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## Protecting the Public from BPA: An Action Plan for Federal Agencies

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# Protecting the Public from BPA:

## An Action Plan for Federal Agencies

**By CPR Member Scholars Noah Sachs, Thomas O. McGarity, and Rena Steinzor, and CPR Policy Analysts Aimee Simpson and Matthew Shutz**



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This white paper is a collaborative effort of the following individuals: **Noah Sachs** is an Associate Professor of Law and Director of the Robert R. Merhige, Jr. Center for Environmental Studies at the University of Richmond School of Law and a CPR Member Scholar; **Tom McGarity** is the Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law at the University of Texas at Austin School of Law and former President of CPR, and **Rena Steinzor** is a Professor at the University of Maryland Francis King Carey School of Law and President of the Center for Progressive Reform. **Aimee Simpson** is a Policy Analyst and **Matt Shudtz** is a Senior Policy Analyst with CPR.

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## Executive Summary

Bisphenol-A (BPA) is a ubiquitous industrial chemical found in everything from baby bottles to cash register receipts. From its inauspicious creation in the laboratory by a group of scientists trying to synthesize an estrogenic compound for the pharmaceutical industry, it has become a fundamental building block of the multi-billion dollar plastics industry.<sup>1</sup> Unfortunately, ever since anomalous results appeared in two research labs using BPA-containing plastic equipment in the 1980s, evidence of the chemical's toxicological risks has continued to mount. The chemical is an endocrine disruptor, meaning that it interferes with the body's hormone system, and BPA's health risks include, but are not limited to, increased susceptibility to prostate and breast cancers,<sup>2</sup> reproductive system defects and abnormalities,<sup>3</sup> hormonal imbalances,<sup>4</sup> brain development abnormalities,<sup>5</sup> gender confusion,<sup>6</sup> heart disease,<sup>7</sup> and diabetes.<sup>8</sup> Particularly alarming is the evidence that the populations most in danger of suffering from BPA's health risks are fetuses, infants, and children. New scientific evidence about BPA also indicates that the familiar concept of "the dose makes the poison" – an idea that underlies most of our federal laws for managing toxic risks – may not apply to BPA. Ordinarily, decreasing exposure to a toxic chemical decreases adverse effects. Thus we manage toxic risks by reducing exposures to a point where health effects do not occur or where the risks are sufficiently low that we consider the exposures "safe." With BPA, however, low doses could cause significant harm, and for certain health effects it appears that low dose exposures to BPA could actually be more harmful than some high dose exposures.<sup>9</sup>

Mounting health and safety concerns over BPA have not only raised consumer anxieties over the prolific chemical's presence, but also given rise to a deceptive consumer environment, in which seemingly reassuring labels of "BPA-Free" offer little meaningful information, protection, or indication of regulatory progress. For one thing, substitutes for the chemical, such as Bisphenol-S (BPS), may be just as risky. For another, federal agencies have not taken effective steps to control BPA exposures. To assist the federal agencies in moving forward with BPA regulation and to provide the public with a more informative and safer consumer environment, this white paper outlines various short-term and long-term regulatory options for protecting the public from the health risks posed by BPA.

The Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Occupational Safety and Health Administration (OSHA) are the federal agencies best situated to tackle BPA risk assessment and risk management, given the present state of scientific information on the endocrine-disrupting chemical, the agencies' regulatory authority, and their resources. This white paper urges a two-phase approach to BPA regulation. The first phase should produce immediate information collection and dissemination, including early warnings for the public and stricter guidance for industry. The second phase should include long-term regulatory controls, standards, and protections, to be promulgated as soon as missing information becomes available.

**For certain health effects it appears that low dose exposures to BPA could actually be more harmful than high dose exposures.**

## Federal Agency Short-Term and Long-Term Action Plan

FDA: Short-Term Regulatory Options	FDA: Long-Term Regulatory Options
<p><b>Aggressively Pursue Additional Scientific Study and Data Collection Efforts</b></p> <p>FDA should continue with its intentions to perform collaborative research projects with the National Center for Toxicological Research and the National Toxicology Program. In conjunction with these efforts, FDA should use its authority under the Food Contact Substance Notification program to issue new guidance on BPA-specific safety testing and data submission requirements.</p> <p><b>Issue “BPA-Free” Labeling Guidance</b></p> <p>FDA should issue labeling guidance on the use of “BPA-Free” labels. Included in this guidance should be a recommendation that any “BPA-Free” labeled product that merely uses a replacement endocrine-disrupting product would be considered misbranded.</p> <p><b>Issue New Guidance for Food Contact Substance Notification Applicants that Imposes Safer BPA Use Standards</b></p> <p>Issue guidance stating that any new Food Contact Substance Notification Applicants applying for a new BPA use will most likely face denial if the new use involves contact with certain foods, such as infant formula, or a dangerous target consumer, such as children.</p>	<p><b>Rewrite Redbook Protocols for BPA and other Endocrine Disruptors</b></p> <p>BPA and other endocrine disrupting chemicals do not fit the traditional risk assessment mold and thus the underlying scientific protocols must be rewritten to account for their unique low-dose adverse affects and expand study endpoints.</p> <p><b>Revoke Existing and New BPA Uses Approved under the Food Contact Substance Notification Process</b></p> <p>Since 2002, packaging uses of BPA have been approved under the Food Contact Substance Notification process. FDA should revoke approved Food Contact Substance Notifications and affirmatively deny any new Food Contact Substance Notification applications with the aim of imposing new safety testing, exposure, and use standards.<sup>10</sup></p> <p><b>Issue New Regulations for BPA Uses</b></p> <p>Beginning in 1958, FDA approved certain uses of BPA as indirect food additives. FDA has the power to issue new regulations prescribing the conditions under which those uses are deemed safe.<sup>11</sup> FDA should utilize this authority and issue new regulations outlining specific use and safety parameters for BPA. These parameters could be as broad as banning specific BPA uses, mandating BPA labeling, or mandating the submission of specific toxicity and exposure testing information on a regular basis.</p>

<p><b>EPA: Short-Term Regulatory Options</b></p>	<p><b>EPA: Long-term Regulatory Options</b></p>
<p><b>Update the Existing IRIS Database to Accurately Reflect BPA’s Known Risks and Datapoints</b></p> <p>EPA needs to update its BPA IRIS entry to accurately reflect the currently known low-dose exposure risks.</p> <p><b>Utilize TSCA to Gather Exposure and Use Information</b></p> <p>EPA should aggressively pursue development of its proposed BPA Test Rule and Chemicals of Concern list. Resulting data collection efforts and studies should include both environmental and human health risk assessments.</p>	<p><b>Managing Risks through Rule Development Under TSCA § 6</b></p> <p>Utilizing current risk assessment information and future exposure data, EPA should consider promulgating BPA regulatory safeguards, such as warning labels, specific use restrictions, and a potential ban.</p>
<p><b>OSHA: Short-term Regulatory Options</b></p>	<p><b>OSHA: Long-term Regulatory Options</b></p>
<p><b>Assess Workplace Risks Through Increased Scientific Research and Data Collection</b></p> <p>NIOSH and OSHA need to perform more U.S. workplace studies and develop a more comprehensive database of workplace exposures and risks.</p> <p><b>Assess &amp; Manage Workplace Risks through the Hazard Communication Standard</b></p> <p>While exposure and risk assessment continues, OSHA needs to implement the new Hazard Communication standards and enforce accurate risk communication and warning labels for BPA through retooled material safety data sheets (MSDS).</p>	<p><b>Manage BPA Risks Using the General Duty Clause and Establishing Permissible Exposure Limits</b></p> <p>As more risk assessment and exposure data come in, OSHA needs to establish a Permissible Exposure Limit for BPA. OSHA should also consider utilizing such data to regulate BPA under the General Duty Clause.</p>

## Introduction

The mounting body of scientific research concerning BPA has provided a solid base of information upon which federal agencies can build public safeguards. What we now know about BPA is ample basis for concern about its safety, and in preparing this paper and the regulatory options we recommend, we have paid careful attention to the current state of that research. Just as important, what we do not yet know about BPA is significant, and those remaining questions provide the basis for recommendations contained in this report. We need to establish a more complete knowledge base of exposure levels through individual pathways (*i.e.*, food, water, air, consumer products, and soil contamination). We also need to know more about cumulative levels of exposure and how the timing and route of exposure impacts metabolism of the chemical. Filling these knowledge gaps is an important component of understanding BPA and how best to protect the public from its health risks. As scientists and regulators gather this information, however, they need not wait to implement certain safeguards against the demonstrated health risks of this endocrine-disrupting chemical.

