



October 21, 2014

Dr. Meredith Williams  
Deputy Director  
Department of Toxic Substances Control  
1001 I Street  
P.O. Box 806  
Sacramento, CA 95812-0806

Re: Safer Consumer Products DRAFT Priority Product Work Plan

Dear Dr. Williams:

The Polycarbonate/BPA Global Group of the American Chemistry Council<sup>1</sup> respectfully submits these comments on DTSC's Safer Consumer Products DRAFT Priority Work Plan (September 2014). The Polycarbonate/BPA Global Group represents the leading global manufacturers of BPA and polycarbonate plastic.

These comments are focused on the Office Machinery (Consumable Products) category and, more specifically, the use of bisphenols as a developer in thermal paper products (e.g., cash register receipts). Although DTSC has not yet selected Priority Products for future action, the information provided in these comments may be useful to evaluate priority and timing should DTSC consider selecting bisphenols and thermal paper as a Priority Product.

Please do not hesitate to contact me if I can be of further assistance to clarify any comments or if additional information is needed. I can be reached at (202) 249-6624 or by e-mail at [steve\\_hentges@americanchemistry.com](mailto:steve_hentges@americanchemistry.com).

Regards,

A handwritten signature in black ink, appearing to read "S G Hentges", with a long horizontal flourish extending to the right.

Steven G. Hentges, Ph.D.  
Polycarbonate/BPA Global Group

cc: Karl Palmer, Chief, Safer Consumer Products Branch, DTSC

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<sup>1</sup> The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is an \$812 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for twelve percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

**Comments of the Polycarbonate/BPA Global Group on the  
Safer Consumer Products DRAFT Priority Product Work Plan  
October 21, 2014**

**I. Introduction and Summary of Comments**

The Safer Consumer Products DRAFT Priority Product Work Plan, issued by DTSC in September 2014, includes the product category Office Machinery (Consumable Products). One of the products cited as an example in this category is Specialty Paper, and Bisphenols are listed as a potential candidate chemical.

Although not described in detail in the work plan, thermal paper products (e.g., cash register receipts) are presumably the products of interest for potential selection as a Priority Product. Some thermal paper products use bisphenol A (BPA), bisphenol S (BPS) and other similar substances as the color developer in the thermally reactive coatings on these paper products.

Thermal paper products have been a subject of interest in other jurisdictions and at least two evaluations of alternatives have recently been published. These evaluations included BPA, BPS and a variety of other potential color developer alternatives, as well as evaluation of alternative technologies to replace thermal paper receipts. Given the availability of these recent evaluations, DTSC should carefully consider whether there would be sufficient added value to justify selection of thermal paper products as one of a small number of Priority Products to be evaluated in the next several years. The availability of recent evaluations suggests that thermal paper products should be low priority for further evaluation under DTSC's Safer Consumer Products program.

Should DTSC nevertheless further consider selection of thermal paper products as a Priority Product, the timing should be set to ensure that results are available from a number of highly significant and relevant studies that are now being conducted. The results from these studies will be critical for evaluation of BPA and BPS, which are both commonly used as thermal paper color developers.

**II. Assessments Of Alternatives to BPA In Thermal Paper Are Available**

**a. U. S. Environmental Protection Agency Design for the Environment Program**

In January 2014, the U.S. Environmental Protection Agency (EPA) released a lengthy report titled *Bisphenol A Alternatives in Thermal Paper*. The report was prepared by EPA's Design for the Environment (DfE) program as the outcome of a multi-stakeholder process that included thermal paper manufacturers, thermal paper converters, chemical manufacturers, point of sale

equipment manufacturers, retailers, trade associations, non-governmental organizations (NGOs), green chemistry and technical experts, and international governmental organizations.

The report describes an alternatives assessment that was conducted on BPA and nineteen alternatives that are potential functional substitutes to BPA in thermal paper. DfE Alternatives Assessments provide information on functional use class, intrinsic hazard, exposure properties, and environmental fate for chemical alternatives. Notably, based on the extensive information evaluated, EPA concluded: “[n]o clearly safer alternatives to BPA were identified ...”.

