk.
- **Critical Windows of Exposure.** While the differences between fetuses, children, and adults are addressed by some regulatory programs, the scientific community is just beginning to elucidate a far wider range of vulnerable periods



throughout life¹⁵¹ that are not accounted for in existing regulatory protocols.

- **Cumulative and Synergistic Impacts.** Food packaging presents a particular risk, since many people consume multiple packaged food items and beverages, and thus a variety of chemicals, every day.¹⁵² With a few exceptions,¹⁵³ most regulatory programs assess health and environmental effects one chemical at a time — a scenario that never reflects reality.¹⁵⁴ In practice, the cumulative effects, synergisms, and antagonisms of multiple-source chemical mixtures — to which all people and wildlife are exposed — remain beyond the scope of most regulatory decisions, even when statutes mandate that such effects be addressed to some degree. The FDA is required to consider the cumulative effects of structurally similar and pharmacologically similar substances.¹⁵⁵ Unfortunately, it rarely does.
- **Data Deficiencies.** Regulatory estimates of environmental exposure and hazard are often predicated on sparse or questionable data. When layers of extrapolations and assumptions are applied to limited data, they generate actionable regulatory thresholds that may or may not have a basis in reality. The fewer the data fed into the estimation, the flimsier and more subjective are its conclusions.¹⁵⁶ In some cases, described more fully below, regulation has had to proceed in the absence of any fundamental data.¹⁵⁷

All of the above impact chemicals policy across media and across a range of federal regulatory programs. The following specific programs that address food packaging chemicals are best understood within the context of these general shortcomings.¹⁵⁸

Federal Food and Drug Administration

The FDA has a specific mandate to address chemicals used in food packaging. Under the 1958 Food Additives Amendment to FFDC, such chemicals are defined as “indirect food additives,” i.e. substances not intentionally added to food but likely to be consumed after migration or other contact.¹⁵⁹ Unlike

TSCA, the default assumption of the Food Additives Amendment is that an additive is unsafe until proven otherwise. In theory, an additive cannot be approved until a review of migration estimates and toxicological data leads the FDA to determine that expected dietary exposure levels will not be harmful.

In practice, the FDA’s history on this score is checkered. Since it first began tackling packaging chemicals (in tandem with other additives), the FDA’s approach has steadily devolved from formal regulation, where the agency conducted safety reviews as part of the decision process, to an array of notification programs where industry makes the safety determination itself and the FDA is left to respond, either accepting the industry’s analysis and allowing the chemical in commerce, or rejecting it.¹⁶⁰ For certain regulatory categories (see discussion under **Generally Recognized as Safe**) not even notification is required, leaving industry entirely in control of the chemicals they use and government regulators and the public completely in the dark as to what’s in the food or the package.

Food Packaging Chemicals Regulations and Approvals by the Numbers

All told, there are four major FDA rubrics covering food packaging chemicals: Indirect Food Additives, Food Contact Substance (FCS) Notifications, FCSs below the Threshold of Regulation (TOR), and substances Generally Recognized as Safe (GRAS). In a recent analysis the first three categories were found to encompass approximately 4,000 substances¹⁶¹ — 3,007 Indirect Food Additives, 701 FCS Notifications, and 101 TORs.¹⁶² The same analysis enumerated an estimated 4,646 substances allowed under GRAS.¹⁶³ Teasing out just how many GRAS substances are used in food packaging and handling, however, is difficult for two reasons. First, GRAS subcategories are more broadly inclusive than Indirect Food Additives, FCS Notifications, and TORs, covering food packaging, processing, and direct food additive substances together. Second, GRAS substances are not fully reported to the FDA (see discussion below), so their true dimension is unknown. However, based on data

cited here, 2,702 of the 4,646 GRAS chemicals are specifically food additives (flavoring and extracts); the remaining 1,944 may be used in food packaging and processing. Combining the 4,000 substances approved for food packaging in the first three categories, with the nearly 2,000 GRAS substances that may be used in food packaging, the universe of food packaging and processing chemicals is in the range of 4,000–6,000.

Indirect Food Additives

The Indirect Food Additive program is the original classification system applicable to food packaging,¹⁶⁴ but it has delivered neither the full assessments nor the proof of safety for which it was designed. On paper, it required a safety review by the FDA and promulgation of a regulation, including opportunity for public comment, before a chemical could be used.¹⁶⁵ Despite this seemingly stringent mandate, the majority of Indirect Food Additives are missing the very data required to demonstrate safety. By one estimate, three-quarters of the approximately 3,000 FDA-approved Indirect Food Additives lack basic toxicological feeding studies.¹⁶⁶ The reasons for this appear to be rooted, at least in part, in the FDA having issued a raft of approvals early in the program, “before it defined safety or issued guidance establishing how a safety determination should be done.”¹⁶⁷ Moreover, many of those approvals are now decades old. Once it has rendered its decisions, the FDA lacks the resources to revisit them, and does so only rarely, even when compelling new science becomes available.¹⁶⁸ Industry’s post-approval responsibility to report on new scientific revelations is limited to most serious, life-threatening effects,¹⁶⁹ not the chronic, low-level exposures that typify food packaging chemicals. Nor is industry obligated to report usage, hobbling the FDA’s ability to determine the magnitude of exposures to specific chemicals.¹⁷⁰

Threshold of Regulation

The FCSs below the Threshold of Regulation (TOR) exemption of 1992 covers non-carcinogenic additives with anticipated exposure levels below either 0.5 ppb or 1% of the acceptable daily intake¹⁷¹ which are not expected to have other health or environmental concerns as approved. The glitch is that once again health or environmental safety is determined

on limited data. Guidance stipulates that industries submit minimal data — migration studies to estimate exposure and a literature search for adverse effects¹⁷² — and the FDA renders a decision to accept or reject the exemption.

Because there is no deadline by which the FDA must respond and because the decision is not proprietary, seeking an exemption through the TOR program has become a less attractive option than simply submitting an FCS Notification. Only 101 total TOR substances have been approved by the FDA, and only 30 of those between the period 2000–2010 after the FCS Notification program was fully up and running.¹⁷³ Although few in number (and no longer a popular pathway by which to seek an exemption), food packaging materials that have won TOR exemptions are notable for their categorical lack of toxicology studies.¹⁷⁴

Food Contact Substance Notification

In 1997, the FDA stepped back from the Indirect Food Additive petitions and the time-intensive regulatory promulgations they required. Congress granted the FDA the authority at that time to shift to a less demanding process: the FCS Notification program, now the dominant route for food packaging chemical approval. Under FCS Notification, industry submits a notification to the FDA (rather than a regulatory petition) containing, among other things, migration and toxicological studies that conform to FDA guidance and that justify the industry’s determination that the substance is safe for use. The FDA has 120 days to respond and, if it has no objections, posts notice of that decision on its website, with no opportunity for public review or comment. In the absence of a timely FDA response, the chemical is approved by default.¹⁷⁵ Industry, however, faces little threat of refusal. Out of 1,000 FCS notifications submitted between 2000 and 2010, the FDA offered no objections to nearly 80% of them.¹⁷⁶ As of January 2011, an estimated 701 substances were allowed under the FCS Notification program.¹⁷⁷ Unlike the regulations issued under Indirect Food Additives, FCS Notification approvals are proprietary — applicable only to the company submitting the notification and not to its competition — making FCS Notifications even more appealing to industry.¹⁷⁸

Industry is not required to submit GRAS judgments for FDA approval, or even to disclose that it has made them.