### BPA Uses

- Plastic food and beverage containers
- Plastic eating utensils
- Baby bottles & sippy cups
- Reusable water bottles
- Canned foods and beverages (including infant formula)
- Kitchen appliances
- CDs & DVDs
- Dental sealant
- Medical devices
- Epoxy linings (used on everything from tin cans to jar lids to soda cans)
- Thermal paper (*i.e.* store receipts)



## The Current State of BPA

### The Known Risks of BPA and Inadequate Regulatory Safeguards

Without credible government regulation of perceived risks, alert consumers sometimes find ways to protect themselves from perceived risks through marketplace pressures. The grassroots movement to ban BPA from such popular items as baby bottles and reusable food containers is a prime example. “BPA-Free” labels abound where just a few years ago most people, including mothers, were unaware of the chemical or its dangerous effects. Individual companies, such as Nalgene, have voluntarily eliminated the chemical from their products. Walmart instituted procurement and sales policies aimed at eliminating BPA from baby bottles. While these measures have helped to spur government action and bring BPA into the consumer spotlight, they do not go far enough to impose broad-spectrum protections for the unaware public or for the individuals who struggle to pay premium prices for “kid-safe” products.

An example of the lack of broad-spectrum protection is that grassroots-induced regulation and marketplace pressures do not prevent companies from substituting one dangerous chemical for another. In the case of BPA, some manufacturers of products labeled “BPA-Free” merely replace BPA with its close chemical cousin Bisphenol-S (BPS), which has also demonstrated estrogenic activity and potential endocrine-disrupting effects in recent testing.<sup>12</sup> Additionally, the narrow, if understandable, focus on BPA in baby products ignores that children are also exposed to BPA in their toddler years, through BPA’s use in food cans, for example. Federal regulation by agencies like FDA, EPA, and OSHA is a more comprehensive solution, one that can offer universal safety standards and guidance to spur innovative and safe solutions, while removing obvious risks to consumers. Federal regulation can also ensure that the information concerning BPA’s known risks and presence in consumer products is being provided to consumers in an accurate, consistent, and meaningful manner.





## A Snapshot of Existing International, State, and Local BPA Controls

BPA is subject to a range of international, state, and local controls aimed at the chemical's use in baby products, primarily bottles, sippy cups, and some reusable beverage containers.

Jurisdiction	Date Passed	Type of Regulation	Effective Date
<b>Cities</b>			
Chicago, IL	May 13, 2009	Ban on the sale of baby bottles and sippy cups containing BPA.	January 31, 2010
Washington, D.C.	January 12, 2011	Prohibits BPA in reusable food or beverage containers meant for children four and younger.	July 1, 2011
<b>States</b>			
California	August 30, 2011	Statewide ban of selling and/or making baby bottles and sippy cups containing BPA.	July 1, 2013
Connecticut	June 4, 2009	Prohibits BPA in infant formula packaging, baby food cans and jars, and reusable food and beverage containers.	October 1, 2011
Delaware	June 30, 2011	Prohibits the sale or offering for sale of bottle, sippy cup, or other food contact container intended for use by children up to the age of four.	Immediately effective against manufacturers. January 1, 2012 - Retailer ban effective.
Maine	April 12, 2011	Prohibits BPA in reusable food and beverage containers.	January 1, 2012
Maryland	April 13, 2010	Prohibits BPA in children's products.	January 1, 2012
Massachusetts	December 15, 2010	Prohibits BPA use in reusable food and beverage containers for children three and younger.	January 1, 2011 – Manufacturer ban effective. July 1, 2011 – Retailer ban effective.
Minnesota	May 8, 2009	Bans BPA in sippy cups and baby bottles.	January 1, 2011
New York	July 31, 2010	Bans the sale of baby bottles and other children's products containing BPA.	December 1, 2010

States			
Vermont	May 20, 2010	Ban of BPA in baby bottles, sippy cups, reusable food and beverage containers, and infant formula cans.	July 1, 2012 July 1, 2014 (metal cans)
Washington	2008	Manufacturers of children's products must report use of "chemicals of concern" (including BPA).	August 2010
	May 19, 2010	Ban of BPA in baby bottles and sippy cups for products intended for children under 3 years of age.	July 1, 2011
		Ban of BPA in sports bottles.	July 1, 2012
Wisconsin	March 3, 2010	Ban of BPA in cups and bottles intended for children 3 and younger.	June 2010
Countries / International Authorities			
Canada	April 2008	Ban of sale of baby bottles with BPA.	March 31, 2010.
	October 2010	BPA declared a toxic chemical.	Effective upon declaration.
Japan	Between 1998 and 2003	Voluntary industry-wide replacement of BPA epoxy linings in soda and tin cans. Voluntary replacement of school tableware.	N/A
China	May 30, 2011	Joint notice from health ministries banning BPA use in production and sale of baby bottles.	Production prohibition – June 1, 2011
Malaysia	March 14, 2011	Ministry of Health announced ban of BPA in polycarbonate baby bottles.	March 1, 2012
European Union	N/A	Ban on manufacturing baby bottles with BPA.	March 1, 2011
		Ban of sale and marketing of baby bottles with BPA.	June 1, 2011
France	June 2010	Joint notice from health ministries banning BPA use in production and sale of baby bottles.	Production prohibition – June 1, 2011
Denmark	March 2010	Temporary ban on BPA use in all food contact materials intended for use by children under three.	July 1, 2010

These initiatives (with the exception of Japan's voluntary initiative) leave unaddressed other major uses of BPA, such as epoxy linings and other common food containers or utensils, leaving a large gap in health and safety protections.

**“The dose makes the poison” is the way toxicologists describe how most chemicals interact with our bodies. But BPA is different.**

### **Meager Efforts at the Federal Level**

Troubled by the inaction of federal agencies charged with responsibility for regulating toxic endocrine disrupters, in late 2010, Sen. Diane Feinstein sponsored an amendment to the Food Safety Modernization Act that would have banned BPA from baby bottles, sippy cups, and materials used in infant food and formula cans; however, in last-minute negotiations, the amendment was dropped. Unfortunately, no efforts to regulate BPA through federal legislation have resurfaced.