#### **b. Danish Environmental Protection Agency**

In April 2014, the Danish Environmental Protection Agency (Danish EPA) released a report titled *Alternative technologies and substances to bisphenol A (BPA) in thermal paper receipts*. The project was carried out by COWI (a consulting firm) and the Danish Technological Institute under contract to Danish EPA with oversight from a multi-stakeholder group. Extensive outreach and research was used to gather information for the analysis of BPA and alternatives. Similar to the U.S. EPA, the conclusion of the Danish EPA report is that “*it cannot be concluded that these alternatives cause a lower impact on health and the environment than BPA.*”

### **III. Recent Biomonitoring Data Show No Significant Exposure To BPA From Handling Thermal Paper Receipts**

A critical consideration for selection of Priority Products is exposure to a Chemical of Concern. If there is no significant exposure, there can be no significant risk. Products with no significant exposure/risk should have low priority for selection as Priority Products. Recent biomonitoring data indicate no significant exposure to BPA from handling thermal paper receipts, which suggests that these products should have low priority.

#### **a. New Study Shows No Significant Exposure to BPA From Handling Thermal Paper Receipts**

Very recently, researchers from the Finnish Institute of Occupational Health published a study aimed at assessing occupational exposure (i.e., cashiers) to BPA from handling thermal receipt paper (Porras et al., 2014). The study included two simulation experiments to assess exposure to cashiers under conditions representing 1) the most likely exposure scenario, and 2) more intensive short-term handling. These experiments should significantly over-estimate consumer exposure since cashiers could handle thermal paper receipts repeatedly in a workday (i.e., about 140 receipts were handled in the first simulation experiment).

The highlights and abstract from the Porras et al. (2014) paper are presented below (underlined emphasis added):

### **Highlights**

- *The mean bisphenol A concentration among the Finnish working-age population was 2.6 mg/l, with a range of 0.8–18.9 mg/l.*
- *The 95th percentile of the non-occupationally exposed population was 8 mg/l, and this was set as a reference limit.*
- *Repeated handling of thermal paper receipts for 8 h did not increase urinary BPA excretion to above the reference limit.*
- *Even with more intensive handling for three times 5 min, urinary BPA levels remained at or below background levels.*

### **Abstract**

*“Bisphenol A (BPA) has one of the highest production volumes of all chemicals worldwide. It has been widely studied because of its endocrine modulating activity. In addition to dietary intake, absorption of BPA via the skin from handling thermal papers is believed to be a relevant route of exposure. We studied BPA exposure via thermal paper receipts in simulation experiments performed by three volunteers, and examined urinary excretion of BPA. We also evaluated background BPA excretion among the Finnish working-age population. The geometric mean BPA excretion among non-occupationally exposed working-age Finns (n = 121) was 2.6 mg/l, the range being 0.8–18.9 mg/l. The 95th percentile of the non-occupationally exposed people was 8 mg/l, and this was set as the reference limit for the non-occupationally exposed population. In the first simulation experiment, which was conducted under conditions representing the most likely exposure, i.e., the work of a cashier in a supermarket, BPA excretion remained below the reference limit in all participants. In the second simulation experiment, with more intensive, short-time handling of thermal paper (three times 5 min), urinary excretion also remained at or below background levels (highest value being 10.3 mg/l). The calculated maximum BPA excretion per day after handling thermal paper was less than 0.2 mg/kg of body weight, suggesting a total daily intake over 25 times lower than the European Food Safety Authority’s (EFSA’s) proposal for a temporary tolerable daily intake (temporary TDI) (5 mg/kg/day).”*

This study provides the best evidence now available on exposure to BPA from handling thermal paper. Even occupational exposure with repeated or aggressive handling of thermal paper receipts did not result in significant exposure to BPA.

#### **b. Population Scale Urine Biomonitoring Data Documents Low Exposure From All Sources, Including Thermal Paper**

Additional relevant information from several recent large-scale biomonitoring studies conducted in the U.S. and Canada indirectly suggests that consumer exposure to BPA from handling thermal paper is not significant. Data from these country programs should be relevant to California since thermal paper usage patterns are likely to be similar throughout North America. The biomonitoring studies focused on pregnant women in Canada (Arbuckle et al., 2014) and on the general populations in the U.S. and Canada (LaKind et al., 2012).

The Canadian study on pregnant women measured exposure to BPA in more than 2000 participants through urine biomonitoring. The U.S. study measures exposure to BPA in the general population on an ongoing basis in the National Health and Nutrition Examination Survey (NHANES). To date, five biennial NHANES datasets, each with data on more than 2000 people, are available covering the years 2003-2012. Similarly, the Canadian study on the general population measured exposure to BPA in more than 5000 participants in the Canadian Health Measures Survey (CHMS). Collectively the data available from these studies consistently indicate that total exposure to BPA from all sources is very low ( $< 0.1 \mu\text{g}/\text{kg}/\text{day}$ ). Furthermore, the exposure data from these studies is consistent with estimated exposure from food sources, with no indication of significant exposure from other sources such as thermal paper.

