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Spring 2016 Regulatory,  
Testing, and Policy Outlook for  
Chemical Consortia

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# FORECAST 2016

## ***The Business Wisdom of Consortia Advocacy***

Engaging in advocacy opportunities with your company's competitor may seem counterintuitive in ultra-competitive times, but doing so as part of a consortium, in which your company benefits as well, makes sense. Working within a group to attain a shared goal offers benefits beyond cost savings. For example, the federal and international agencies prefer to work with coalitions to save time and leverage their resources; there is truth to the old adage, "There is strength in numbers." The beneficial outcome of competitors working together to elevate standards and 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.

The reasons for forming and maintaining a coalition are varied. There is great truth to the proverb, "Many hands make light work." As companies and related stakeholders consider the regulatory, policy, and stewardship challenges facing them today, they would be well-served to consider if it makes sense to tackle those challenges under a consortium umbrella. The likelihood is that an individual entity is not always well-suited to complete a costly testing program, influence policy change, or raise industry standards, but entities working together with a unified voice are.

In 2016, **B&C® Consortia Management, L.L.C. (BCCM)** will be leveraging its considerable resources on a wide range of advocacy, regulatory, science policy, testing, and communication activities for BCCM consortium members. BCCM is authorized to operate in the U.S. and Europe. We identify below specific initiatives, including group formation invited by regulatory actions, focused on needed policy changes or desires to improve worker safety. We invite stakeholders to consider whether they too should engage in any existing BCCM consortia, or to identify other testing or advocacy areas where consortia work makes sense.

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**REGULATORY TRIGGERS: ORGANIZE NOW – BEFORE FINAL ACTION IS TAKEN**  
**EPA Endocrine Disruptor Screening Program**

Producers and importers of chemicals included in the [U.S. Environmental Protection Agency \(EPA\) Endocrine Disruptor Screening Program \(EDSP\)](#) will be required to respond to test orders for their subject chemical(s). Given the high price tag of the EDSP test program, companies that continue to manufacture the listed chemicals will likely address the EDSP regulatory components within a consortium to share costs.

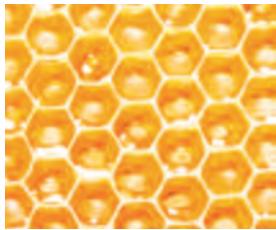
BCCM currently manages two groups focused on the EPA EDSP -- the [N-Methylpyrrolidone Producers Group, Inc. \(NMP Producers Group\)](#) and the **MTBE Consortium** -- and anticipates several more groups to organize in 2016. These groups appreciate that organizing efforts now -- before EPA formally issues EDSP test orders for their chemicals of interest -- is a smart strategic move. They have already begun the hard work of developing effective advocacy positions regarding testing needs and will be ready to engage immediately when EPA issues test orders.

Some companies may be concerned that forming or joining an EDSP consortium prior to the test order could result in an inequitable cost allocation. They fear that companies that choose not to join early will gain an advantage. This is incorrect. Under the EDSP, all companies that produce or import the subject chemical when the test order is issued must conduct the testing themselves, form or join a consortium that will conduct the testing, agree to provide fair and equitable reimbursement for testing conducted by others, or exit the market. Thus, there is no benefit to companies that choose not to proceed with a consortium. On the other hand, companies that opt to create or join an existing consortium will have the advantage

of leading critical decisions on cost sharing, membership fees, and reimbursement provisions for late comers. Through BCCM's affiliation with [Bergeson & Campbell, P.C. \(B&C®\)](#), its EDSP-focused groups have access to highly-experienced, sophisticated attorneys, scientists, and other non-legal professionals with significant expertise in regulatory law, science, data compensation, and EPA policy guidance. Test programs such as EDSP often present substantial risk information reporting questions, the answers to which experienced legal counsel may be needed. B&C is one of the few law firms in the country with a comprehensive domestic and international pesticide and industrial chemicals practice group.

BCCM is also 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.

While the EDSP test program does not mandate coordination prior to the issuance of test orders, sophisticated entities recognize that being a consortium member now allows adequate time comprehensively and thoughtfully to address administrative issues, agree upon cost sharing mechanisms, identify potential testing laboratories, retain experienced scientific consultants, and begin the important process of reviewing available data to support test waivers. These steps take time to do correctly, and waiting to form a consortium until EPA formally issues the test orders is unwise and disallows time to complete these tasks efficiently and effectively. Stakeholders need to be ready to engage in testing immediately, and will lack the necessary time to organize a group and secure limited testing capacity to fulfill the test orders.