Most of the statutory regimes under which the federal agencies operate require intensive risk assessment prior to moving forward with any risk management regulations.<sup>13</sup> Fully assessing BPA’s risks has been a complicated endeavor because the protocols that federal agencies have established over the years were designed to investigate chemicals that impact human health in relatively straightforward ways. “The dose makes the poison” is the way toxicologists describe how most chemicals interact with our bodies. But BPA is different. Researchers have found “nonmonotonic dose response functions” (adverse effects at both low-dose and high-dose ends of the spectrum) when they have exposed pituitary, prostate cancer, and other cells to BPA.<sup>14</sup> Despite these testing protocol struggles, scientists have made progress in identifying BPA’s hazards and dose-response relationships but more information is needed concerning low-dose exposure and non-acute adverse effects. Accordingly, federal agencies have taken a more cautious approach than state legislatures in the BPA battle by focusing on revisiting toxicological risk assessments and funding additional exposure studies.

Beginning in 2008, the National Toxicology Program’s Center for Evaluation of Risks to Human Reproduction (NTP-CERHR) released a report, which concluded that some concern existed about infants’ and children’s exposure to BPA.<sup>15</sup> Nevertheless, right on the heels of this report, FDA released its own findings that an adequate margin of safety remained for BPA’s use in food contact sources.<sup>16</sup> Two years later, in 2010, FDA changed its position in a new report, titled “*Update on Bisphenol A for Use in Food Contact Applications*,” and adopted (with some caveats) the position of NTP-CERHR that it shared some concern “about the potential effects of BPA on the brain, behavior, and prostate gland of fetuses, infants and children.”<sup>17</sup> FDA emphasized that despite its change in position, “substantial uncertainties” existed concerning the scientific studies and recommended that future efforts focus on clarifying these scientific uncertainties.<sup>18</sup> As data mounts, FDA is expressing more and more concern about our exposure to BPA through food and announced its support for “a shift to a more robust regulatory framework for oversight of BPA.”<sup>19</sup> Despite these intentions, the regulatory tools available to the agency are difficult to muster for reasons we explain below, and little progress has been made.

The Environmental Protection Agency (EPA) has made a few more tangible steps toward regulating BPA. In March 2010, EPA issued a *BPA Action Plan* outlining its intentions to increase scientific evaluation of BPA, monitor, and analyze environmental exposure pathways and risks, and, depending on the research findings, potentially issue new regulations under the Toxic Substances Control Act (TSCA).<sup>20</sup> The *BPA Action Plan* noted that the agency will defer to FDA and the National Institute of Environmental Health Sciences (NIEHS) for all human-related risk or exposure analysis of BPA—a position encouraged by the White House.<sup>21</sup> EPA proposed new testing requirements that would solidify the knowledge base about BPA’s impacts on plants, animals, aquatic life, and environmental accumulation.<sup>22</sup> The agency also may include BPA in a first-of-its-kind “Chemicals of Concern List.”<sup>23</sup>

Combined, these efforts from the federal agencies show promise but do little for the public in the near future to provide tangible safeguards or, at the very least, meaningful consumer information. Furthermore, the proposed regulatory efforts do little to clear a path for more stringent and long-term regulatory options. With this basic lay of the land in mind, we now turn to each of the three agencies individually to examine what tools they might use now and what tools might become available to them as the science develops.

## Short Term & Long Term BPA Regulatory Options

### Food and Drug Administration

The majority of human exposure to BPA comes through consuming food and beverages. It can be found in a variety of the containers used to store, process, and serve food and beverages, making the chemical a significant public health concern. From reusable water bottles, to baby bottles, to plastic utensils, to linings on soda cans, infant formula cans, and tin cans, BPA comes into contact with the food and beverages of a large swath of the population. One study specifically designed to represent an accurate cross-section of the U.S. population showed BPA's presence in the urine of 95 percent of adults who participated in the Centers for Disease Control screening program.<sup>24</sup>

Through BPA's use in food packaging and containers (or "food contact materials"), the chemical can leach into the food or beverage becoming what is known to FDA as an "indirect food additive" or a "food contact substance."<sup>25</sup> Despite FDA's clear authority to regulate BPA's presence in the American food supply, BPA occupies a space in FDA's regulatory landscape that is complicated by a number of overlapping legal mandates, regulations, exemptions, and loopholes.

### A Complex Regulatory Landscape

FDA first obtained authority to regulate food additives in 1958 and the half-century saga of subsequent regulatory efforts is not a success story from a public health policy perspective. The theory behind the regulatory system was sound – if a company wanted to use a chemical in food packaging, it had to petition FDA for a premarket clearance determination that the use was safe. Unfortunately, the system has failed in practice.

To begin, Congress passed a law which had two major loopholes: (1) if the use of a chemical was already sanctioned by FDA prior to 1958, a petition wasn't necessary; and (2) if qualified experts would generally recognize the use of a chemical as safe, a petition wasn't necessary. Industry exploited the first loophole by reading pre-1958 sanctions broadly. It exploited the second loophole by funding enough research on diet and toxicology that, over time, industry and FDA reached something of a stalemate and industry stopped petitioning FDA for safety determinations if a chemical cleared certain toxicological assays or simply could be calculated to migrate into food at low levels.<sup>26</sup>

Through litigation and administrative advocacy, industry opened other loopholes in the law.<sup>27</sup> Under the "housewares exemption" to the petition process, industry presumes that a petition is not necessary if the end-use of a chemical will be a "houseware" item like paper

cups or plates, plastic utensils, or cooking utensils. Further, under a policy on mixtures of already-approved substances, industry will not submit a petition if all of the components of a new food packaging material have been individually approved and the new use fits within the already-approved conditions of use. And under the “basic resin” (or “basic polymer”) policy, industry does not submit petitions for the various chemicals used as catalysts, reactants, or other agents in the complex process of creating resins (assuming the chemical is used in small quantities and isn’t subject to other regulatory provisions). As a result, while some BPA uses in food contact materials went through the approval process, these loopholes have likely been exploited for many other uses of BPA, raising concerns about FDA’s basic knowledge about exposure routes and the underlying human health hazards of BPA.

Congress attempted to repair the system when it amended the FDCA in 1997. As part of the amendments, Congress created the Food Contact Substance Notification system.<sup>28</sup> It didn’t replace the petition process—a company can still petition FDA for a premarket determination that the use of a particular substance is safe—but it did attempt to streamline some of the administrative procedures. Under the new notification system, companies simply inform FDA that they had made their own determination that a new use of a substance for food packaging was safe under certain conditions. If FDA doesn’t respond to the notification in 120 days, the use of the substance as described in the notification is considered to be sanctioned by FDA (or, in FDA parlance, the notification is “effective”).<sup>29</sup> As a backstop against dangerous substances slipping into the market because of the short timeframe for FDA review in this new process, FDA can request that a manufacturer submit a petition under the old process when FDA feels reviewing a petition is “necessary to provide adequate assurance of safety.”<sup>30</sup>

The overlapping regulatory schemes created by the notification process and petition process, along with the various loopholes that could be utilized, create a complicated landscape for promulgating new safety standards on BPA. Further confounding matters, the scientific evidence regarding BPA’s health hazards and the range of exposure scenarios faced by the public continues to evolve. Nevertheless, FDA has the option of taking several key regulatory actions that could promote public confidence and safety.



### Sharpening FDA's New Food Safety Tool

With the passage of the Food Safety Modernization Act in 2009, Congress at long last granted FDA mandatory recall authority. While this recall authority was granted to more effectively deal with acute outbreaks of food-borne illnesses, such as salmonella and *e. coli*, FDA should consider using this new food safety tool to recall certain foods containing toxins such as BPA, if health hazard concerns become too great and traditional regulatory methods ineffective at protecting the public.

