



B&C[®] CONSORTIA MANAGEMENT

Summer 2017 Regulatory,
Testing, and Policy Outlook for
Chemical Consortia

B&CCM[®]

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FORECAST SUMMER 2017

In Unsettled Times, Stay the Course with Consortia Advocacy

For the chemical industry, 2017 has been a year of evolutionary change, coupled with increasing uncertainties. Implementation of the amended Toxic Substances Control Act (TSCA) is underway. With the aggressive deadlines in the Frank R. Lautenberg Chemical Safety for the 21st Century Act, companies are required to review a multitude of proposals, often issued by the U.S. Environmental Protection Agency (EPA) at the same time. Such reviews require surgically close scrutiny given that decisions today will impact industry stakeholders for decades to come. Beyond regulatory rulemaking actions, there are many unknowns on the general directions and policies that EPA and other regulatory agencies will adopt under a Trump Administration. Further questions continue to linger on how budget reductions and the existing lack of senior leadership will impact current and future programs.

Achieving business growth goals during uncertain times is certainly difficult, but the risk can be lessened with a group effort. Engagement in chemical consortia affords companies opportunities to network with like-minded entities; expand member knowledge through information sharing; strengthen chemical-specific databases on hazard, exposure, and use information; and reduce costs on proposal review, comment development, and testing or research programs. It is well known that regulatory agencies often prefer to work with coalitions to save time and leverage their own resources.

Beyond direct engagement in regulatory activities, the beneficial outcome of competitors working together to elevate standards and enhance business practices for the good of the whole is undeniable. Consolidating experience, knowledge, and finances allows consortium members to achieve far more and faster than they would individually.

This mid-year review of [B&C® Consortia Management, L.L.C. \(BCCM\)](#) activities highlights a wide range of advocacy, regulatory, science policy, testing, and communication activities and strategies in which our consortia groups are engaged. As you review the listed activities, we invite you to consider whether your organization would benefit from membership in an existing BCCM consortium, or in the formation of a new group to address issues of particular interest.

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PROTECTING CONSORTIA INTERESTS IN TSCA IMPLEMENTATION

BCCM groups recognize the critical importance to business of ongoing activities implementing new approaches under amended TSCA and how these will impact the future of chemical regulation in the U.S. As such, BCCM consortia groups, such as the [North American Metals Council \(NAMC\)](#) and the [Biobased and Renewable Products Advocacy Group \(BRAG®\)](#) have carefully evaluated EPA proposed rules and prepared comprehensive comments to EPA on the framework regulations on chemical prioritization, risk evaluation, and Inventory reset. These groups have also participated in networks of other industry trade groups to gain further understanding of the processes and to solicit support for their positions.

[NAMC](#) members are particularly focused on the legislatively mandated regulatory negotiations (reg-neg) on reducing regulatory reporting burdens for recycled inorganic byproducts under the TSCA Chemical Data Reporting (CDR) rule. [NAMC is a member of the Regulatory Negotiation Committee formed under TSCA to reassess CDR reporting obligations for certain recycled byproducts.](#) This initiative is particularly important for the metals industry because for many byproduct recycling situations, extraction of valuable metal components can only be achieved through chemical reaction processes. This means that the byproduct streams used in these recycling operations would not be exempt under CDR. Byproduct manufacturers are left to decide whether to proceed with environmental sustainability and recycling, but take on the significant compliance obligations under CDR, or dispose of the byproduct and have no reporting obligations. In many



cases, the metals extracted from these processes are very valuable. NAMC is confident that the negotiation committee will find an

option that will reduce reporting burdens for those innovative companies looking to reduce waste and support sustainability practices.

[BRAG](#) members continue their ongoing efforts to minimize complexity and commercialization barriers associated with naming conventions for evolving renewable sources for chemicals. Often when a biobased chemical is manufactured using a new renewable feedstock, it is subject to "new chemical" review and evaluation processes by EPA scientists due to the inclusion of the feedstock source in the description of the chemical substance. BRAG is collaborating with other stakeholders to execute an effective solution to this commercialization obstacle, such as expanding the current nomenclature system to include new biobased sources and developing an approach to draw chemical equivalence between existing chemicals and "new" biobased chemicals.



The **Alliance for Chemical Nomenclature (AChN)** is likewise interested in reducing complexities associated with TSCA Inventory Class 2 nomenclature. Its members are coordinating with other stakeholders related to TSCA implementation and Inventory issues in hopes of providing clarity on the application of certain existing nomenclature conventions pertinent to paraffin waxes.