*Companies with commercial interests in Work Plan chemicals that delay action, based on the hope the program will go away, will be disappointed.*

## TSCA WORK PLAN CHEMICALS

Updated in 2014, [EPA maintains a list of 90 chemicals for assessment under the Toxic Substances Control Act \(TSCA\)](#). Chemicals on this list will be subject to the TSCA Work Plan Chemical Assessment process that includes problem formulation, initial assessment, data needs assessment, final assessment, and potential risk management measures.

Of the currently completed assessments, BCCM groups engaged in two -- antimony trioxide (ATO) under the [North American Metals Council \(NAMC\)](#) and NMP under the [NMP Producers Group](#). The ATO assessment concluded that no further work was necessary regarding the uses considered under the program. The NMP assessment concluded potential

occupational risk for certain uses; the NMP Producers Group is actively engaged now with EPA on next steps. Several other BCCM groups have chemicals on the TSCA Work Plan list and will be well-positioned to engage when their chemical assessments are initiated.

Given concerns with the commercial impacts of an EPA assessment and possible use or application restrictions, companies with chemicals listed as TSCA Work Plan chemicals should be coordinating with other producers or importers now to be well-positioned to engage meaningfully in EPA's chemical assessment process. Similar to the EDSP work, entities should work together under the protection of a consortium structure before EPA initiates its Work Plan assessment. 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 data to identify potential gaps, particularly on use and exposure information.

Companies with commercial interests in Work Plan chemicals that delay action, based on the hope the program will go away, will be disappointed. It is well-recognized that the TSCA Work Plan Chemical Program is expected to be incorporated under TSCA reform legislation as the template for chemical prioritization for existing chemicals under a new TSCA framework.

## FIFRA ACTIVITIES

[As part of the Federal Insecticide, Fungicide, and Rodenticide Act \(FIFRA\), EPA must review each registered pesticide at least every 15 years to determine whether it continues to meet the FIFRA registration standard.](#) EPA has implemented an aggressive schedule to complete needed assessments for pesticides registered as of October 2007. In addition to EPA, a number of state agencies focus significant regulatory attention on pesticide practices. Pesticides are increasingly a subject of interest from public interest groups, public health activists, and communities. These extended interests add further layers to the complexity of challenges faced by registrants and other agricultural stakeholders.

Companies manufacturing the same active ingredient are urged to collaborate under FIFRA to share testing costs and conserve resources. Beyond tests, and as

noted, pesticide stakeholders are increasingly challenged to address policy issues that warrant a co-ordinated advocacy strategy to ensure success and leverage resources. Having a group of like-minded entities organized and accustomed to working together before EPA initiates resources to reregister an active ingredient could prove to be a critical factor for success. This allows for a coordinated voice to address EPA, pool much needed use-specific information of application practices and exposure scenarios, gather information on what data are already available, and assess how those data should be applied in EPA's consideration of any additional data generation requirements.

The **BCCM Ethylene Oxide Task Force, Metam Task Force, and Methyl Isothiocyanate (MITC) Task Force** are currently engaged in advocacy, communications, and data development to support the continued U.S. registration of their products. With assistance from B&C professionals, BCCM groups are able efficiently to meet data production requirements, and obtain data compensation from appropriate others.

## IRIS REVIEWS

Companies with chemicals subject to the [Integrated Risk Information System \(IRIS\) assessment](#) should be prepared to engage efficiently with EPA given that final IRIS hazard values are widely relied on by EPA program offices as well as state and local health agencies, other federal agencies, and international health organizations. Like other EPA programs, co-ordinated group advocacy is essential and the results of such action will carry more weight and garner more attention than individual entity input.

The IRIS process, which is managed by EPA's National Center for Environmental Assessment (NCEA), involves multiple phases. While stakeholders have several opportunities to engage with EPA, it is crucial that advocacy and cooperation among stakeholders begin early. The IRIS assessment itself represents the first part of the risk assessment process and can take many years to complete.