### Expanding Data-Gathering Requirements

New information about BPA's health hazards and toxicological modes-of-action seems to be hitting the scientific literature on a daily basis, yet more is needed to implement any new food packaging safeguards. Not only does FDA need more information on real-life exposures, how BPA is used, and how much of it we're ingesting, but the agency also needs to revisit some of its fundamental risk assessment protocols and policies that instruct any health hazard data collection efforts. FDA has several different regulatory tools that it can use to expand its data-gathering capacity and implement stricter use standards, each with relative strengths and weaknesses.

**The agency should pursue its plan to perform both independent and collaborative research projects to assess newly identified health risks and exposures.** In FDA's January 2010 *BPA Update Report*, the agency affirmed its commitment to both its own independent research efforts and inter-agency research efforts focused on investigating BPAs low-dose endocrine-disrupting effects. FDA cited three collaborative projects between the National Center for Toxicological Research and National Toxicology Program, as well as a \$30 million fund from the National Institute of Environmental Health Sciences (a portion of which would go to FDA) to conduct further independent or collaborative research projects.<sup>31</sup> These risk assessment efforts are critical and FDA must continue to be assertive in its pursuit of collecting additional toxicity and exposure data on BPA through both independent and collaborative research efforts. Understanding that these research projects take time to complete, starting these research projects and continuing with those already moving forward must be a paramount **short-term goal** undeterred by reduced agency budgets, industry bullying, and political pressures. Results from this research will bridge the gap between the more recent scientific studies demonstrating low-dose adverse effects of BPA and the outdated scientific research underlying the ineffective food contact substances guidance and regulations.

**As another short-term option, the agency should also use its authority under the Food Contact Substance Notification program to collect more specific toxicity and exposure data from BPA manufacturers and processors.** FDA need not shoulder the entire burden of implementing new testing procedures and culling BPA toxicity and exposure data. Instead, FDA can issue new guidance recommending that any company that applies for a new BPA use through the Food Contact Substance Notification process must provide toxicity, safety, and exposure data as a part of its submission. These data should include risk and exposure data beyond that which is already required and/or recommended.<sup>32</sup> To obtain these data, the manufacturer or processor would mostly likely need to conduct experiments using dose levels below those traditionally thought to be “safe,” expand the definition of adverse effects to include more subtle endocrine-disrupting effects, and expand the scope and diversity of study endpoints (i.e. the symptoms, disease, behavior, etc. that a study aims to determine).<sup>33</sup> These changes in testing protocols would require testing beyond that which is specifically outlined in the official FDA food safety assessment manual called the *Toxicological Principles for the Safety Assessment of Food Ingredients*, more commonly known as the Redbook.<sup>34</sup>

For example, Food Contact Substance Notifications must include a Comprehensive Toxicology Profile (CTP) in support of an applicant’s “safety summary,” which is simply the applicant’s assertion of a food contact substance’s safety as used in the specific manner described in the notification application.<sup>35</sup> The CTP should include “summaries of all the available toxicological information pertinent to the safety evaluation of the [food contact substance].”<sup>36</sup> Beyond these submission requirements, FDA also asks its Food Contact Substance Notification applicants to perform certain safety studies, as determined by the food contact substance’s “cumulative estimated daily intake” (CEDI). The CEDI is often based on the “no observed adverse effect level” (NOAEL), which is the highest dose of a substance that does not show adverse effects.<sup>37</sup> Thus all the safety data submitted for a Food Contact Substance Notification application rest on the traditional “dose makes the poison” risk assessment philosophy and often focus on assessing only overt adverse effects like severe birth defects or tumors.<sup>38</sup> Again, in the case of BPA (and other endocrine disruptors) this traditional approach to safety assessment fails to identify some of the key health hazards that recent scientific studies operating outside of the traditional Redbook protocols have identified.

To remedy this risk assessment disconnect, ideally, FDA needs to rewrite its Redbook protocols for endocrine disruptor testing, but this would require a lengthy scientific and administrative process, pushing this solution into the long-term category and requiring a look at more than just BPA. As an alternate **short-term option**, FDA can issue new BPA Food Contact Substance Notification guidance that redefines not only the parameters for which existing studies should be summarized and included in the CTP, but also expands the range of safety studies that a Food Contact Substance Notification applicant should conduct as a part of its submission for a new BPA use.



### ***Establishing Stricter Use Standards***

FDA could also develop new Food Contact Substance Notification guidance that establishes stricter and more precautionary new use standards. When a BPA manufacturer or processor submits a Food Contact Substance Notification application, they are requesting approval for a specific use. Accordingly, FDA expects that once a Food Contact Substance Notification is approved, the holder of the effective Food Contact Substance Notification will operate within the use limitations. These use limitations include maximum concentrations of particular chemicals in a food contact material, restrictions on the types of food that should be packaged in the material, and limitations on temperatures and durations of food contact.<sup>39</sup> To better protect consumers from BPA hazards, FDA should establish through guidance a new set of stricter use conditions for potential Food Contact Substance Notification applicants. This guidance should announce that any proposed new BPA use involving contact with certain types of food (e.g. infant formula) or distribution to certain companies (e.g. baby bottle manufacturers) is unsafe and will result in a denial letter.<sup>40</sup>

### **Voluntary Food Contact Substance Notification Submissions**

In its BPA Update Report, FDA announced an intention to extend potential BPA testing and data collection requirements to BPA manufacturers and processors holding already-approved Food Contact Substance Notifications, through a voluntary program. Because voluntary programs lack any threat of sanctions, the obvious problem with this approach is that companies that would have no obligation to notify FDA of their BPA use are unlikely to voluntarily invest time, money, and effort into compiling a Food Contact Substance Notification submission just because FDA would like them to. Without some incentive to comply (e.g. potential fines or revocation), it is doubtful that this voluntary method would lead to any significant strides in BPA regulation or monitoring.

To extend these data collection and stricter use standards to existing Food Contact Substance Notifications, FDA would need to revoke existing notifications and require reapplication under the new guidance and safety standards. Reforming the Food Contact Substance Notification guidance and underlying policies is only a first step toward improving our understanding of food-contact risks posed by BPA, because these data collection requirements and stricter use standards would only apply to a small and somewhat insignificant portion of the food contact material market—previously unapproved uses. Once a notification is approved, really the only way for FDA to impose new data collection requirements and use standards is to revoke the notification, thus requiring a resubmission. FDA rarely invokes this revocation authority. For this reason (and for the potential litigation that might follow any revocations) this regulatory option is considered **longer-term**. While these actions would be new territory for FDA in utilizing the notification process, it is a territory worth exploring.

### **Consumers' Right-to-Know**

FDA has the ability to empower people to act in their role as consumers and further motivate industry behavior through implementing new BPA labeling guidance and regulatory standards. Progressive consumerism, or “regulation via internet,” often achieves results where traditional legislative and regulatory methods lag or run into administrative hurdles. Progressive consumerism is not a full solution because the outcome often lacks coherent results on which consumers can rely, but it is a partial solution and one that has proven successful in altering BPA usage and consumer awareness. Through labeling guidance and regulation, FDA can provide consumers with more information and safety assurances and take any existing BPA regulation to the next level.

#### **A short-term option for establishing labeling standards would be to issue guidance concerning the use of “BPA-Free” labels.**

This guidance should establish basic safety standards for the use of the “BPA-Free” label and ban the use of such a label if the food contact material used in a product contains a BPA substitute that has demonstrated any similar endocrine disrupting effects. One example of such labeling guidance is the document in which FDA offered detailed advice on the “appropriate labeling statements” for milk products claiming to be “rbST free.”<sup>41</sup> This guidance demonstrates FDA’s ability and willingness to regulate industry-created labels aimed at cashing in on consumer concerns about potentially unhealthy chemicals.