#### **IV. Ongoing Studies Will Provide Important, Relevant Data On Exposure To BPA From Thermal Paper**

Extensive and highly relevant exposure information will be available in the near future from three studies currently underway. These studies include: 1) exposure to BPA from handling thermal receipt paper (NTP study to be submitted for publication in the near future); 2) human pharmacokinetics with controlled oral and dermal exposures (NTP studies underway); and 3) dermal penetration and metabolism (industry study underway). In light of the research underway, with results expected in the near future, selection of thermal receipt paper as a Priority Product is premature at the present time.

A brief synopsis of the most relevant research underway is provided below:

##### **a. U.S. National Toxicology Program - Cashier Study**

A brief description of the study being conducted by the U.S. National Toxicology Program (NTP) is described below in an excerpt from Birnbaum et al. (2012):

*“NIEHS/NTP cashier study. Another source of uncertainty regarding human exposure to BPA is the potential role of sources of exposure other than diet. Because BPA is used in numerous consumer products and industrial processes, inhalation and absorption through the skin have been proposed as potentially significant routes of exposure (Liao*

*and Kannan 2011). For example, Von Goetz et al. (2010) proposed that people may inhale or ingest BPA through house dust, or inhale it through smoke from cigarettes with filters containing BPA. People may also absorb BPA through the skin when they touch objects containing the chemical. Although these sources of BPA exposure have not been well characterized, they could pose a greater health risk than ingestion because BPA that is inhaled or absorbed dermally may spend more time circulating through the bloodstream in unconjugated form than does BPA that enters the body through the oral route, which is subject to first-pass elimination.*

*BPA is commonly used in thermal receipt paper, and although many people touch receipts regularly, cashiers handle them more frequently than most people. The NIEHS/NTP cashier study will measure BPA and BPA conjugates in cashiers' blood and urine samples before and after their work shifts. The study is expected to yield insights about the degree to which thermal receipt paper contributes to BPA exposure, although it will not determine whether the route of exposure is dermal or oral."*

We understand that the study has been completed and the results will be submitted for publication in the peer-reviewed scientific literature in the near future.

#### **b. U.S. National Toxicology Program - Human Pharmacokinetic Studies (Oral And Dermal Exposures)**

In addition to the observational study to assess exposure of cashiers to BPA, NTP is also conducting two related human pharmacokinetic studies with controlled oral and dermal exposures. The oral exposure study was described by Birnbaum et al. (2012) as shown below:

*“NIEHS/NTP pharmacokinetic study. Consumption of canned foods and beverages is thought to be a major route of human exposure to BPA, and Teegarden et al. (2011) detected measurable blood levels of total (free and conjugated) BPA in a small fraction of individuals consuming a diet heavy in canned foods and juices. However, only one study has directly examined the kinetics of BPA metabolism and elimination in human volunteers given measured amounts of BPA orally (Völkel et al. 2002), and that study used analytical methods that were less sensitive than current techniques (Vandenberg et al. 2010). Because our understanding of human pharmacokinetics remains limited, the NTP and the NIEHS Clinical Research Unit have developed a protocol to investigate BPA metabolism and excretion in humans after oral ingestion. To support development of a refined physiologically based pharmacokinetic model, up to 50 healthy adult volunteers will be administered a low oral dose of deuterated BPA (d-BPA; 100 µg/kg body weight). Blood (starting at 10 min) and urine samples will be collected for 5 days following dosing to measure d-BPA and its conjugates. By assessing how the body processes and excretes BPA, the study aims to inform investigations of human exposure to BPA as well as the chemical's potential toxicity. Combined with extramural research on BPA*

*pharmacokinetics in animal models, the study will further elucidate how BPA is processed in the body and will help improve researchers' ability to integrate animal and human studies."*

We understand that the NTP oral exposure pharmacokinetics study has been completed and a manuscript has been submitted for publication in the peer-reviewed scientific literature. The results of this study are relevant since exposure to BPA from thermal paper can be either through the skin, to the extent that BPA penetrates skin, as well as orally through hand-to-mouth behavior. This oral exposure study will be useful to evaluate the significance of any oral exposure to BPA through hand-to-mouth behavior.

Of more direct relevance is a related human pharmacokinetics study with controlled dermal exposure that was initiated subsequent to publication of the Birnbaum et al. (2012) paper. The protocol for the oral exposure study described above was amended to include a new dermal exposure study, and that dermal exposure pharmacokinetics study is currently underway.