Within BCCM, several groups are actively engaged in or carefully monitoring the IRIS program, including the [Ethylene Oxide Sterilization Association, Inc. \(EOSA\)](#) and [NAMC](#). The groups actively engage EPA through participation in public meetings and preparation of comments for consideration by EPA and its

Science Advisory Board (SAB). When a substance is undergoing IRIS assessment, it is critical to conduct independent technical reviews of data and modeling. Existing consortia are able to complete these tasks swiftly and efficiently through the retention of expert consultants. Costs to individual entities are greatly reduced when this type of leveraged advocacy is performed by a consortium.

## POLICY CHANGES: WORKING TOGETHER FOR THE COMMON GOOD

Recognizing problems within the current regulatory framework is easy; trying to resolve those problems can be difficult. Unless an entity wishes to spend a great deal of time and money, going it alone is not the best or only way to effectuate change and solve



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problems. By coordinating with other like-minded entities, flawed policies or misguided rules can be addressed leveraging the additional resources, coordinated advocacy, and strength offered by a consortium.

Several BCCM groups were formed specifically to address policy-related issues. The **Alliance for Chemical Nomenclature (AChN)** brings together companies and organizations engaged in the manufacture and/or use of fractionated chemical substances or other unknown, variable, complex, or biological substances, or otherwise have a vested interest in the commercial availability and regulatory TSCA classifications of such substances. AChN ensures its members' rights are adequately represented before EPA regarding the consequences of evolving, and often flawed, re-interpretations of TSCA nomenclature conventions that have significant commercial and enforcement consequences on AChN member companies. We need look no further than the current debacle involving EPA's medium and long chain chlorinated paraffins to appreciate the consequential legal, policy, and commercial implications of EPA's unlawful and misguided decision to interpret existing chemicals listed on the TSCA Inventory as "new" despite their robust commercial presence over the past 50 years in U.S. commerce.

The **Industry Consortium for Environmental Measurement of Nanomaterials (ICEMN)** was a consortium of industry, academic, and government stakeholders that recognized policy makers were not well-versed in available information on measuring nanomaterials in the environment. That group organized a highly successful workshop with the California Office of Environmental Health Hazard Assessment (OEHHA) and followed up with a [series of articles](#) about nanomaterial measurement in water, air, and soil that now serves as a practical guide for state and federal regulatory agencies.

Other BCCM groups working on important policy issues include the [Biobased and Renewable Products Advocacy Group \(BRAG®\)](#), [NAMC](#), and the [Titanium Dioxide Stewardship Council \(TDSC\)](#).



BRAG members have long recognized that regulatory barriers exist for biobased chemistries and have coordinated efforts to address these regulatory hindrances and commercial inequities. [BRAG has successfully advocated for reduced federal reporting requirements under the TSCA Chemical Data Reporting \(CDR\) that provides biodiesel manufacturers the same diminished reporting opportunities afforded petroleum-based diesel manufacturers -- saving the industry significant time, energy, and resources](#). In 2016, BRAG will continue to advocate policy changes related to naming differences for new biobased chemicals and



their derivatives, even though those new chemicals are substantially similar in terms of functionality and chemical structure to older chemicals.

NAMC will continue its advocacy drum beat with EPA, Congress, state, and international organizations that metals have special attributes and behaviors that must be uniquely considered when assessing human health and ecological risks. The unique attributes are highlighted in the "[Framework for Metals Risk Assessment](#)," a science-based document that NAMC members worked closely with EPA in developing, and continue to emphasize as persistence, bioaccumulation, and toxicity (PBT) issues continue to be the subject of extraordinary government attention.

TDSC has and will continue to be actively engaged in proposed reporting and recordkeeping requirements impacting nanoscale materials. "Nano" issues extend far beyond the titanium dioxide (TiO<sub>2</sub>) industry and



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TDSC is one of many consortia that have engaged EPA on the issue. While these requirements impact many industries, TDSC members understood early on that the “strength in numbers” approach can extend beyond a particular industry segment. By working with other organizations, TDSC members see the benefit of working not only with competing companies, but with other industries, to advocate for a shared goal.

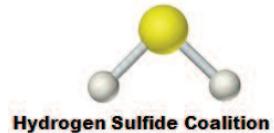
### **PRODUCT STEWARDSHIP: COLLABORATION RESULTS IN IMPROVED SAFETY**

While regulatory requirements are often a catalyst for companies to form an industry group, there are a growing number of “soft” non-regulatory factors that jump-start group formation. Industry leaders are often in the best position to execute needed changes within their sectors, which includes recognizing the need to promote important product stewardship activities related to research, worker safety, and/or communication needs across the value chain.