The “BPA-Free” guidance should outline specific criteria that FDA deems proper use of the “BPA-free” label. For example, the manufacturer, producer, or distributor wishing to use the “BPA-free” label must submit a list of food contact materials included in its product, identify if BPA previously existed in the food contact material, and, if so, what substitutes took the place of BPA. Additionally if a substitute for BPA was utilized, the manufacturer, producer, or distributor should be prohibited from labeling its product “BPA-free” if the substitute exhibits any endocrine-disrupting or estrogenic qualities. This labeling guidance could apply to both existing notifications and new use applications.

### **BPA Labeling in France**

In September, France's ecology minister announced that the French version of the FDA, the Agency for Food Health Safety, would seek systematic and mandatory labeling of BPA-laden food packaging products that come into contact with the public. Not stopping there, the minister also intended to ban BPA use in specific products where a proven safer substitute existed.

**FDA should issue BPA labeling regulations setting forth mandatory BPA identification requirements, substitution standards, and "BPA-Free" usage standards.** Consumers have a right to know what toxins are in their food, whether that toxin's presence enters the food supply directly or indirectly. In BPA's case, FDA can acknowledge this right-to-know by issuing a regulation that establishes mandatory BPA labeling standards and disclosure requirements for any food contact material containing BPA. To issue such a regulation, however, would indeed be a long-term option because of the complex and often drawn-out rulemaking procedures that accompany the promulgation of a regulation. The long-term nature of such rulemaking, however, has not stopped FDA from issuing mandatory labeling regulations before.<sup>42</sup> Ideally BPA labeling

standards would take the form of a regulation that sets specific labeling and substitution requirements and applies to all BPA food-contact uses, manufacturers, and distributors.

### **FDA's Long-Awaited Response to the Natural Resources Defense Council Petition**

In 2008, the Natural Resources Defense Council (NRDC) filed a petition much like that of the ACC requesting that FDA promulgate a new regulation concerning BPA's use in food contact substances. Of course, there were two major differences between the two requests: First, unlike the ACC's petition requesting a mere amendment to existing regulations to ban the very specific use of BPA in baby bottles and sippy cups, the NRDC petition requested that FDA promulgate a new regulation prohibiting all uses of BPA in all food contact substances. Second, the NRDC asked that FDA issue this ban based on a finding that BPA is unsafe to human health. The NRDC received no response from FDA and was forced to file a complaint in the Southern District of New York to compel agency action. On December 7, 2011, FDA and NRDC reached a settlement and a Consent Decree was filed with the court, setting March 31, 2012 as the deadline for FDA to make a final and reviewable agency decision on the NRDC petition.

### ***Implementing Universal Safeguards Against Dangerous Uses of BPA***

**To address the full spectrum of BPA uses and establish the most meaningful regulatory safeguards against unsafe uses, FDA should implement new, health-based BPA regulations.** Taking its regulatory authority one step further than testing and labeling requirements and using both the existing risk assessment data and data arising from on-going scientific studies, FDA needs to promulgate new regulations and corresponding guidance that account for BPA's (and its substitutes') low-dose endocrine-disrupting effects. For a starting point, the scope of these rules should restrict BPA's uses in food contact materials targeted for use in the sensitive populations of pregnant women, infants, and children, because the mounting scientific data indicate these are the populations most at risk to suffer from BPA's low-dose endocrine disrupting effects and achieving scientific data on these populations is challenging.

**As a long-term option, FDA should issue new regulations concerning all BPA uses, regardless of loopholes and previous approvals.** Whether FDA approved the use of a substance through the petition process or the notification process, or the use falls under one of the many statutory exemptions and loopholes, the agency retains the discretion to consider new regulations for any additive if the Commissioner determines that the use is unsafe and existing regulations do not adequately protect the public health. "If new evidence suggests that a product already in use may be unsafe, or if consumption levels have changed enough to require another look, federal authorities may prohibit its use or conduct further studies to determine if the use can still be considered safe."<sup>43</sup> Although time-consuming and certain to be faced with industry challenges, FDA thus has the power to issue new regulations concerning any use of BPA in a food contact material. FDA should use this authority to impose a range of potential safeguards, from banning BPA in all food contact substances to banning particular uses (e.g. baby bottles) to requiring new risk assessment and monitoring data submissions for *all* manufacturers or processors of BPA.

#### **A Recommendation of What *Not* to Do:**

**In September, the American Chemistry Council, a staunch defender of unfettered BPA use, caused a stir amongst anti-BPA advocates by filing a petition with FDA that requested an amendment of an existing BPA regulation that designated BPA's use in baby bottle and sippy cups as safe. Shockingly, the ACC requested that these specific uses be removed from the "safe use" category because BPA manufacturers had stopped using BPA for these products. Issuing a new regulation that fails to identify the true reasons for BPA regulation—health hazards—is not an effective use of energy, time or resources.**

**The EPA has a number of statutes at its disposal that could be utilized to manage BPA risks, including the Safe Drinking Water Act (SDWA), Clean Air Act (CAA), Clean Water Act (CWA), and Resource Conservation and Recovery Act (RCRA).**

## **Environmental Protection Agency**

Limiting exposure to BPA through food is an important regulatory goal, but it would affect a very small portion of the total BPA production output. Consider:

Chemical companies and trade groups aren't willing to divulge numbers, but market analyst reports estimate global annual BPA demand at up to 12 billion [pounds] and growing at 5 percent per year. Polycarbonate makes up 74 percent of BPA use, and epoxy resins consume about 20 percent of production. But the baby bottle and food-can applications combined accounted for less than 5 percent of BPA consumption. That means the [grassroots-spurred] phaseouts haven't put a big dent in overall BPA use.<sup>44</sup>

In other words, to address all the risks posed by BPA, regulation must also focus on the myriad sources of BPA in our lives that FDA cannot address. This is a job for EPA, whose authority is broader than food packaging and thus can reach up the supply chain to the manufacturers of the raw material.<sup>45</sup>

According to EPA's Toxics Release Inventory, companies that manufacture and use BPA release the chemical into the air, water, and soil in quantities exceeding 1 million pounds per year.<sup>46</sup> EPA has even identified BPA's potential effects on aquatic species as an area of concern.<sup>47</sup> The agency has a number of statutes at its disposal that could be utilized to manage BPA risks, including the Safe Drinking Water Act (SDWA), Clean Air Act (CAA), Clean Water Act (CWA), and Resource Conservation and Recovery Act (RCRA). But before the agency can use the tools available under those statutes, it must first develop a fuller risk assessment, combining what is already known about BPA's hazards with up-to-date information on the human and environmental exposures that could be regulated under each law.

### ***BPA's IRIS Profile***

EPA maintains a database, called the Integrated Risk Information System (IRIS), that contains toxicological profiles on hundreds of industrial chemicals. Updating the IRIS profile for BPA to reflect current hazard and dose-response information should be an immediate priority. The existing profile is woefully out-of-date (July 1993 is the most recent revision listed) and it is lacking in meaningful information. Where other chemicals have "inhalation reference concentrations" that indicate conservative levels of concern for various adverse health effects caused by chemicals found in the air, BPA's IRIS profile has "no data."<sup>48</sup> Where other chemicals have quantitative estimates cancer risks, BPA's IRIS profile has "no data." The one datapoint that can be found in the BPA profile is an oral reference dose—but the "critical effect" that undergirds that number is reduction in body weight, as opposed to a health effect that is more relevant to the state of current knowledge about BPA's hazards, like impacts on the endocrine and reproductive systems.