As with Indirect Food Additives, data on which to assess the safety of FCS Notifications are thin, with more than two-thirds of all FCS Notifications lacking toxicological feeding studies.¹⁷⁹ Unlike Indirect Food Additives, some of the data gaps for FCS Notifications are not simple regulatory failures. They are designed into the program by virtue of the fact that the toxicological data “recommended” for submission is keyed to estimated exposure levels.¹⁸⁰ If the estimated exposure from a single use (i.e. incremental, not cumulative exposure) is 0.5 parts per billion (ppb) or less, no safety studies are required. Between 0.5 ppb and 50 ppb cumulative exposure, genotoxicity tests are recommended. Between 50 ppb and 1 part per million (ppm) cumulative exposure, further genotoxicity and subchronic feeding tests are recommended.

This tiered structure allows some chemicals to enter commerce with virtually no testing. It fails to account either for changes in the market for packaged foods that alter exposure estimates or for the growing scientific understanding of low dose effects. For example, recent science has demonstrated that BPA’s adverse effects have been shown to occur at levels lower than the 0.5 ppb cutoff that exempts a chemical from safety testing.¹⁸¹

These same data gaps also hamper the FDA’s recent efforts to begin compiling estimates of cumulative exposure for FCSs.¹⁸² The FDA states that “[i]n the absence of appropriate information, such as migration studies, on which to base a numerical estimate of exposure,” the Office of Food Additive Safety assumes a default cumulative estimated daily intake (CEDI) of 7 ppb.¹⁸³ While the FDA acknowledges that “limitations in the submitted chemistry information could affect the magnitude of an exposure estimate,”¹⁸⁴ it nonetheless continues to rest its data requirements and approval decisions alike on a rickety foundation of limited information.

FCS Notification’s industry-friendly bent and its 120-day decision timeframe have led industry to abandon the formal Indirect Food Additive process, though the latter still exists.¹⁸⁵ As of January 2011, only one Indirect Food Additive petition has been made since 2001.¹⁸⁶

Generally Recognized as Safe

The final regulatory category with relevance for food packaging is known by the acronym GRAS, for “Generally Recognized as Safe.” It is the most opaque of the programs that apply to FCSs and direct food additives alike. Established by a 1958 amendment to FFDCa, the GRAS designation was created to exempt common food ingredients (spices, oils, vinegars, etc.) from regulation as additives. The original GRAS list was vetted by the FDA and early additions were subjected to a modicum of agency oversight. By 1997, however, the FDA was swamped with GRAS petitions and switched to a notification process similar to that used for FCS Notifications.

As with FCS Notifications, industry makes its own GRAS safety determinations as part of the notification process. In a striking departure from FCS notifications, however, industry is not required to submit GRAS judgments for FDA approval, or even to disclose that it has made them.¹⁸⁷ Businesses can choose to submit GRAS notifications to the FDA (in which case the FDA will either accept or reject the designation), but there is no mandate to do so. The FDA can thus neither attest to the safety of GRAS substances, nor make a full account of them. As a program, GRAS has been repeatedly assailed for the potential hazards of these unvetted decisions,¹⁸⁸ particularly with regard to nanotechnology products,¹⁸⁹ and for the inherent conflicts of interest entailed by having industry render judgments on its own products without agency oversight.¹⁹⁰ The FDA itself has acknowledged the program’s profound weakness. Referring to GRAS substances as a whole, Michael Taylor, the FDA’s Deputy Commissioner for Foods and Veterinary Medicine stated, “[w]e simply do not have the information to vouch for the safety of many of these chemicals.”¹⁹¹

Due to the lack of transparency about GRAS determination, no one knows how many and which chemicals have been determined to be GRAS, though researchers estimate that approximately 4,646

OVERVIEW OF FDA REGULATORY PROGRAMS FOR FOOD PACKAGING CHEMICALS

Regulatory Program	Citation	Number and type of chemicals addressed	Information and Public Process Required	Other Issues
Indirect Food Additives	21 CFR Parts 174-179	1,020	<ul style="list-style-type: none"> • 3/4 of chemicals approved without submission of basic toxicological testing • A safety review by the FDA and promulgation of a regulation, including opportunity for public comments. • FDA issued most of these approvals without any determination on what constitutes a safe chemical — no criteria for safety 	These approved chemicals are exempted from further regulation, according to 21 CFR 170.39. Once approved, almost no way to reconsider based on new science. Industry not required to report usage. No understanding of where, how, and how much people are exposed to.
Food Contact Substance (FCS)	21 CFR Parts 170.100-170.106, 67 FR 35724	As of 2001, FDA allowed 701.*	<ul style="list-style-type: none"> • Industry submits a notification to FDA containing migration and toxicological studies that show that the substance is safe for use. • FDA has 120 days to respond and, if it has no objections, posts notice of that decision on its website. • There is no opportunity for public review or comment. • In the absence of a timely FDA response, the chemical is approved by default. • More than 2/3 of all FCS Notifications lacking toxicological feeding studies • If the estimated exposure from a single use is 0.5 parts per billion (ppb) or less, no safety studies are required. Between 0.5 ppb and 50 ppb or cumulative exposure, genotoxicity tests are recommended. Between 50 ppb and 1 part per million (ppm) cumulative exposure, further genotoxicity and sub chronic feeding tests are recommended. 	FCS Notification approvals are proprietary — applicable only to the company submitting the notification and not to its competition — making FCS Notifications even more appealing to industry.
Threshold of Regulations (TOR) – 1992	21 CFR Parts 174-179	101 substances are listed through this mechanism.* They are required to be non-carcinogenic additives with anticipated exposure levels below 0.5 ppb or 1% of acceptably daily intake that are not expected to have health or environmental concerns.	No toxicological studies required.	No deadline by which FDA must respond. Decision is not proprietary. As a result, most applicants now use FCS pathway.
Generally Recognized as Safe (GRAS) – applies both to food and packaging additives	21 C.F.R. § 170.30 21 CFR 182-186	Unknown — estimated at approximately 4,646, but 2,007 are flavors and extracts. Therefore, 1,944 are potentially used as packaging additives.	Industry makes its own GRAS safety determinations and is not required to submit GRAS judgments for FDA approval, or even to disclose that it has made them.	