### **c. REACH Substance Evaluation - Dermal Penetration and Metabolism Study**

In December 2013, the European Chemicals Agency (ECHA) issued a final Decision on Substance Evaluation (SEv) under REACH. One requirement of the Decision is for industry to conduct an *in vitro* skin absorption study (OECD 428) with modifications, most notably to investigate metabolites of BPA in the relevant skin compartments. The deadline for submission of the study to ECHA is December 20, 2015 and the initial phases of the study are now underway. A brief description of the requested study from the Decision is below:

*"1. Skin absorption: In vitro method (Test method EU B.45; OECD 428) with specifications and with additional modifications as specified in Section III, in particular:*

*The study shall be performed using well characterised viable human skin from appropriate locations of the human body, an appropriate solvent and doses which are representative of relevant human exposure situations.*

- The study shall be designed such that a minimum of 8 skin samples from at least four donors can be evaluated. The study shall be in line with the Scientific Committee on Consumer Safety (SCCS) basic criteria for the in vitro assessment of dermal absorption of cosmetic ingredients (SCCS/1358/10).*
- Additionally, the study shall investigate metabolites of Bisphenol A in the relevant compartments of the skin."*

## **V. Health Effects Research On BPA: U.S. National Toxicology Program/Food And Drug Administration Chronic Toxicity Study**

In addition to the exposure and pharmacokinetics research mentioned above, ongoing research being conducted by U.S. Food and Drug Administration in conjunction with NTP will provide

high quality data that should be suitable for assessing BPA in thermal paper as well as in other applications. In particular, the program is centered on a chronic toxicity study that is well underway. The program was briefly described by Birnbaum et al. (2012) as shown below:

*“CLARITY-BPA program. Findings from studies conducted in accordance with GLP are often used to inform regulatory decision making for potentially harmful chemicals. Several past animal studies designed in accordance with GLP have examined the toxicity of BPA (e.g., Tyl et al. 2002, 2008). Although these studies have made valuable contributions, some gaps remain with regard to the exposures and end points that have been investigated. For example, none of the GLP-compliant studies on chronic BPA exposure have included developmental exposure with direct, rather than lactational, exposure of pups. In addition, none of these studies have evaluated the internal doses of BPA that are associated with health effects, nor have they evaluated several disease end points that, although not traditionally included in GLP studies, have been linked to BPA exposure by other animal and human studies (Myers et al. 2009).*

*To validate previous findings and address remaining research gaps, the NIEHS/NTP has collaborated with the FDA to establish the CLARITY-BPA program to advise the design and execution of a comprehensive GLP-compliant study of BPA toxicity in rats. The study, which began in summer 2012, is being conducted at the FDA’s National Center for Toxicological Research (NCTR). The strain of animal, animal diet and housing conditions, numbers of animals, dosing regimen, and route of exposure to BPA will be tightly controlled.”*

## **VI. Health Effects Research On BPS - The Key Alternative To BPA In Thermal Paper**

A BPS Research Concept has been developed by NTP and was recently approved by NTP’s Board of Scientific Counselors. The Research Concept is available at [http://ntp.niehs.nih.gov/ntp/about\\_ntp/bsc/2014/june/bisphenols\\_concept\\_508.pdf](http://ntp.niehs.nih.gov/ntp/about_ntp/bsc/2014/june/bisphenols_concept_508.pdf). As stated by NTP:

*“Currently, there is insufficient in vivo toxicological data to adequately characterize the possible human health effects of BPS (data are limited in scope and power and has not been peer reviewed); however, of the limited toxicological data (primarily available from industry), there is evidence that BPS has effects on select organs and hematological factors.”*

The specific aims of the research as summarized in the Research Concept are:

- “• Characterize the dose-response effects of oral exposure to BPS on target organ systems with a focus on reproductive, developmental, neurological, and hematological endpoints.*

- *Assess in vivo absorption, distribution, metabolism, excretion, and toxicokinetic (ADME/TK) profiles for BPS and in vitro clearance and metabolism information for BPS and each of the BPS derivatives (with a focus on understanding the core BPS structure).*
- *Determine the need for chronic toxicology studies based on target organ toxicity (e.g., carcinogenic evaluation of BPS).*
- *Compare and contrast BPS in vivo and in vitro data with other analogues and derivatives to build a knowledge base of bisphenol chemicals.”*

## VII. Reference List

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