



B&C<sup>®</sup> CONSORTIA MANAGEMENT

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**Regulatory, Testing, and  
Policy Trends for  
Chemical Consortia**

**B&CCM<sup>®</sup>**

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# FORECAST FALL 2018

## ***Consortia Engagement -- Stronger Voices, Increased Opportunities, Reduced Costs***

Now more than ever, chemical industry stakeholders with shared business and advocacy interests are urged to consider collaborating on regulatory, testing, and related advocacy opportunities. Two years post-passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act means the U.S. Environmental Protection Agency (EPA) is well underway with implementation of the amended Toxic Substances Control Act (TSCA). By the end of this year, EPA is required to identify the next set of high priority chemicals subject to prioritization and evaluation under TSCA Section 6. Industry fees assessed by EPA for such evaluation are expected to exceed \$1,000,000 per chemical. We anticipate that EPA will soon begin to utilize its expanded testing authorities under TSCA Section 4, which will have its own set of fees that must be paid in addition to the actual testing costs. EPA has expressed repeatedly and clearly in its rulemaking preambles that it anticipates these types of TSCA obligations will be shared collaboratively and addressed by consortia groups.

Industry groups that are already established and working efficiently when EPA initiates an action under TSCA will be most successful in nimbly and effectively engaging immediately. Groups that have yet to organize will deplete valuable limited time to form, leaving little time to comment effectively and comprehensively on EPA's proposed action. Getting industry groups organized now -- before EPA begins to express interest in a new round of high priority chemicals -- means reduced cost, greater flexibility, increased time for strategic planning, and less aggravation in the long run.

TSCA is by far not the only game in town. Companies should consider the benefits realized when organizing around advocacy and implementation effort pertinent to other regulatory initiatives such as Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) data call-ins (DCI), food and drug initiatives pursued by the U.S. Food and Drug Administration, and a wide range of state-specific programs. Benefits can also be realized by coordinated industry efforts on safety education, product stewardship, and other proactive initiatives intended to enhance stakeholders' communication and advocacy efforts.

This year's **B&C<sup>®</sup> Consortia Management, L.L.C. (BCCM)** forecast highlights our groups' interests and activities on these and other issues that can and should be addressed under a consortia canopy. While we enjoy sharing our success stories, the goal of the forecast is to highlight the critical importance of leveraging resources by sharing the load through organizing groups of interested stakeholders, to summarize activities pertinent to our existing BCCM consortia, and to encourage you to consider allowing us to help with the formation of a new group to address issues of particular interest.

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## BCCM GROUPS AT THE FOREFRONT OF TSCA IMPLEMENTATION

BCCM-managed consortia have remained vigilant in monitoring and responding timely and effectively to EPA's implementation efforts under amended TSCA. BCCM groups have the unique advantage of access to the talents and expertise of Bergeson & Campbell, P.C.'s (B&C®) internationally recognized team of [professionals](#) to advise consortia on critical and emerging TSCA issues. With guidance from B&C experts, the [Biobased and Renewable Products Advocacy Group \(BRAG®\)](#) prepared comments focused on reporting and listing of chemically equivalent



substances under the Inventory notification rule, as well as other components related to implementation. BRAG has also highlighted the need for EPA to consider pollution prevention attributes as part of its new chemical and risk evaluation processes. But BRAG's highest TSCA priority is working with EPA to establish updated nomenclature guidance for biobased products, including approaches to identify chemical equivalency among biobased sources. BRAG's white paper, "[Proposal for a Toxic Substances Control Act \(TSCA\) Inventory Representation and Equivalency Determinations for Renewable and Sustainable Bio-based Chemicals](#)," provides an excellent overview of the issue, TSCA's impact on the development of sustainable chemical products, and potential options.

As the name implies, the Alliance for Chemical Nomenclature (AChN) also is focused on chemical naming conventions under TSCA, and has maintained a close watch on the ongoing activities by EPA on this issue.