Adapted from Neltner TG et al (2011), Navigating the U.S. Food Additive Regulatory Program, *Comprehensive Reviews in Food Science and Food Safety*, 10:342-368.

*Source: Neltner TG et al (2013).

chemicals are claimed as GRAS by the food industry as of January 2011; 1,000 through manufacturer self-determination, 2,702 by association expert panel, and nearly 1,000 through FDA listing, review, or affirmation.¹⁹² Since those substances approved via an association expert panel are only flavors and extracts, these are unlikely to be used in food packaging. The remainder of the 4,646 GRAS chemicals (1,944) are potentially used in food packaging.

Given the gaping holes in our knowledge of GRAS substances, it is not possible to say definitively how many such designations there are.¹⁹³ It is also not possible to know how many food packaging chemicals are designated as GRAS. Several in-depth analyses have concluded that FCS Notification is used in preference to GRAS,¹⁹⁴ but the absence of a full accounting of GRAS substances makes this conclusion, ultimately, unverifiable.

With the exception of the essentially dormant Indirect Food Additives program, industry is in the driver's seat when it comes to making safety determinations for food packaging chemicals. There is no public review or comment allowed under current

FDA reasserted as recently as last November that, based on its “ongoing safety review of scientific evidence, the available information continues to support the safety of BPA for the currently approved uses in food containers and packaging.” This stands in contrast to the European Food Safety Authority’s recent decision, based on the same data available to FDA, to lower the level of BPA it considers safe from 50 to 4 ug/kg of body weight a day.

notification programs, which would serve to challenge industry's assertions and shine a light on questionable data or claims. On those infrequent occasions when the FDA is compelled to reassess a particular additive, the regulatory inertia generated by prior approval has stymied new restrictions.

Examples of Regulatory Failure

The programmatic deficiencies at the EPA and the FDA lead to real, ongoing public health hazards from food packaging chemicals, as illuminated by the following specific examples.

Bisphenol A

The EPA acknowledges that “BPA is a reproductive, developmental, and systemic toxicant in animal studies and is weakly estrogenic... [with] questions about its potential impact particularly on children's health and the environment.”¹⁹⁵ Rather than issue restrictions in light of this indictment, the EPA instead generated a three-point “action plan” that calls for consideration of whether to include BPA on the Concern List (a prelude to, but not a guarantee of, possible future regulation); consideration of whether to develop more environmental data on BPA's effects; and encouragement for alternative technologies to reduce certain industrial BPA uses (not including food packaging). While these actions may have been a shot across the bow for industry, they made no material, regulatory change in BPA's current use patterns.

The FDA has been even less responsive with regard to BPA, which it approved as an Indirect Food Additive in the 1960s. The agency recently stated:

Heightened interest in the safe use of BPA in food packaging has resulted in increased public awareness as well as scientific interest. As a result, many exploratory scientific studies have appeared in the public literature. Some of these studies have raised questions about the safety of ingesting the low levels of BPA that can migrate into food from food contact materials. To address these questions the National Toxicology Program, partnering with FDA's National Center for Toxicological Research is carrying out in-depth studies to answer key questions and clarify uncertainties about BPA.¹⁹⁶

To date, the FDA's only action in the face of intense public pressure, mounting evidence of harm, and

funding from Congress to continue research on BPA, has been to disallow the chemical's use in children's Sippy cups, baby bottles, and infant formula cans (though, as noted above, there is evidence that BPA substitutes pose their own hazards). In describing this action, however, the agency takes pains to note that it was not due to an assessment that BPA is unsafe, but rather that those uses had been "abandoned" by industry and authorization for them was no longer required.¹⁹⁷

Despite the agency's acknowledgement that it is pursuing and reviewing new data on BPA, it has yet to move on any other restrictions, or to revise its acceptable daily intake level for BPA, which has been vociferously challenged by its own scientific advisors.¹⁹⁸ Instead, the FDA reasserted in November 2014 that, based on its "ongoing safety review of scientific evidence, the available information continues to support the safety of BPA for the currently approved uses in food containers and packaging."¹⁹⁹ This stands in contrast to the European Food Safety Authority's decision, based on the same data available to the FDA, to lower the level of BPA it considers safe from 50 to 4 ug/kg of body weight a day.²⁰⁰

California is taking its safety assessment on BPA further as well. Public notification requirements of BPA's presence in food containers as a result of its Proposition 65 listing went into effect May 11, 2016. Since OEHHA has not yet established a Maximum Allowable Dose Level (MADL) for oral exposures from food and beverages, and anticipating that many warehoused packaged food items will not yet have a printed warning, OEHHA has promulgated an interim "emergency action" requiring a general warning in stores selling food in BPA containing packages, despite strong advocacy from public interest groups for more targeted warnings that specify which food products contain BPA.²⁰¹ A MADL is not expected before late 2017 or early 2018, pending the conclusions of research related to low-dose exposures to BPA.²⁰² OEHHA has proposed a MADL of 3 micrograms per day from dermal exposure from solid materials.²⁰³

Phthalates

In its 2012 Phthalate Action Plan, the EPA highlighted the "toxicity and the evidence of pervasive human and environmental exposure"²⁰⁴ of phthalates,



particularly for infants and children. The growing understanding of phthalate hazards has spurred a flurry of recent regulatory activity. In 2008, Congress restricted six phthalates²⁰⁵ in many children's items, such as toys and teething aids. In 2012, the FDA, citing endocrine disruption concerns, issued guidance recommending that certain phthalates be removed from medical equipment,²⁰⁶ stating the following:

Although the current available human data are limited, the Agency has determined that there is evidence that exposure to DBP²⁰⁷ and DEHP from pharmaceuticals presents a potential risk of developmental and reproductive toxicity... and safer alternatives are available. Therefore, the Agency recommends that you avoid the use of DBP and DEHP as excipients in CDER-regulated drug and biologic products.²⁰⁸

Phthalates are used as plasticizers in PVC food packaging, where they pose a particular exposure risk. Because phthalates are not chemically bound in PVC polymers, they readily migrate out of packaging²⁰⁹ and into foods and beverages. Despite the direct hazard this presents, the evidence of phthalate hazards that spurred action on toys and medical devices, and the fact that the FDA's approvals for phthalates in FCSs are between 50 and 30 years old, the FDA has taken no regulatory action to limit phthalates in food packaging to date.²¹⁰

Fluorochemicals

In 2011, at the FDA's request, several manufacturers voluntarily ceased using certain fluorochemicals in food packaging. The FDA described this action as follows:

Because phthalates are not chemically bound in PVC polymers, they readily migrate out of packaging and into foods and beverages. Despite the direct hazard this presents, the evidence of phthalate hazards that spurred action on toys and medical devices, and the fact that FDA's approvals for phthalates in FCSs are between 50 and 30 years old, FDA has taken no regulatory action to limit phthalates in food packaging to date.