**As a short-term option to address BPA, EPA should update BPA's IRIS entry to include current data to reflect the risks that have recently come to light, especially concerning low-dose effects.** As part of the update process, EPA should develop generic guidance for hazard identification and dose-response assessment of endocrine-disrupting chemicals, using BPA as a test case. The agency already has generic guidance for various principles of risk assessment, like exposure assessment or determination of reference doses that focus on carcinogenicity and other adverse health outcomes. It does not have guidance specific to endocrine disruptors. EPA also has generic guidance documents related to assessing risks for certain classes of chemicals, like metals or dioxins. Building off of these existing guidance documents and policies, the agency should develop guidance for assessing risks posed by endocrine disruptors. The process of developing that guidance would enable EPA to simultaneously update its IRIS profile for BPA to reflect the newest research on its hazards.

### ***TSCA Regulatory Options***

Congress passed the Toxic Substances Control Act (TSCA) in 1976 as a gap-filling measure, because the major air pollution, water pollution, and waste disposal statutes failed to fully address the problem of human and environmental exposure to potentially dangerous chemicals in productive use. TSCA has two main environmental objectives. First, TSCA was intended to protect humans and the environment from risks posed by industrial chemicals and other substances. Second, the drafters of TSCA were prescient in understanding that lack of environmental and health information (the “data gap”) would present the biggest hurdle for regulation of industrial chemicals, and so TSCA also contains several provisions to require the manufacturers of covered chemicals to generate and report such data to EPA. TSCA's short-comings have prompted environmental advocates to press for new, replacement legislation, but the current statute nevertheless provides EPA with several options to improve exposure and use information about BPA through testing requirements and manage the chemical's risks through regulation.

#### ***(1) BPA Test Rule***

**The first short-term option available to EPA is for it to continue its progress toward issuing a BPA Test Rule under TSCA § 4.** This section of TSCA allows EPA to promulgate rules requiring manufacturers to shoulder the responsibility for exposure and risk assessment testing of chemicals that EPA finds may present an unreasonable risk of injury to health or the environment and/or are present in the environment in such quantities that they present a significant exposure risks to either the environment or humans.<sup>49</sup> These findings are commonly referred to as a “hazard” or “A” finding (the “A” referring to subsection A of § 4) or an “exposure” or “B” finding.<sup>50</sup> One or both of these findings must be made in addition to a showing that existing data are inadequate for risk assessment and that the proposed testing is necessary to develop the data.<sup>51</sup> EPA rarely imposes test rules on manufacturers of chemicals that were already in commerce when TSCA was created,<sup>52</sup> but seems willing to

make one of its rare exceptions in the case of BPA because new exposure pathways and new information about low-dose effects are only recently coming to light.<sup>53</sup>

EPA initiated the § 4 rulemaking process for BPA in October 2010 and sent a draft Advance Notice of Proposed Rulemaking (ANPRM) to the Office of Information and Regulatory Affairs (OIRA) at the White House for review in December 2010. Although EPA hoped to publish the ANPRM by March of 2011 (and, by Executive Order, OIRA had only 10 days to review the ANPRM), the edited announcement was not published in the Federal Register until July 2011.<sup>54</sup> Delayed but still holding true to EPA's intended purpose, the published document proposes requirements for sampling and monitoring of surface water, ground water, drinking water, soil, sediment, sludge, and landfill leachate in the vicinity of expected BPA releases. These testing requirements are designed to aid EPA in determining whether potentially sensitive organisms may currently be exposed to concentrations of BPA in the environment that are at levels of concern for adverse effects.<sup>55</sup> None of the proposed testing in the BPA Test Rule would focus on human health effects or exposure analysis, a focus seemingly driven by administrative and industry pressures based on the Office of Information and Regulatory Affairs' edits to EPA's Advanced Notice of Proposed Rulemaking for the proposed BPA Test Rule released this past summer.<sup>56</sup>

EPA's intentions to address only environmental exposure and risks (and to specifically exclude human health effects) squanders an opportunity to collect valuable information. EPA's authority to protect human health is separate and distinct from FDA's. Should FDA take no action to regulate BPA or ensure proper labeling, EPA would have that authority under TSCA, but the agency hamstringing itself by not including human health effects in its proposed test rule. Moreover, TSCA gives EPA jurisdiction over the many manufacturers and commercial users of BPA who profit from the 95 percent of the chemical that does not go into baby bottles and sippy cups. The information that these companies already possess (or could develop if prompted by a § 4 test rule) could significantly enhance our knowledge about exposure scenarios that EPA might regulate using its powers under the CWA, CAA, RCRA, or another statute. Because of the time it takes to develop the testing requirements, promulgate a final rule, compile the test rule data, and then analyze this data, EPA must act expediently and finalize the BPA Test Rule.

### ***(2) TSCA § 5(b)(4): Chemicals of Concern***

**Another short-term option available to EPA is to list BPA on its “chemicals of concern” list to further educate the public about the chemical’s risks.** EPA has indicated a willingness to include BPA in a sort of “regulatory watch” under TSCA § 5(b)(4), which gives the agency the authority to “compile and keep current a list of chemical substances ... which the Administrator finds ... presents or may present an unreasonable risk of injury to health or the environment.”<sup>57</sup> The § 5(b)(4) list is otherwise known as the “chemicals of concern list.” From a regulatory standpoint, the effect of adding a chemical to the list is limited to “soft” regulation that does not impose any restrictions on a chemical’s manufacture or use.

Once listed, loopholes for small manufacturers and importers of the chemical cinch up, forcing them to periodically provide EPA with data on production volumes and downstream uses; significant new use notifications related to the chemical must include data showing that the new use will not present an unreasonable risk; and certain export notification rules will apply.<sup>58</sup> The real power of the list lies in its potential to begin reducing toxic ignorance. Government has a duty to inform the public about toxic risks that they may not recognize, and to do so in a way that empowers the public to act (make wise purchasing decisions, engage in government decision-making). Listing could also impact the supply chain, prompting downstream firms to demand feedstock or components that are free of substances found on the chemicals of concern list. BPA presents widespread concerns across many federal agencies' jurisdictions, so it is an ideal chemical for inclusion on EPA's chemicals of concern list.

To date, EPA has not utilized its 5(b)(4) authority—a fact most likely due to the threat of litigation. Citing judicial precedent from other EPA applications of TSCA controls, the U.S. Chamber of Commerce and others who oppose EPA's use of this regulatory tool argue that to place a chemical on the 5(b)(4) concern list, EPA must produce a substantial risk analysis *before* listing the chemical.<sup>59</sup> Given that the statutory text states that EPA need only demonstrate that a chemical of concern “*may* present unreasonable risk” and thus sets a standard lower than that required for stricter regulation under other TSCA sections, it does not follow that Congress envisioned this list to impose a regulatory burden equal to its more stringent counterparts. Logically, the chemicals of concern list is one of the middle steps between unfettered use of a chemical and full on regulatory bans or use restrictions. Establishing significant hazards and widespread use should be enough to list a chemical that we need to know more about.