Like BRAG and other industry groups, the [North American Metals Council \(NAMC\)](#) has tracked EPA's

TSCA implementation proposals to ensure final rules are scientifically sound, particularly as they relate to the Congressional mandate that EPA rely on the [March 2007 Framework for Metals Risk Assessment](#) document in identifying priorities for risk evaluation and for conducting risk evaluations on metals and metal compounds. Given the vast number of use applications for metal and metal substances, NAMC has also advocated that EPA follow a flexible and pragmatic approach in assessing conditions of use under TSCA. Because of industry's interest to reclaim and recycle precious metal substances, NAMC was among impacted stakeholder groups engaged in the Negotiated Rulemaking Committee (NRC) for addressing recycled inorganic byproducts under the Chemical Data Reporting (CDR) rule. This committee and the issues of recycled inorganic products under CDR were specifically mandated under amended TSCA. Unfortunately, despite a series of meetings and conference calls, the NRC did not achieve consensus agreement on proposals offered. NAMC continues to dialogue with EPA on CDR reporting and its impact on companies engaged in metal processing.



The [N-Methylpyrrolidone Producers Group, Inc.](#) (NMP Producers Group) is fortunate to have formed and established advocacy and communication plans prior to the announcement of the first ten chemicals subject to TSCA Section 6 risk evaluation under amended TSCA, including NMP. By being ahead of the curve, its members have played an effective and extensive role in assuring that EPA utilizes the best available data when assessing the various uses of NMP. Of particular concern are a number of inappropriate assumptions and approaches used by EPA in its prior risk assessment of NMP in paint removers. In addition to multiple meetings and communications with EPA and the Office of Management and Budget





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(OMB) on the ongoing risk evaluation work, the NMP Producers Group also coordinated with multiple downstream user groups to encourage them to educate EPA on their specific workplace processing and exposure information.

### BCCM AND STATE ACTIVITIES

Recognizing that federal programs are only part of industry's regulatory requirements, BCCM groups have continued to monitor carefully chemical issues on the state level, and engaged as needed. The [Ethylene Oxide Sterilization Association, Inc. \(EOSA\)](#) submitted comments to the Oregon Department of Environmental Quality (ODEQ) regarding proposed changes to the **EOSA** Ambient Benchmark Concentration (ABC) for ethylene oxide (EO). The group also submitted comments to the Michigan Department of Environmental Quality (MDEQ) regarding a proposed update to the Initial Risk Screening Level (IRSL) and the Secondary Risk Screening Level (SRSL) of EO.

Like EOSA, the Tetrahydrofuran (THF) Task Force communicated with the MDEQ, which agreed with the Task Force's position that THF should not be listed as a carcinogen because mode of action data demonstrate that tumors seen in animals are not relevant to humans. The NMP Producers Group was also successful in its engagement with MDEQ, which increased its health-based screening level for NMP within the Air Quality Division based on the group's submission. The THF Task Force communicated with the New Jersey Department of Health (DOH) to request an update to the 2016 THF



hazardous substance fact sheet to reflect appropriate scientific findings on THF, including elimination of reference to carcinogenicity and modification of reproductive toxicity discussion. While the requested changes have not yet been implemented, DOH has acknowledged the group's submission and agreed to consider the requested modifications during the next review. Similarly, the [Titanium Dioxide Stewardship Council \(TDSC\)](#) submitted comments to DOH requesting it update the 2011 titanium dioxide (TiO<sub>2</sub>) Hazardous Substance Fact Sheet. TDSC sought to correct inaccurate statements regarding the suggestion that poisonous gases are produced in fire, overstatement of health and physical hazards, responses to spills and emergencies, and safe handling and storage.



The [Aseptic and Antimicrobial Processing and Packaging Association \(AAPPA\)](#) submitted comments to the California Occupational Safety and Health Administration's (CalOSHA) Health Effects Advisory Committee (HEAC) in response to its request for information on occupational exposure to and detection methods for peracetic acid. The Hydrogen Sulfide (H<sub>2</sub>S) Coalition also engaged in advocacy with HEAC related to its proposal to reduce the permissible exposure limit (PEL) for H<sub>2</sub>S, an effort that is part of a larger coalition initiative that will continue into **2019**.