As an organization representing one of the first ten chemicals being evaluated under amended TSCA, the [NMP Producers Group, Inc.](#) conducted outreach to numerous trade associations and companies with the goal of ensuring relevant use and application information was submitted to EPA prior to the risk assessment process. Such an effort would have been difficult, if not impossible for members to achieve on their own, but as a collective group, the NMP Producers Group successfully collected and submitted information



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from six key industry sectors, and encouraged other sectors to submit their input separately.

With the NMP Producers Group’s experience in mind, BCCM strongly encourages companies concerned with how EPA intends to address “conditions of use” within the amended TSCA framework to consider how engagement within a consortium will facilitate its ability to compile real-world use and exposure information for use by EPA within a risk assessment. Collecting such information can be difficult, time consuming, and challenging for any value chain. But without such information, EPA will rely on worst-case assumptions or modeling that may not reflect realistic situations, which will adversely impact the outcomes of the EPA risk assessment.

Indeed, companies with chemicals listed under the TSCA Work Plan chemicals that are already part of an existing consortium will be better positioned to engage meaningfully in EPA’s chemical assessment process under amended TSCA. We encourage chemical manufacturers with chemicals on the Work Plan list that are not already organized in a trade group to consider doing so as soon as possible. Amended TSCA directs EPA to rely on the Work Plan list as it identifies chemicals for prioritization, so it is likely that these chemicals will be identified for further work under TSCA within the next few years. Preparatory actions by an organized group would include early advocacy with EPA regarding available hazard and exposure information, providing updates to EPA on any ongoing reviews or testing, and carefully reviewing existing use information.

ENGAGEMENT IN OTHER REGULATORY ARENAS

While implementation of amended TSCA seems to have most of the regulatory world’s focus at this time, we are well aware that stakeholders are continuing engagement with EPA and other regulatory bodies on non-TSCA issues. Within BCCM, several groups remain actively involved with registration review requirements under the [Federal Insecticide, Fungicide, and Rodenticide Act \(FIFRA\)](#). In 2017, the BCCM **Ethylene Oxide Task Force, Metam Task Force, and Methyl Isothiocyanate (MITC) Task Force** continue their advocacy, communications, and data development work to support the continued U.S. registration of their important commercial products. As with other BCCM consortia, these groups readily utilize the available legal, scientific, and regulatory expertise available through BCCM’s affiliation with the [Bergeson & Campbell, P.C. \(B&C®\)](#) law firm and [The Acta Group](#). In addition to addressing the data production requirements as part of the registration review process, members of these groups are also focused on ensuring that their rights for data compensation are appropriately protected and invoked.

While there are uncertainties with the timing of test orders for chemicals included in the [EPA Endocrine Disruptor Screening Program \(EDSP\)](#), most stakeholders agree that continued diligence on relevant information collection and data evaluation is the most prudent course of action. BCCM consortia with chemicals included on the EDSP List 2, including the **MTBE Consortium, the Styrene and**

Ethylbenzene EDSP Testing Group, and the [NMP Producers Group](#), have or are working to complete summaries of “other scientifically relevant information” (OSRI) to support reduced testing. Companies manufacturing or importing List 2 chemicals may wish to do the same as such an exercise can take months if not years to finish.

To ensure its consortia members impacted by the EDSP are kept up to date on key activities and have the information they need for strategic planning, BCCM is an associate member of the Endocrine Policy Forum (EPF), a cooperative effort among EDSP stakeholders designed to facilitate communication, networking, and scientific dialogue on the testing program, interpretation of results, and guideline development. Through its associate membership of EPF, BCCM provides the impacted consortia groups with access to an online clearinghouse of relevant materials, technical papers, and meeting minutes.

BCCM groups are also involved in regulatory advocacy related to workplace exposure limits. The [Aseptic and Antimicrobial Processing and Packaging Association \(AAPPA\)](#) continues to confer with the National Institute for Occupational Safety and Health (NIOSH) regarding its draft immediately dangerous to life or health (IDLH) value for peracetic acid. AAPPA submitted comprehensive written and oral comments to NIOSH on human, animal, and workplace case studies that demonstrate the proposed IDLH value was set artificially low. Based on recent



communications between AAPPA members and NIOSH staff, it appears NIOSH is

willing to defer a final decision while additional information is collected. AAPPA members are committed to collaborating with other aseptic industry groups to assist NIOSH in its efforts to gather sufficient data for the development of a scientifically valid IDLH value.