Recent scientific studies have raised safety concerns with perfluorinated chemicals known as C8 compounds. These compounds have perfluorinated chain lengths of 8-carbons (C8) or longer. The studies indicate that these C8 compounds persist in the environment and can have toxic effects on humans and animals.

In response to these studies, FDA initiated a comprehensive review of the available data on C8 compounds and worked with several manufacturers to remove grease-proofing agents containing C8 perfluorinated compounds from the marketplace. As a result of FDA's initiative, these manufacturers volunteered to stop distributing products containing C8 compounds in interstate commerce for food-contact purposes as of October 1, 2011.²¹¹

Though a decided step forward for public health, this action was only a partial response to the danger. The precise hazards that sparked the FDA's above action — developmental and reproductive toxicity, and carcinogenicity — are also concerns for other members of the same chemical family still used in food packaging. To address the persistent hazard, a coalition of public health advocacy organizations petitioned the FDA in late 2014 to revoke approvals for three

related classes of perfluoroalkyl ethyl substances used to coat paper and paperboard food packaging.²¹² On January 4, 2016 the FDA announced that it was disallowing the use of these three fluorochemical substances as “oil and water repellants for paper and paperboard for use in contact with aqueous and fatty foods because new data are available as to the toxicity of substances structurally similar to these compounds that demonstrate there is no longer a reasonable certainty of no harm from the food-contact use of these FCSs.” While a positive decision, this change only occurred when the public interest pushed for the restriction.

Perchlorate

Simultaneously with the perfluoroalkyl ethyl substance petition, the same advocacy coalition also petitioned the FDA to prohibit the use of perchlorate compounds for certain food packaging uses, specifically in sealing gaskets and as anti-static additives for dry foods.²¹³ In calling for these revocations, petitioners cite “the well-recognized toxicity of perchlorate, its widespread presence in food and in the bodies of virtually all Americans, and the likelihood that the dietary exposure may cause permanent damage to

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This expanded understanding of the dangers of very low levels of perchlorate to vulnerable populations, including pregnant women, has not, however, triggered a reassessment of perchlorate food packaging uses.

a fetus' or infant's brain by irreversibly altering its development."²¹⁴

The accumulation of information on these hazards in the scientific literature has accelerated in recent years. It has resulted in various health warnings, including the FDA's *Interim Health Advisory for Perchlorate in Public Water Systems* and efforts to assess background levels of perchlorate in the food supply.²¹⁵ Lacking a federal legal drinking water standard for perchlorate, Massachusetts and California established their own standards in 2006 and 2007 of 2 ppb and 6 ppb respectively.²¹⁶ However, on February 27, 2015, California revised its public health goal, which is the level of daily exposure in drinking water

at which no significant public health effects would be expected, from 6 ppb to 1 ppb because of potential impacts to fetuses and infants (the actual standard has not yet been revised).²¹⁷ This expanded understanding of the dangers of very low levels of perchlorate to vulnerable populations, including pregnant women,²¹⁸ has not, however, triggered a reassessment of perchlorate food packaging uses.

In addition to the FDA's failure to address new data on hazards, the petitioners also cited a host of specific analytic and regulatory errors with respect to perchlorate's approvals for use in food packaging: erroneous exposure and migration assumptions, data gaps, and the expansion of narrow approvals to product categories and additive levels not formally assessed. To date, the issue of perchlorate in food packaging remains unresolved. The FDA failed to respond to the petition by a June, 2015 deadline, leading petitioners to bring suit against the agency in March 2016.²¹⁹

The continued presence of BPA, phthalates, florochemicals, and perchlorate in the food packaging stream, along with that of the other comparably hazardous chemicals described earlier, highlights how evolving science is not, and cannot be, met with a commensurate regulatory response under the current federal structure.

IV. Industry Influence and Political Failure

The EPA and the FDA's limited authority and resources are partially a function of Washington D.C.'s frozen political landscape. For instance, multiple TSCA reform bills have been under active consideration since 2010. After years of wrangling, Congress finally passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act²²⁰ on June 7, 2016 and President Obama signed it into law on June 22.²²¹ The bill is an improvement over the 40 year old TSCA. Most notably it gives the EPA important new authorities to regulate chemicals and more efficient mechanisms to require chemical toxicity testing; enforceable deadlines for decisions with expedited action on chemicals that are persistent, bioaccumulative, and toxic; and dedicated funding

from industry paid fees. However, it also contains flaws, such as a cumbersome process for prioritizing chemicals and the preemption of state restrictions on chemicals once the EPA names those chemicals "High Priority" and indicates it will do a risk evaluation.²²²

Recent changes to the FDA practices, under the Food Safety Modernization Act (FSMA) of 2011, dealt chiefly with acute, microbial illnesses and the safety of imported food. These are the kind of dangers that grab headlines and jolt elected officials, while chronic chemical exposures from packaging do not. A proposed amendment by Senator Dianne Feinstein (CA-D) to FSMA that would have banned BPA in food

and beverage containers was rejected when the bill was moving through Congress²²³ and separate legislation that would have achieved the same end failed.²²⁴ The BPA in Food Packaging Right to Know Act (S 821), introduced in March 2015 by Senators Feinstein and Leahy (VT-D), and requiring manufacturers to publicly disclose if the package is made of or with BPA, is unlikely to advance before the Congressional session ends.²²⁵

Industry interests employ battalions of lawyers, engineers, scientists, and public relations specialists to delay, block, or undo legislative and regulatory steps that would restrict chemical hazards.²²⁶ No study is too small to dispute, and limitations on chemical use are challenged by lawsuits.²²⁷ In an example of such obstruction from the food packaging arena, industry vigorously fought the FDA's attempt to set the allowable levels of DEHP migration from PET water bottles at 0.006 mg/l, the same level of DEHP allowed in public drinking water,²²⁸ a seemingly uncontroversial, common sense action. The FDA's efforts were ultimately successful, but industry managed to block them for decades.²²⁹

The deck is stacked against publicly funded agencies that do not have resources comparable to those of industry. The EPA's overall proposed budget for FY 2015, for example, was \$310 million less than its allotted budget for FY 2014,²³⁰ and a recent assessment of the FDA's capacity concluded that it had "significant workforce and management challenges in the scientific and medical arenas that need to be addressed for the agency to fulfill its public health obligations to the American public and its responsibilities to the industries it regulates."²³¹ In the current political climate, the likelihood that these agencies will receive the resources necessary to fully execute their responsibilities is slim to none. Even though FSMA is now law, Congress has appropriated less than half the funds needed for the FDA to implement it.²³²

Finally, not all of industry's efforts to obstruct regulation take the form of outside pressure. The "revolving door" between regulated industries (or their lobbyists) and the agencies charged with overseeing

Conflicts of interest in the GRAS program are especially pointed. One recent analysis of the 451 GRAS notifications reported during the years 1997 to 2012 found "22.4% of the safety assessments were made by an employee of an additive manufacturer, 13.3% by an employee of a consulting firm selected by the manufacturer, and 64.3% by an expert panel selected by either a consulting firm or the manufacturer."

them, mean that agency staffers have often spent time in both worlds, creating conflicts of interest and loyalty. Despite efforts to curtail the back and forth between agencies and industry/lobbying firms, both through Executive Order²³³ and federal law,²³⁴ the revolving door continues to spin,²³⁵ eroding the distinction between the regulators and the regulated.

