

WHAT'S IN THE PACKAGE?

Unveiling the Toxic Secrets of Food and Beverage Packaging



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 FFDC. 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 anti-mony, 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 FFCA, 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 FFCA, 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.

For the full report, go to: http://www.cleanwateraction.org/sites/default/files/CA_TIP_rpt_08.24.16a_web.pdf