**EPA should proceed with plans to compile the list and its intention to include BPA on it.**<sup>60</sup> The agency has created a draft rule that would for the first time establish a chemicals of concern list (including BPA), but that rule has been under review by OIRA since May 12, 2010.<sup>61</sup> OIRA's exceptionally slow review has prevented EPA from taking the smallest step toward promulgation of the list—proposing it in the Federal Register and collecting public comment on the proposal. This goes against principles of good government by forestalling broad public engagement but encouraging moneyed interests to dominate the debate. Extracting a stalled rule from OIRA's review process is a difficult political task for EPA officials given OIRA's role as the White House enforcer on regulatory priorities; however, the chemicals of concern list has the potential to enhance EPA's entire toxics program by creating a new avenue for communicating with the public, chemical manufacturers, and the entire supply chain about potential toxic hazards.

### ***Labeling and Other Regulatory Options Under TSCA § 6***

Building on the known risks of BPA and the additional scientific data collected through the short-term regulatory options described above, **EPA should utilize TSCA § 6 and**

**BPA presents widespread concerns across many federal agencies' jurisdictions, so it is an ideal chemical for inclusion on EPA's chemicals of concern list.**



**move forward in a long-term effort to develop more stringent and comprehensive regulations such as warning labels, specific use restrictions, and even bans on specific uses.** In § 6, Congress granted EPA broad authority to regulate the manufacture, processing, distribution, use, and disposal of a chemical substance using a wide variety of regulatory tools, ranging from labels to outright bans.<sup>62</sup> This power, however, was conferred to EPA under two conditions. First, EPA must determine that the chemical in question presents an unreasonable risk of injury to health or the environment. Second, according to the U.S. Court of Appeals for the Fifth Circuit, EPA must compare its preferred regulatory option to all other possible regulatory options available under TSCA and other statutes and determine that the net benefits of the agency's chosen option exceed the net benefits of all other available options.<sup>63</sup> Because of these judicial and statutory limitations, in TSCA's 40-year history, EPA has only used § 6 to regulate five chemicals.<sup>64</sup>

EPA must determine BPA presents an unreasonable risk regardless of the severity of regulations it chooses to pursue, but once this determination is made it can improve its chances of success by tailoring the recommended regulation. An outright ban on the production or use of a chemical is the most extreme action that EPA can take under § 6, but this would most likely face the greatest judicial scrutiny. Other “[a]vailable restrictions include limiting uses or production volumes, mandating warnings, prohibiting manufacture or distribution, or regulating disposals.”<sup>65</sup> Even if EPA does not feel that it can pursue an all-out ban under § 6, it can institute less intrusive regulatory options like mandating warnings about the presence of BPA in base plastic materials. Starting small, like mandating warnings, may help EPA overcome the judicial hurdles yet have a significant impact on worker and consumer awareness. These tailored regulations, however, should not preclude EPA from attempting more comprehensive and stricter regulations in the future.

### **Occupational Safety & Health Administration**

Workers who develop, construct, and use materials containing BPA are at an increased risk for exposure to the chemical and its negative health effects because of the frequency of exposure and the more direct methods of that exposure, such as inhalation and direct dermal absorption.<sup>66</sup> Unfortunately, very little information about worker exposures is available. The best source of information is EPA's 2006 TSCA Inventory Update, which indicates that more than 1000 workers were exposed to BPA at “100 to 999” U.S. worksites, and it was produced, stored, or used in various forms (“dry powder, pellets or large crystals, other solid, liquid”) at many different concentrations (the “maximum concentration” is listed as “greater than 90 percent”).<sup>67</sup> These data are insufficient for regulatory purposes, much less communication of any meaningful information to workers about their exposure to BPA and the associated risks in the workplace.

While OSHA's purview is limited to workplace exposures, the agency could have a broad impact on BPA's overall use because the “hierarchy of controls” principle of industrial hygiene that undergirds OSHA regulations emphasizes elimination of hazards, substitution

of safer products and practices, and engineering controls to prevent worker exposure—all strategies that could significantly reduce BPA use in products that spread from OSHA-covered manufacturing sites throughout the marketplace. Moreover, OSHA has a potential advantage over the other protector agencies because workers, the beneficiaries of OSHA's efforts, can be a stronger partner in pressuring manufacturers to eliminate BPA risks than the general public, particularly when those workers have the strengths provided by collective bargaining agreements.

As with FDA and EPA, OSHA could help eliminate risks posed by BPA exposure by first establishing a strong knowledge base about exposures to the chemical, then using existing tools (such as the Hazard Communication Standard and the OSH Act's General Duty Clause) to eliminate or reduce those exposures.

### ***Increased Scientific Research and Data Collection***

**As a short-term option, NIOSH and OSHA should perform more workplace studies and develop a more comprehensive database of workplace exposures and risks.** A February 2011 study and report (supported in part by NIOSH funding)<sup>68</sup> linking male manufacturing workers' low sperm counts and decreased sperm quality to high levels of occupational BPA exposure in China brought the public's attention to workplace risks posed by the chemical in the manufacturing setting.<sup>69</sup> When an early draft of the study first came to light in late 2010, it also brought attention to how we have very little publicly available information about U.S. workers' exposures to the chemical.<sup>70</sup> BPA exposure risks in the workplace are not limited to the manufacturing realm. Cashiers and anyone who frequently handles thermal paper, like that used in store receipts, are also exposed to BPA through dermal absorption.<sup>71</sup> OSHA has ready partners at NIOSH and the labor unions that can help the agency develop a better understanding of the occupational risks posed by BPA and the potential risk management options.

Part of this collaboration should include NIOSH's Health Hazard Evaluations (HHE) program.<sup>72</sup> This program encourages workers, their representatives, and managers to request worksite evaluations (including chemical exposure monitoring) when unregulated hazards or undiagnosed symptoms or illnesses present themselves. A series of HHEs focused on certain industries where many workers are exposed to BPA could provide useful information for targeting particularly risky uses and exposure routes.

### ***The Hazard Communication Standard***

**Without implementing new regulations and thus offering another short-term option, OSHA could ensure workers are informed about risks of occupational BPA exposure using the Hazard Communication (HazCom) standard.**<sup>73</sup> The standard embodies the principle that workers have a "right to know" about the hazards to which they are exposed while on the job. It requires chemical manufacturers and importers to evaluate the hazards

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of the chemicals they produce or import and create warning labels and material safety data sheets (MSDS) that will ensure that downstream users of the chemicals have access to information about those hazards.<sup>74</sup> Employers must ensure that an MSDS is available to workers for each chemical to which they are exposed, and distributors must also transmit the required information to downstream employers.<sup>75</sup> OSHA could undertake some manageable activities that would improve what workers know about BPA and other endocrine disrupting chemicals.

Though MSDSs do not follow a prescribed format they must include certain categories of safety information, including physical hazards and health hazards.<sup>76</sup> The rules defining the health hazards that must be included in a properly formed MSDS utilize broad language, in furtherance of workers' right to know about the full range of hazards they might encounter in the workplace. The rules exhibit a precautionary bent, requiring hazard identification not only when there is clear evidence that a chemical is a carcinogen or otherwise highly toxic, but even when "there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees."<sup>77</sup>

Under these rules, BPA's endocrine-disrupting health hazards should be included in manufacturers' MSDSs, and OSHA can ensure that happens through publication of guidance on the subject. The study of workers in China that linked occupational BPA exposure to negative impacts on sperm quantity and quality indicates that BPA poses reproductive health hazards to workers that should be reported on all BPA MSDSs. Other studies on laboratory animals also have identified chronic health effects. OSHA staff should work with NIOSH staff to review all studies relevant to BPA's inhalation and dermal absorption routes of exposure to determine whether other health hazards ought to be reported on MSDSs. An example of how OSHA has taken this sort of precautionary approach in light of an emerging hazard is its recent actions related to the food flavoring chemical diacetyl. When evidence of "popcorn workers' lung" began to mount, OSHA published a guidance document that instructed manufacturers to include notifications about potential respiratory disease in all MSDSs covering diacetyl and other food flavorings containing the chemical.<sup>78</sup>

The ultimate problem with MSDSs lies in the conflict of interest inherent in having the manufacturer acting as both the evaluator of the hazard and the entity charged with communicating that hazard to workers, with little input and oversight from OSHA. The HazCom standard's guidance on hazard determinations does little to mandate an unbiased evaluation process: under the rule, "[c]hemical manufacturers, importers, and employers evaluating chemicals are not required to follow any specific methods for determining hazards."<sup>79</sup> While they "must be able to demonstrate that they have adequately ascertained the hazards of the chemicals...in accordance with the criteria set forth in [the standard]," that provision seems to be insufficient in the case of BPA.