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Taken together, resource constraints, political stalemates, outside industry pressure, internal conflicts of interest, and inadequate statutes serve to render federal reforms a distant hope.

V. What's in the Package is a Secret

The absence of effective regulation creates an added imperative for disclosure — consumers should have the right to protect themselves and their families when the government does not. Avoiding dangerous chemicals requires that people know when they are being exposed to or consuming them. The lack of information up and down the supply chain means that even retailers and food processors are often unaware of all the myriad contaminants in their products.²³⁷ The end result is that food packaging chemicals are shrouded in secrecy, disallowing informed individual choice and innovation of benign alternatives. Transparency is not, however, an end in itself. It is ultimately a driver of change as consumers become aware of threats to their health or environment and market demand for safer alternatives grows. It is also essential for government to use its regulatory power to protect the public and for food manufacturers to identify which packaging meets the safety demand.

The most obvious roadblock to transparency is that packaging chemicals do not appear on food labels.²³⁸ Such chemicals, however, are statutorily categorized as indirect food additives for a reason — a plain acknowledgement that they are part of the food itself.

Nor can consumers, state and local governments, health and environmental watchdogs, or even diligent food companies who wish to avoid hazardous packaging learn much more by sifting through public databases that ostensibly exist to catalog this information. The dearth of actual data discussed above is only one impediment to understanding. Another roadblock is the fact that even those data that do

exist are often shielded from view behind layers of trade secrecy protection.

Trade secret laws allow companies to keep various types of information confidential, largely as a protection from competition. Examples include internal business and financial information, product formulations or ingredients, and research and development. While some of this is a legitimate need in a global marketplace where patents and copyrights cannot be relied on to protect a company's competitive

advantage, trade secrets can clash with public safety and environmental protection, including the right to know the ingredients in the foods one purchases.

Many consumers are avid readers of labels, choosing products based on whether they believe the products to be safe for themselves and their families. Trade

secrets about basic ingredients, particularly chemicals, in everyday products take away their right to knowledge and choice, leading to the exposure to toxic substances without the individual's permission. A case in point is the ability of companies to hide the list of chemicals in products, either completely or behind vague phrases such as inert or inactive ingredients, food coloring, fragrance, and flavoring, even if these substances pose a threat to health or the environment. The lack of chemical ingredient disclosure, in the name of protecting trade secrets, has become indefensible in cases where technology enables companies to back-engineer their competitors' products and identify chemical components. The idea that a company can keep secret the ingredients used in food packaging is a myth when simple lab analysis can enable any competitor to identify the chemicals used.



At FDA, FCS notifications are proprietary and the information contained in the notification may not be disclosed during the review process, foreclosing the opportunity for public scrutiny or comment prior to a decision.

The FDA's regulation of food packaging chemicals allows ample protection of corporate trade secrets, even with GRAS chemicals that are supposed to be well known and publicly recognized as safe. If a manufacturer determines that an ingredient is generally recognized as safe — i.e. GRAS — it is supposed to be based on publically available safety information and there must be consensus among food safety experts that the ingredient is safe. However some manufacturers maintain trade secrets on GRAS ingredients. For example, Robert McQuate, CEO of GRAS Associates, LLC, a food ingredient-consulting firm, says that about half of his clients do not voluntarily submit their GRAS determinations to the FDA for review as a means of protecting their trade secrets. Companies can do that because disclosure of GRAS chemicals is voluntary. Trade secret protections create a kind of Catch-22. Although GRAS determinations are supposed to be based on publicly available safety information, manufacturers do not have to disclose either the identity of the chemical for which it has made a GRAS determination or the safety information upon which it based its decision.²³⁹

An FDA spokesperson clarified that a manufacturer may be able to make a GRAS determination and maintain non-critical trade secrets information for that substance: “If the company’s trade secret information *is critical* to its GRAS determination, then the use of the ingredient is not eligible to be GRAS. . . . If the company’s trade secret information *is not critical* to its GRAS determination, then the use of the substance may be considered eligible for GRAS.” In addition, she clarified that if trade secret information is critical, then the manufacturer has the option to

submit the substance for review as a food additive, which has trade secrets protections: “Trade secret, confidential commercial or financial information submitted as part of a food additive petition is not available for public disclosure.”²⁴⁰

For chemicals that are not widely recognized or commonly used in food, the food contact substance petition is a more likely method of keeping the use of certain ingredients in food or food packaging confidential. According to food additive and chemical safety legal expert Tom Neltner, “Food additive petition allows you to submit confidential information and to be able to keep it confidential. If people don’t know what it really is, it can’t be generally recognized.”²⁴¹

At the FDA, FCS notifications are proprietary and the information contained in the notification may not be disclosed during the review process,²⁴² foreclosing the opportunity for public scrutiny or comment prior to a decision. Public assessment after a decision is further constrained by industry’s right to claim trade secret protection for information that would reveal “manufacturing methods or processes, including quality control procedures;” “production, sales, distribution, and similar data and information;” and “quantitative or semi quantitative formulas.”²⁴³ These broad categories encompass information necessary to assess whether migration and exposure estimates are accurate. Some evidence exists, for example, that the FDA regularly holds information on impurities confidential.²⁴⁴ The FDA retains the right to deny these trade secret claims,²⁴⁵ but it is unclear how often or under what circumstances it does so.

There is a greater level of public process under the FDA’s Indirect Food Additives program, where decisions are promulgated as regulations and thus subject to public comment before being finalized. However, petitions under this program are also subject to claims of trade secret confidentiality. Decisions under this program are also now decades out of date and plagued by the data gaps described above.

The combination of legal trade secret protections and significant data gaps gives industry a pass on both understanding and disclosing the risks of food packaging chemicals. This status quo serves no defensible public interest.

VI. California's Limited Framework for Reducing Chemical Hazards from Packaging

While it is essential to press on with efforts to improve regulation at the federal level, the risk from food packaging chemicals is daily and immediate. States must lead where the federal government has not.

California already has several statutes and programs in place that empower it to address food packaging chemicals, and which could be built upon to address both hazard and disclosure. The foundational statute in California that grants this authority is the Sherman Food, Drug, and Cosmetic Law (Sherman Law).²⁴⁶ The Sherman Law adopts and incorporates all federal food additive regulations, sanctions, and other approvals as California's own. It uses these as a floor, however, not a ceiling, granting California's Department of Public Health the authority to be more stringent than the FDA:

Section 110085. The department may, by regulation, prescribe conditions under which a food additive may be used in this state whether or not these conditions are in accordance with the regulations adopted pursuant to the federal act.