The [NMP Producers Group](#) anticipates that its multi-year engagement with the Occupational



Alliance for Risk Science (OARS) will result in an updated Workplace Environmental Exposure Level (WEEL) value for NMP in 2017. As part of its advocacy work, the Group sponsored additional refinements to its physiologically-based pharmacokinetics (PBPK) model and provided expertise and technical support through participation in numerous WEEL Committee conference calls.

The [Titanium Dioxide Stewardship Council \(TDSC\)](#) is also engaged in regulatory matters related to workplace issues, such as efforts to correct state-issued hazardous substance fact sheets and engaging in the upcoming transition in Canada to the Workplace Hazardous Materials Information System (WHMIS). TDSC



regularly engages with the Titanium Dioxide Manufacturers Association to address global titanium dioxide (TiO₂) challenges, including the recent Risk Assessment Committee (RAC) of the European Union’s European Chemicals Agency (ECHA) recommendation to classify TiO₂ as a category 2 carcinogen by inhalation, a major decision impacting many paint and coating manufacturers.



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In December 2016, the [International Technical Caramel Association \(ITCA\)](#) submitted to the United States Pharmacopeia (USP) a comprehensive document and supporting materials for proposed amendments to the Food Chemicals Codex (FCC) monograph for caramel color. As articulated in ITCA's submission, the FCC caramel color monograph needs to be updated to reflect current analytical methodologies, clarify parameters for measurement of constituent limits to ensure parties are using the specifications correctly, facilitate the use of the monograph for practitioners by providing clearer guidance and explicit calculations/formulas in test specification descriptions, and reflect the evolution of caramel colors and their uses. The ITCA submission, which took almost a year to prepare, followed the USP Guideline for Submitting Proposals for Revisions to the *Food Chemicals Code*. ITCA is confident that its submission will be included in the USP review forum in December 2017.

PUBLIC ENGAGEMENT/COMMUNICATION OUTREACH

BCCM groups recognize that communication on science and regulatory issues is critical to a group's success. Most groups have established public websites in which they share information related to ongoing testing programs, regulatory issues, or other areas of interest. Several BCCM groups have taken the need for public engagement further and are exploring other approaches to ensure stakeholders are fully informed.

To help BRAG members and industry stakeholders stay informed of significant developments impacting the

fast-paced biobased industry, BCCM publishes the [Biobased Products News and Policy Report](#). The weekly publication provides a reliable source of information on legislative actions, outlooks, and key developments at federal and state agencies that affect biobased and renewable products. Key industry developments, research, and events related to renewable chemicals, biobased products, biofuel, and biotechnology, as well as feedstocks and products throughout those supply chains, are also featured in the report.

The North American Metal Packaging Alliance, Inc. (NAMPA) [Facebook page](#) and [Twitter account](#) include a wide variety of postings for the public, including information on the environmental sustainability of aluminum cans, the role canned fruits and vegetables can play in a balanced diet, the importance of cans in emergency planning and response efforts, and innovations within the food industry on how cans are used. NAMPA also operates [Can Science News](#), a resource for news and information on metal packaging. These communication sources allow NAMPA members to have meaningful engagement with concerned stakeholders on the many issues related to cans and can technology.

The NMP Producers Group members recognize the importance of keeping their many stakeholders informed of the ever-evolving regulatory landscape for NMP, given its inauspicious situation as one of the first ten chemicals going through risk evaluation under amended TSCA and as a chemical undergoing scrutiny under the European Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program. In an attempt to ensure key parties understand the

ongoing issues and potential impacts to their businesses, the Group posts periodic [regulatory news briefings on its website](#) and encourages entities to set up and maintain communications with the Group.

The [Ethylene Oxide Sterilization Association, Inc. \(EOSA\)](#) maintains a public website to highlight upcoming industry events and communicate industry positions on key issues and emerging issues that are relevant to the entire ethylene oxide (EO) sterilization value chain. As with many BCCM consortia groups, EOSA also maintains a limited-access website for its members to access and retrieve key consortia materials, publications, and other technical information.