The California Department of Toxic Substances Control's (DTSC) Safer Consumer Products Regulation (SCPR), implemented in 2013, seeks to identify specific products containing potentially harmful chemicals

to determine whether the chemical is necessary and if there are safer alternatives. With more than 1,000 Candidate Chemicals listed and the potential for significant regulatory action for impacted products, BCCM groups recognize the large scale impact of this program. As such, many BCCM consortia closely monitor this activity, including the TDSC, the THF Task Force, EOSA, the Carbon Disulfide (CS<sub>2</sub>) Coalition, the H<sub>2</sub>S Coalition, the Ethyleneamines Product Stewardship Discussion Group (EPSDG), and NAMC.

On the California legislative front, the TDSC successfully engaged with stakeholders in opposition of a California bill that would have required state-specific labeling measures for products containing TiO<sub>2</sub>. TDSC and others noted the bill's provisions would be overly burdensome, would provide much of the information already contained in a safety data sheet (SDS), and would inspire undue consumer confusion and alarm.

### **BCCM GROUPS AND OUTREACH ON WORKPLACE SAFETY**

The AAPPA is uniquely focused on educating stakeholders on the safe use of peracetic acid in workplace settings. Its members continue development of a training document on workplace recommended practices, including practices on spill clean-up, personal protective equipment (PPE), engineering controls, and general work practices. As an outgrowth of this workplace focus, the AAPPA and its member organizations have developed comments in response to the National Institute of Occupational Safety and Health (NIOSH) review of occupational exposure thresholds for peracetic acid.

Following recent guidance by the U.S. Occupational Safety and Health Administration (OSHA), EOSA has initiated a project to develop a document on the Recognized and Generally Accepted Good Engineering Practices (RAGAGEP) for EO Sterilization Facilities and Equipment. The intent is for stakeholders to use the document in the design, operation, and maintenance of in-

dustrial EO facilities. EOSA is also planning a multi-day technical conference in **2019** that will include sessions on regulatory developments, environmental, health, and safety issues, emerging technologies, and training sessions. This conference is the first of its kind dedicated to the U.S. EO sterilization industry and will provide critical information relative to the entire value chain.



To increase awareness on confined space issues, the H<sub>2</sub>S Coalition developed wallet cards to be distributed to stakeholders by its member entities that could potentially find themselves in a confined space entry scenario with H<sub>2</sub>S.

EPSDG has developed the Ethyleneamines Technical Manual that focuses on the safe handling and storage of ethyleneamines. This manual was prepared by EPSDG as a service to the industries that use these chemicals. While not required by state or federal regulation, EPSDG is developing a publication based on the evaluation of the dermal absorption of aminoethylethanolamine (AEEA) and will consider further work on Benchmark Dose (BMD) analyses to understand better its relevance to humans. The NMP Producers Group has likewise been involved with workplace exposure limits through its continued engagement with the Toxicology Excellence for Risk Assessment (TERA) in the development of a Workplace Environmental Exposure Level (WEEL) for NMP.

### **BCCM GROUPS AND NETWORKING**

Networking with key government representatives is an important aspect of BCCM groups' work. While responding to regulatory activities or developing recommended practices are clearly important projects for the groups, the need to initiate and maintain a strong network is also a critical factor of the groups' future successes. In 2018, BRAG representatives participated in an informational session with a Senior Energy Advisor for a Senate Chemistry Caucus to educate him on the evolution and importance of



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biobased products and innovations in the U.S. economy, as well as key legislative and regulatory activities impacting the biobased industry. BRAG also connected with EPA Smart Sectors staff to discuss the inclusion of biobased products in the program.

In addition to connecting with government contacts, BCCM groups also recognize the need to maintain strong connections with their international affiliates. The International Technical Caramel Association (ITCA) has a close working relationship with the European Technical Caramel Association (EUTECA) and is planning a joint scientific workshop with EUTECA later in 2018. TDSC coordinates efforts with its sister association, the Titanium Dioxide Manufacturers Association (TDMA), to ensure key issues are covered while avoiding duplication of efforts. NAMC works closely with the International Council on Mining and Metals (ICMM) and Eurometaux on multiple fronts on those issues that have global impacts, such as International Maritime Organization (IMO) testing requirements, development of implementing guidance documents for the Minamata Convention, and submissions to the Organization for Economic Cooperation and Development (OECD) on scientific approaches for metal and metal substances.