The Sherman Law further provides for parallel incorporation of federal food labeling decisions, with corresponding authority to be more stringent.

Section 110100: (a) All food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on or after that date shall be the food labeling regulations of this state. (b) The department may, by regulation, adopt additional food labeling regulations. Prior to the adoption of any food labeling regulation pursuant to this subdivision, the department shall seek comments from consumer groups and representatives of the food industry that have been identified by the department as being affected by the proposed regulation.

California thus possesses a foundation of broad authority on which to base more protective and transparent regulation of food packaging chemicals if it chooses to do so. Several other statutes and

programs augment the Sherman Law, in different ways:

- California's Toxics in Packaging Prevention Act bans four heavy metals from any type of packaging²⁴⁷ — lead, mercury, cadmium, and hexavalent chromium. Despite this, and other such laws across the country,²⁴⁸ heavy metals are still detected in many food packaging products,²⁴⁹ often from the inks and colorants.²⁵⁰
- Proposition 65 requires that people be informed when they are exposed to chemicals that OEHHA has determined to cause cancer, birth defects, or other reproductive harm,²⁵¹ unless such exposures are deemed too low to require disclosure.²⁵² Inclusion on the lists occurs through a variety of mechanisms, some of which can entail a time-consuming regulatory assessment and be open to industry challenge.²⁵³
- The Safer Consumer Product regulations, promulgated in October 2013 by California's Department of Toxic Substances Control (DTSC) allow the state to address hazards from certain chemical/product combinations. DTSC has compiled an overarching *Candidate Chemical List* of chemicals (approximately 2300) gleaned from various authoritative bodies that are deemed to pose public health or environmental hazards.²⁵⁴

After a winnowing process that allows for public comment, DTSC is expected to generate a prioritized short list (three to five, a new list every few years) of chemical/product combinations, and requires companies selling them to conduct a comprehensive alternatives assessment to establish if a toxic chemical is necessary, and what safer alternative designs or chemicals could replace it. Individual companies will be required to propose their chosen options and DTSC will then decide on a regulatory response

to each. Three chemical/product groups have already been chosen as the first priorities for alternatives analysis, and the effort is underway.²⁵⁵ The Department has also collected public comment on a draft three-year workplan for the next set of chemical/product candidates for future alternatives assessment.²⁵⁶ However, as expected, industry interests related to specific products have pushed back against the selections and the process itself. In addition, the agency itself is moving very slowly to establish proper guidelines for alternative analyses and the overall program.

Despite the slow progress, there is ample reason to expect that DTSC's program will tangibly reduce chemical hazards, both for chemical/product combinations on the targeted priority list and for others that industry would like to avoid being included on the list. The process, however, is a deliberative one and lacks a sustainable funding mechanism. Food packaging chemicals are not among its initial priorities, nor given the breadth of chemicals and products in commerce, is there a guarantee that they will be in the foreseeable future. In addition, while DTSC can require chemicals to be disclosed to the agency, it is not allowed to require full public disclosure of all chemicals in products or share chemical information that industry claims as a trade secret.

California's Laws Do Not Adequately Address Food Packaging Disclosure

California's landmark right-to-know program, Proposition 65, has had a tangible effect overall on toxic exposures,²⁵⁷ and on lead and cadmium-containing inks on soft drink bottles and lead-containing inks on candy wrappers. The law is limited, however, because many hazardous food packaging chemicals are either not listed, or are the subject of time-consuming disputes. BPA is a case in point. OEHHA added BPA to the Proposition 65 list as a reproductive toxicant on April 11, 2013.²⁵⁸ Eight days later, it was forced to delist it after a successful industry lawsuit that claimed the agency had not met its burden of proof for listing.²⁵⁹ On December 5, 2014, however,

a California Superior Court overturned that previous decision, finding that the burden of proof had indeed been met, and OEHHA relisted BPA as a known female reproductive toxicant in 2015.²⁶⁰

This kind of industry challenge is a reflexive response to any regulatory limitation. Industry beat back two proposals by OEHHA to list styrene under Proposition 65.²⁶¹ While it finally listed the chemical as a known carcinogen on April 22, 2016,²⁶² the agency is proposing a No Significant Risk Level (NSRL) of 27 micrograms per day for styrene.²⁶³ This "safe harbor" level is likely to ensure that few if any warnings will be required. The bottom line, however, is that even when unsuccessful, such challenges eat up agency bandwidth and contribute to the plodding pace of regulatory responses across the board.

Despite such roadblocks, a handful of food packaging chemicals — including styrene oxide, DEHP, DiNP, and benzophenone — have managed to make the Proposition 65 cut, but they are still not listed on food labels.²⁶⁴ The reasons for this are unclear.²⁶⁵ It may be that it is difficult for the state to enforce the law when it is difficult to know if these chemicals are present in the packaging. Another potential explanation may be that exposure from each individual piece of packaging is estimated to be cumulatively below levels at which disclosure is required, though it should be noted that neither benzophenone or DINP have established "No Significant Risk Levels" (applicable to carcinogens) or MADLs (applicable to reproductive toxicants) under Prop 65.²⁶⁶ Consequently, these chemicals should have to be listed on the package. Prop 65 requires it, as evidenced by the pending warnings about packaging containing BPA described above.

OEHHA is also developing a Toxics Information Clearinghouse, compiling information about chemical characteristics and hazards for public access. The Clearinghouse will make existing information easier to find, but it carries no requirement that industry generate new information for it. It will thus be subject to all the same data limitations and trade secret strictures as federal databases.

VII. Recommendations: Advancing the Public's Right To Know About Chemicals in Food and Beverage Packaging

When structured properly, chemical disclosure is a powerful driver for innovation by which manufacturers avoid harmful materials and practices, and find safer alternatives. Proposition 65, for example, requires that manufacturers, retailers and other businesses provide notice to Californians when they are being exposed to toxic chemicals. In response, many manufacturers have reformulated their products to eliminate any chemical on the publically available Proposition 65 list, rather than have to show a Proposition 65 warning on the product label or supermarket shelf. One of those chemicals is lead. According to Californians for a Healthy and Green Economy (CHANGE), “products that have removed lead include: cords for electronics, vinyl lunchboxes and backpacks, children’s jewelry, Mexican candy, brass faucets, ceramic ware, calcium supplements, water meters, water filters, galvanized and PVC pipe, crystal decanters, foil caps on wine bottles, brass keys, hand tools, exercise weights, raincoats, electrical tape, electrical cords and wires, bicycle cable locks, CD wallets, baby rash powders and creams, anti-diarrheal medicines, and hair dyes.”²⁶⁷