ITCA also maintains a [public website](#) that provides information on the history, safety, benefits, and regulatory status of caramel color, and other resources for more in-depth research. In the year following its launch in 2016, the ITCA website attracted 6,700 visitors, primarily through direct visits and google searches. The website allows ITCA to engage with interested stakeholders and address questions and issues related to the caramel color industry.

PRODUCT STEWARDSHIP -- WORKING TOGETHER FOR THE COMMON GOOD

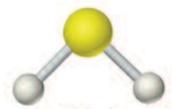
BCCM consortia members recognize that the benefits of working within a group go far beyond addressing regulatory requirements. The organized forces afforded by BCCM groups allow its members to pursue important product stewardship activities that benefit the larger industry. Such activities could not be successful if individual members attempted to accomplish them on their own.

[AAPPA](#) members continue their ongoing efforts to develop and implement strategies focused on best

practices for worker protection in the aseptic processing and packaging industry. AAPPA seeks to provide practical advice for the safe use of aseptic and intervention chemicals to ensure the ongoing safety of food and beverage processing workers and safeguard the quality of products. By compiling the knowledge and experience of its members, AAPPA works to generate and communicate worker safety training and educational resources for the industry.

The Hydrogen Sulfide (H2S) Coalition, whose

membership consists of other industry groups with a common interest in health and safety matters regarding H2S, addresses product stewardship issues across multiple industry sectors. H2S Coalition members have developed product stewardship materials such as a wallet card that addresses the unique safety concerns associated with confined space entry when H2S may be present. This material has been developed with non-industry specific content so that it can be used in virtually any of the 80+ industries in which workers may come into contact with H2S.



Hydrogen Sulfide Coalition

The Tetrahydrofuran (THF) Task Force

completed a voluntary research project investigating cancer effects seen in female mice livers from a National Toxicology Program (NTP) study. In its report, NTP concluded the liver cancer occurred due to non-genotoxic modes of action (MOA); the Task Force research program focused on understanding the MOA and whether it is relevant to humans. The findings of the research, available [online](#), support the hypothesis that THF-induced carcinogenicity in mice is likely mediated via activation of a specific protein expression receptor (Constitutive Androstane Receptor (CAR)) that has limited, if any, relevance to humans.





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EXPANDING MEMBERSHIP OPTIONS

The increasing uncertainties in the chemical industry and the challenges faced are not limited to the U.S. Regulatory, communications, and product stewardship issues are increasingly global in nature. With the complexity of emerging issues and ever increasing global reliance on regulatory and health and safety information, many BCCM consortia are looking to expand their membership opportunities and organizational expertise.

[EOSA](#) recently opened its membership requirements to facilitate participation of international companies. In 2017, EOSA membership expanded to cover the U.S., Canada, and seven international countries, with goals for the expansion to continue. This expansion provides unique perspectives to the membership on the global product stewardship needs and the impacts of key regulations beyond the country in which they are implemented.

[ITCA](#) continues to expand its global membership as well, with the addition of organizations from the U.S., Mexico, Japan, France, Argentina, and Malaysia. To encourage additional members, ITCA has implemented an associate membership option that allows interested organizations to participate in ITCA conference calls and meetings for one year at no cost so those potential members can appreciate first-hand the work that ITCA is conducting.

As a consortium focused on the development of recommended practices and engagement in the estab-

lishment of worker exposure thresholds, [AAPPA](#) relies on the expertise of its members to inform and provide a framework for its endeavors. Increasing the size and diversity of the membership would benefit greatly the information-sharing activities for which AAPPA is involved. AAPPA, therefore, is seeking to expand its membership through the addition of food and beverage companies of all sizes using aseptic chemicals, including meat and poultry processing plants, as well as producers and suppliers of aseptic chemicals.

Many BCCM groups routinely expand their advocacy reach by leveraging resources through careful coordination with other global associations. For example, [TDSC](#) works closely with the Titanium Dioxide Manufacturers Association; [ITCA](#) engages with the European Technical Caramel Association; and [NAMC](#) works with Eurometaux and the International Council on Mining and Metals.

CONCLUSION

The uncertainty in today's political and regulatory environment, coupled with fast-evolving scientific developments, is likely to continue. As industries mature, new technologies emerge, and regulatory priorities shift, the needs for and benefits of effective and efficient collaboration through an industry consortia are more important than ever. In some cases, consortia have the opportunity now to influence issues that industries will be addressing for decades to come. Effective management and leveraged resources make many doors easier to open and unlock solutions to what otherwise could be overwhelming challenges.



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