### **BCCM GROUPS' ENGAGEMENT IN TESTING PROGRAMS**

As part of its goal to understand better the mode of action for cancer effects reported in animal studies, the THF Task Force embarked on a three-pronged research program with Concept Life Sciences in 2017/2018. The outcome of that research program

provided evidence that supports the theory that THF-induced carcinogenicity is caused by constitutive androstane receptor (CAR) activation, a mechanism that is not applicable to humans. The THF Task Force successfully prepared and completed peer review on the study findings for final publication of "[Mode of Action and Human Relevance of THF-Induced Mouse Liver Tumors](#)," in Toxicology Letters in May 2018. The study is an important piece of information for groups assessing data and human cancer potential.

While test orders have not yet been issued by EPA, the BCCM groups with chemicals on List 2 of the EPA Endocrine Disruptor Screening Program (EDSP) are proactively preparing documentation on available data to support reduced testing under the EDSP. While the timing of EDSP test orders remains unclear at this time, these BCCM groups, the NMP Producers Group, the MTBE Consortium, and the Styrene and Ethylbenzene EDSP Testing Group, will be well-positioned to advocate with EPA when EDSP activities on List 2 re-engage.

The Ethylene Oxide Task Force (EOTF) and the Metam and Methyl Isothiocyanate (MITC) Task Forces are focused on engaging with EPA on testing programs associated with their chemicals of interest under FIFRA. EOTF continues to confer with EPA on its waiver requests for testing identified in the EO DCI. The Metam and MITC Task Forces have sponsored and nearly completed testing required in the metam DCI that began in 2011 in addition to the ambient air monitoring DCI. Pursuant to FIFRA guidelines and rules, MITC Task Force members have successfully sought data compensation from non-member companies that hold registrations for metam sodium and/or metam potassium.

**BCCM GROUPS’ COMMUNICATIONS AND EDUCATION EFFORTS**

BCCM groups recognize the importance of public outreach and education efforts related to their unique chemical interests. In 2017, ITCA members initiated a formal review of the Food Chemicals Codex (FCC) monograph for caramel colors by submitting a comprehensive proposal for specific amendments that were needed to reflect today’s technologies. As a result of the ITCA submission, an updated FCC monograph has been published and will go into effect later this year. ITCA also contracted for an update of the available literature review on the safety of caramel colors, which was published in *Food Chemistry and Toxicology*. ITCA coordinated with several organizations, including the Grocery Manufacturers Association (GMA), on the publication, “[Benchmark dose \(BMD\) modeling: current practice, issues, and challenges.](#)”

The Metam Task Force collaborated with other soil fumigant registrants to develop and implement a successful applicator training program that was approved by EPA. The program trains certified applicators as required by soil fumigant product labels. Soil fumigant registrants developed general modules as well as active ingredient-specific modules.

[The Selenium Working Group](#), organized under the NAMC (NAMC-SWG), continues to engage with EPA on its revisions to the Draft Implementation Guidance for Aquatic Life Criteria for Selenium Criterion. The NAMC-SWG intends to conduct research and analysis to address time to reach study state, which is one of the information gaps identified as part of the EPA guidance revision process.

A 2010 NAMC-SWG commissioned white paper, “[Review of Available Technologies for Removal of Selenium from Water](#),” has served as an important source of information for industry and government stakeholders. Specifically, the document contains an inventory of technologies and the removal efficiency of selenium using these technologies (at bench-, pilot-, and full-scales). The NAMC-SWG will issue an update of this paper that will reflect new or enhanced technologies and address recent regulatory developments.

**NEW GROUP FORMATION**

Our newest BCCM organization, the Chemistries of Heated Carbohydrates Consortium (CHCC), formed as a result of networking among trade associations on a chemical constituent that had recently been added to the California Proposition 65 (Prop 65) list. While each of the trade associations had members potentially impacted, it was difficult for the individual trade groups to address fully on their own. As part of the exploration process to form the group, members have identified additional chemistries that could be best addressed under the consortium umbrella.

As part of BCCM’s annual review, we encourage company and association representatives to consider potential benefits of working in collaboration with others on issues of shared concern, as the CHCC members have done. Whether addressing regulatory requirements, advocating for new policies, educating stakeholders, or conducting research, our initiatives are executed efficiently and effectively.



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