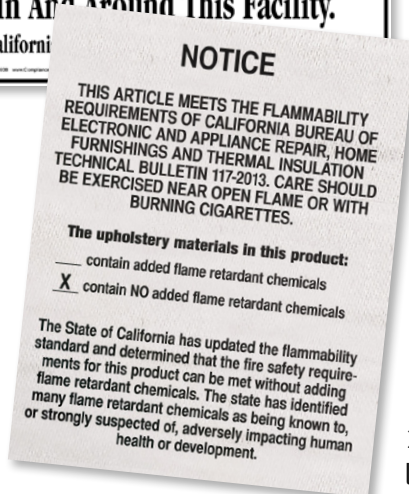
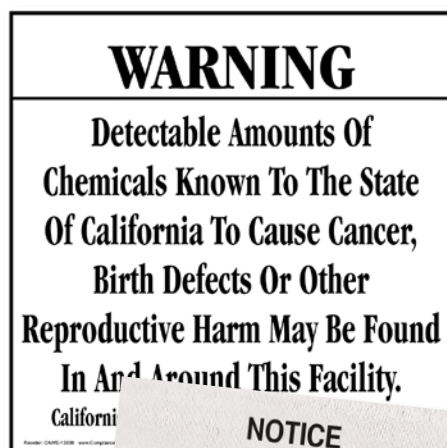
Other right-to-know programs, like the Toxics Release Inventory (TRI), have demonstrated this effect. When industrial facilities were forced to publicly disclose annual emissions of 651 chemicals used and stored on site in a publicly accessible

inventory, releases of these chemicals declined by 45% in the first eight years of implementation.²⁶⁸

Public information about the emissions of toxic chemicals resulted in decreased stock prices for the worst offenders. These companies put the most money into reviewing and cleaning up their operations and made the biggest progress in reducing emissions significantly in subsequent years. A few years after the law took effect, a Dow Chemical executive said in a newspaper interview that “Mandatory disclosure has done more than all other legislation put together in getting companies to voluntarily reduce emissions.”²⁶⁹

A more recent example is the result of recent law regarding the labeling of furniture that contains flame retardants. In 2014, the Governor signed into law SB 1019 (Leno), a law that requires that furniture be labeled

as to whether or not it contains foam treated with flame retardants. The law went into effect in January 2015 and almost immediately, Ashley Furniture announced that it was removing all flame retardants from its furniture products, not just in products sold in California, but all products it sells across the U.S. as well as complying with the labeling requirement.²⁷⁰



A Dow Chemical executive said in a newspaper interview that “Mandatory disclosure has done more than all other legislation put together in getting companies to voluntarily reduce emissions.”

Transparency drives change due to pressure exerted by consumer purchasing, but consumer right to know also incites companies to get out ahead of competitors in the marketplace by changing their practices or ingredients (like Ashley Furniture). Some companies are motivated by the pressure exerted from regulatory “blacklists” (like Prop 65) and public interest scorecards that impact their reputation.²⁷¹

Shining a light on toxic chemicals is thus the first step in creating an economy where hazardous substances do not exist — where green chemistry, product reformulation, and other innovations obviate the need for warnings. Until such a time arrives, however, disclosure allows people to know about dangerous chemicals, protects workers, enables government to regulate chemical use, and aids in tracking environmental contamination.

The widespread and insidious hazards of dietary exposure to food packaging chemicals have, to date, fallen through the regulatory cracks when it comes to disclosure. Moreover, the piecemeal accretion of information regarding high profile food packaging chemicals has so far failed to cohere into regulatory action proportional to the risk. While new revelations about the carcinogenicity of styrene and the portfolio of hazards posed by BPA and phthalates, have sparked scattered voluntary product substitutions,²⁷² such substitutions may simply offer a new array of risks, ones less well studied and understood than those of older, higher profile chemicals, but no less real. Until disclosure is complete and mandatory, there will be little impetus for a fuller examination of all food packaging chemicals, or accountability for their dangers.

In order to address the risks of food packaging chemicals, therefore, new right-to-know legislation to require labeling is required. There are four basic issues that should be addressed in this legislation:

1. Disclosure should be based on the simple presence of a chemical, not an estimate of exposure.

Models that rely on risk estimates fall short of providing the level of disclosure appropriate for food packaging chemicals. As noted above, for example, California’s Proposition 65 bases its disclosure requirements on anticipated levels of exposure. The

few food packaging chemicals that have made the Proposition 65 list are present in quantities that, in each separate product, are small, but this does not reflect either the actual risk posed by food packaging chemicals, many of which are known to be biologically active at very low doses, or their exposure patterns, which entail numerous daily exposures that are significant in the aggregate (as evidenced by the NHANES biomonitoring data discussed in Section I.). Nor does it account for synergistic effects or effects in accumulation with other endocrine disrupting chemicals. It also assumes a level of certainty in making such estimates that is not justified by the slimness of the data on which they rest.

Other programs offer better models to emulate. Labeling requirements for pharmaceutical products, for example, are comprehensive. Individual ingredients in a pharmaceutical product, whether that product is a prescription drug, or over-the-counter drug, must be disclosed to patients and consumers.²⁷³ No exceptions are made for the amount of the ingredient, or whether it is an active or inactive ingredient.

2. Trade secret claims on chemical ingredients should be prohibited.

Industry uses the claim of trade secrets as a first line of defense to prevent disclosure. Wherever a trade secret option is available, industry takes it. Although many statutes, such as TSCA, do not allow trade secret claims to apply to health and safety information regarding chemicals that are the subject of the regulation, in practical terms, public agencies do not have the resources necessary to systematically challenge them. Trade secret claims should be categorically disallowed for food packaging chemicals that, like other food ingredients and pharmaceuticals, are directly consumed.

California has recently taken a notable step toward limiting trade secret claims when public health is at stake. Under SB4 (Pavley), a bill enacted in 2013, addressing hazards of oil and gas well stimulation,²⁷⁴ California requires full public disclosure of all chemicals used in hydraulic fracturing and other well stimulation. These right-to-know provisions are among the most far-reaching in the nation for environmental hazards. The use of trade secret claims to shield chemical



identity is not allowed. Only the concentration of each chemical may be claimed as CBI, and even then, such claims are subject to approval by the California's Division of Oil Gas and Geothermal Resources. This approach, both progressive and protective, is an excellent precedent that should be broadened to encompass other chemical hazards.

3. The first line of disclosure should be directly on the label.

Having to search for chemical ingredients on-line or through a secondary outlet is a significant hurdle for consumers making immediate in-store decisions about food and beverage products for their families or who do not have internet access at all. To be fully protective of public health and accessible to all, legislation should require packaging ingredients to be displayed on the product label, with more comprehensive information available by phone or via a company website.

4. The Sherman Law should be updated to establish a more stringent regulatory program to ensure the safety of food and indirect food additives.