One need only look at The Dow Chemical Company's MSDS for BPA to see how OSHA guidance would greatly improve the accuracy of health hazard communications and ensure that employers are meeting their duties under the HazCom standard to inform workers of BPA's low-dose effects, reproductive health hazards, and the potential carcinogenic qualities. Dow's MSDS for BPA states that reproductive health hazards are limited to fetal impacts which occur in conjunction with maternal toxicity. In other words, Dow is only reporting on reproductive health hazards that occur at doses high enough to cause significant and acute harm to both the mother and fetus. With mounting evidence of low-dose impacts on fetal development and organ function, this warning is likely insufficient, so guidance from OSHA would help clarify manufacturers' duties under the HazCom standard. BPA's potential health effects from skin contact should also be revisited. Dow's MSDS only refers to skin irritation and redness resulting from prolonged or repeated contact. However, new evidence suggests that BPA can be absorbed through the skin, raising concerns about cashiers' health risks from exposure to the chemical through regular contact with carbonless register receipts.<sup>80</sup>

It was precisely these deficiencies and similar ones abroad that spurred OSHA and the international community to develop *The Globally Harmonized System of Classification and Labelling of Chemicals* (GHS).<sup>81</sup> The GHS formulated new standards and protocols for toxics identification, labeling, and health hazard communication. In September 2009, OSHA issued a proposed rulemaking to amend the HazCom Standard to integrate GHS and make its provisions binding on American chemical manufacturers and workplaces. The proposed health hazard standards would significantly modify MSDS requirements, including the establishment of a new classification system for reproductive toxicity.<sup>82</sup> Hazard labeling would receive a dramatic overhaul as well. While some of the newly proposed HazCom standards need to be reconsidered,<sup>83</sup> many of the standards and MSDS requirements would provide further support for new guidance from OSHA on BPA.

Once the proposed rulemaking goes into effect, OSHA should use BPA as a model for guiding implementation of the new standards. Warning labels for BPA and other endocrine-disrupting chemicals must properly convey to workers the reproductive and other risks associated with low-dose exposures to the chemicals.

### ***Permissible Exposure Limits and the General Duty Clause***

OSHA's primary regulatory tool for limiting workers' exposures to toxic chemicals is known as a Permissible Exposure Limit, or PEL. PELs are numerical limits for airborne concentrations of toxic chemicals. To set a PEL, OSHA must determine that the chemical

### **What about the Consumer Products Safety Commission (CPSC)?**

Notably missing from the list of potential regulators is the CPSC. While it would seem that the agency in charge of consumer product safety would be at the forefront of BPA regulation, the existing CPSC regulatory regime and statutory limitations all but bar meaningful action on the part of this agency without an act from Congress. Ideally, CPSC BPA regulations would take forms similar to those promulgated under the Consumer Product Safety Improvement Act of 2008 for phthalates—a group of endocrine-disrupting chemicals that pose similar health hazards and are prevalent in children's toys and products.<sup>87</sup>

poses a significant risk at current exposure levels, then establish an allowable exposure level at which the risk will be eliminated or reduced while ensuring the standard is technologically and economically feasible.<sup>84</sup> Each of these determinations requires substantial data gathering and analysis, none of which have been accomplished at sufficient levels for BPA. Once the agency has set a PEL for a chemical, federal inspectors can sample the air at a particular worksite and analyze the sample to ensure that workers' exposures are within acceptable levels.

**As a long-term option, OSHA needs to establish a PEL for BPA and potentially other endocrine disrupting chemicals that exhibit BPA's same low-dose effects.**

There is no Permissible Exposure Limit (PEL) for BPA against which inspectors could judge compliance with the law, and this needs to change; however, setting a PEL for BPA is not a straightforward task because of BPA's low-dose effect risks. Even without these unique properties, establishing regulatory limits on a chemical under the OSH Act is not an easy task. According to a recent analysis by Public Citizen's Congress Watch division, during the last three decades "it has taken OSHA an average of six years to move from deciding to regulate a hazard to issuing a final rule."<sup>85</sup> The agency's standard-setting budget is highly constrained (in recent years, it has amounted to less than 5 percent of OSHA's meager \$560 million budget), and more acute under-regulated hazards with clear links to thousands of worker deaths (*e.g.*, silica dust) rightly take precedence over emerging hazards. Accordingly, establishing a PEL for BPA—or, preferably, endocrine disruptors as a class—is a long-term option for OSHA.

**An alternative long-term regulatory option is to issue worker exposure regulations using the General Duty Clause (GDC) of the OSH Act, which requires employers to ensure all employees have a safe and healthy workplace.**<sup>86</sup> The GDC has been used to cite employers for failing to address chemical hazards in cases where employees faced recognized hazards that were likely to cause death or serious physical injury and a feasible means of abatement was available.

The main legal sticking point for regulating BPA under the GDC would be establishing that workers' exposures are likely to result in death or serious physical injury. In general, OSHA can establish this element of a GDC violation by measuring worker exposures in excess of an Occupational Exposure Limit (OEL) that is recognized by professionals in the field as a threshold above which serious physical injury is likely to occur. Organizations that produce such OELs include NIOSH, ACGIH, and the American Industrial Hygiene Association (AIHA). However, NIOSH has not published a recommended OEL for BPA, nor has AIHA, and ACGIH may have abandoned its efforts to create one.<sup>87</sup> Thus, the GDC option will only be available to OSHA when better occupational risk data on BPA have been collected and synthesized and the occupational hazards are better recognized in the relevant employer communities. As EPA, FDA, OSHA, and other agencies begin to gather additional data and incorporate the newer studies into their regulatory programs, OSHA enforcement of the GDC may become a more viable option.

## Conclusion

Managing the risks posed by BPA presents fundamental challenges to the regulatory systems that Congress designed to protect the public and the environment from toxic chemicals. FDA, EPA, and OSHA are the federal agencies best poised to implement short-term protections, focused on data collection, hazard warnings, and information dissemination, but also long-term protections, focused on varying levels of use restrictions and regulatory safeguards. The regulatory options and proposed action plan for EDA, EPA, and OSHA discussed in this paper are meant to support the actions being taken by U.S. agencies, but also encourage more meaningful and progressive regulation of a concerning chemical.

## Endnotes

- <sup>1</sup> See Sarah Vogel, *Battles Over Bisphenol A*, DEFENDINGSCIENCE.ORG, Apr. 16, 2008, [http://www.defendingscience.org/case\\_studies/Battles-Over-Bisphenol-A.cfm](http://www.defendingscience.org/case_studies/Battles-Over-Bisphenol-A.cfm).
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