While changing federal regulations would be preferable, Congress or the FDA is unlikely to take bold action at this time to reframe the regulation of food and food packaging. Change more likely needs to be inspired by public market pressure and regulatory reform at the state level. California is particularly well

positioned to require greater chemical transparency that can drive market change given its overall leadership on protection of public health and the environment and the size of its economy.

First and foremost, the state should review all indirect food additives currently in use in products sold in California and subject to safety review. Determinations should be made as to whether the chemicals in use have been established through sound scientific research. For chemicals that lack adequate scientific support, the state should require that the research be conducted within a narrow time frame if the chemical is to continue to be approved for use in California. The review process should include complete transparency regarding the basis for decision-making and the data on which the decision is based. The process must include a robust public participation program, including ample opportunity for public comment and opportunities to appeal approvals for specific chemicals.

New legislation, with these core elements as scaffolding, would fill a dangerous hole in the public's knowledge of what it ingests. It would also spur a critical examination of the full universe of food packaging chemicals, which current regulations have failed to provide, and jumpstart research into genuinely safer alternatives. Such alternatives would benefit all consumers, but they would be a particular boon to lower-income consumers who, having less access to fresh and affordable food, are disproportionately exposed to packaging hazards.

VII. CONCLUSION: What's in the Package is in our Food... and it's a Secret

One hundred years since Upton Sinclair published *The Jungle*, U.S. consumers still have reason to feel insecure about the safety of their food. However, contemporary concerns are no longer based on unsafe and unsanitary conditions in the meat packing plants, but rather about the untested or unknown toxic chemicals used in food and food contact materials, including packaging. Many consumers are fearful of the things that are widely publicized in the media, such as, antibiotics, pesticides, and highly debated chemicals, such as BPA. But the vast majority of consumers have no idea of the breadth of carcinogenic and endocrine disrupting chemicals used in food contact materials and the lax regulatory approach to identifying chemical ingredients and evaluating their potential hazard. Looking at the ingredients label on a box of cereal or package of raw chicken, a consumer does not know all the ingredients inside. The label doesn't disclose what chemicals have migrated into the food and will bioaccumulate in the body and later leach into the environment through human excretion or when disposed of. This shroud of secrecy goes beyond simply not serving the public's interest. It can actually cause harm. Consumers are exposed to toxic chemicals without their knowledge or permission. Some of these chemicals are linked to a wide range of serious health problems and environmental consequences, with disproportionate impacts in low-income communities. And it is all legal.

In the absence of effective national regulation, it is time for the state to act. California can and should require disclosure of food packaging chemicals. No less than food itself, packaging chemicals are part of a daily diet — an ever-renewed exposure source with grave hazards for current and future generations, and for the environment. Disclosure just for disclosure's sake is not the end goal, however. While in some cases, product information allows shoppers to make immediate purchasing decisions based on health concerns, in the end shining a light on chemical



ingredients will serve as a more upstream driver of change. Labeling requirements for food packaging chemicals would push the packaging industry to find alternatives that are genuinely safer, rather than simply substituting chemicals that are less fully investigated — and potentially as or more toxic — than the ones they replace.

No doubt, many food and packaging companies will seek safer alternatives voluntarily out of a desire to protect both their customers and their public image. In those unfortunate cases where producers refuse to act, greater transparency about what is in packaged food will enable both public interest groups and regulators to take protective action on the public's behalf.

All of the recommendations in this report are realistic. Since 1906, U.S. law has evolved — albeit slowly at times — out of consideration of new health and environmental science. In each case the food industry has acclimated and complied with greater demands for safety.

ENDNOTES

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- 254 See: <https://www.dtsc.ca.gov/SCP/ChemList.cfm>
- 255 The first three chemical/product priorities for DTSC are spray polyurethane foam systems containing diisocyanates, children's foam padded sleeping products containing the flame retardants Tris or TDCPP, and paint and varnish strippers and surface cleaners containing methylene chloride. For more details, see: <http://www.dtsc.ca.gov/SCP/program.cfm>
- 256 See: <http://www.dtsc.ca.gov/SCP/PPWP.cfm>
- 257 Rechtschaffen C, Williams P (2005), The Continued Success of Proposition 65 in Reducing Toxic Exposures, *Environmental Law Reporter*, 35:10850-10856.
- 258 See: <http://oehha.ca.gov/prop65/law/041913BPAdelist.html>
- 259 See full text of ruling at: http://www.ceh.org/wp-content/uploads/BPA_0720-RULING-ON-SUBMITTED-MATTER.pdf
- 260 See: http://oehha.ca.gov/prop65/CRNR_notices/list_changes/051115listBPA.html
- 261 See: http://www.oehha.ca.gov/Prop65/CRNR_notices/admin_listing/intent_to_list/010413_NILstyrene.html Also see: Keller and Heckerman LLP (March 14, 2013), California Withdraws Latest Notice To List Styrene Under Prop 65; Study Finds Exposure To Styrene Does Not Increase Cancer Risk, *PackagingLaw.com*. See: http://www.packaginglaw.com/3498_.shtml
- 262 See: http://oehha.ca.gov/prop65/CRNR_notices/list_changes/042216P65liststyrene.html
- 263 See: http://oehha.ca.gov/prop65/CRNR_notices/NRPStyreneNSRL042216.html Public comments on the NSRL were accepted until June 6, 2016.
- 264 See: <http://oag.ca.gov/prop65/faq>
- 265 Clean Water Action reached out to both OEHA and the State Department of Public Health for clarity on this issue, but could not discover a definitive explanation as to why food and beverage packages do not include Prop 65 warnings. However, the organization did participate in discussions with California EPA and OEHA on how best to provide initial warnings on BPA, advocating for interim listings in the store of which products had BPA packing and ultimate listing on the product label itself.

- 266 See: <http://www.oehha.ca.gov/prop65/pdf/safeharbor081513.pdf>
- 267 <http://www.changeocalifornia.org/2010/07/prop65.html>
- 268 Fung, D and O'Rourke, A, Reinventing Environmental Regulation from the Grassroots Up: Explaining and Expanding the Success of the Toxics Release Inventory, *Environmental Management* Vol. 25, No. 2, pp. 115-127; Rechtschaffen C, Williams P (2005) Graham M, Miller C (2001), Disclosure of Toxic Releases in the United States, *Environment: Science and Policy for Sustainable Development*, 43:8-20.
- 269 http://www.pbs.org/tradesecrets/evidence/pop_reg01.html
- 270 <http://saferchemicals.org/2015/03/03/ashley-furniture-to-phase-out-toxic-flame-retardants-from-furniture-but-when/>
- 271 Fung, D and O'Rourke, A.
- 272 See: <http://www.plasticstoday.com/blogs/Some-fast-food-brands-look-beyond-polystyrene-others-embrace-it-08120201301>
- 273 See: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=201>
- 274 See: <http://www.conservation.ca.gov/dog/Pages/Index.aspx>



WHAT'S IN THE PACKAGE?

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