The **BCCM Tetrahydrofuran Task Force (THF)** has been deeply involved with voluntary research to understand better the mechanism of action related to certain hazard endpoints associated with THF. The Task Force appreciates that such proactive research can diminish areas of scientific uncertainty that would otherwise result in the application of uncertainty factors in regulatory contexts.

Recognizing the critical importance of an informed worker population, the **Hydrogen Sulfide Coalition (H<sub>2</sub>S Coalition)** is engaged in a unique

program with the National Institute for Occupational Safety and Health (NIOSH) to develop educational and training materials covering the issues uniquely associated with H<sub>2</sub>S, including confined space, transportation, and handling issues spanning nearly 100 occupations across various industries. The H<sub>2</sub>S Coalition is able to address these concerns as it is a consortium consisting of multiple industry associations, each with their own member companies that collectively share an interest in H<sub>2</sub>S matters. This type of organization provides immense technical resources and expertise among the membership. Furthermore, it creates efficiency as multiple organizations are able to leverage time, resources, and costs required to address concerns.



**Hydrogen Sulfide Coalition**

One of BCCM’s newer groups is the [Aseptic and Antimicrobial Processing and Packaging Association](#). It is focused on the goal of enhancing industry practices to promote worker safety and protection. It is engaging food and beverage producers, processors, packaging suppliers, equipment manufacturers, and other stakeholders to enhance best practices for worker protection, spill cleanup, and other safety areas.



### **BCCM SERVICES TO SUPPORT ALL CONSORTIA GOALS**

While the reasons for forming a consortium are varied, the objectives are the same -- to work together in a cost-effective manner in support of a common goal. BCCM can provide the necessary infrastructure,

framework, and support to ensure that those goals are met quickly and efficiently.

BCCM creates and manages business consortia that have evolved in response to targeted advocacy, research, required product testing for entities in the industrial, agricultural, specialty chemical, or product/article area, or product stewardship interests. An industry group organized under BCCM allows for maximized impact because participants can leverage resources to address issues critically important to their needs and essential to their continued success.

All BCCM consortia work toward consensus decisions on issues related to membership dues, cost sharing for specific research programs, consideration of communication approaches, decisions on selection of testing laboratories, and advocacy strategies. BCCM recognizes that alignment among consortium members is essential for success and BCCM groups strive to achieve consensus decisions among members under the skilled, diplomatic, and experienced direction of BCCM staff. An important part of the decision-making process is the availability of carefully crafted and comprehensive bylaws that clearly identify the individual consortium's goals, objectives, work practices, and membership expectations. BCCM managers are sophisticated and experienced in the development and implementation of such bylaws as part of their day-to-day consortium management.

BCCM is unique in the services and talents it can offer its clients due to its affiliation with [B&C](#), a Washington, D.C. law firm focusing on environmental and chemical control regulations, and [The Acta Group \(Acta®\)](#), a global regulatory and scientific consulting provider headquartered in Washington, D.C., with offices in Manchester, UK, and China.

BCCM is a core part of the B&C law firm's business platform to service clients efficiently. B&C has an international reputation for providing high-quality, cutting edge legal and regulatory counsel to Fortune 100 companies; medium size manufacturers; and trade associations and start-ups commercializing innovative, emerging technologies, including nanotechnology, biotechnology, and synthetic biology. B&C authored the report, "[The DNA of the U.S. Regulatory System: Are We Getting It Right For Synthetic Biology?](#)" B&C has been consistently ranked among the highest, most qualified firms by providing unfailing, spot-on legal advice, strategic counseling, and business acumen. Additional information is available at [lawbc.com](http://lawbc.com).



BCCM is also affiliated with Acta, an international consulting firm that offers a broad range of regulatory and scientific consulting services to entities worldwide. Acta focuses on chemical and other heavily regulated product approval issues and the supply chain notification, customer demand, communication, media attention, and regulatory issues associated with these regulatory requirements. Acta has been a consistent player in all matters under the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) legislation for over a decade, and is very much engaged in notifications and supply chain matters in China, Korea, Turkey, and elsewhere. More information on Acta is available at [actagroup.com](http://actagroup.com).

Given its affiliation with B&C and Acta, BCCM can provide its groups with immediate access to highly-trained, sophisticated attorneys, non-lawyer professionals, and scientists with significant expertise in

competition law compliance, global chemical law and regulation, data management, data compensation, supply chain management, and regulatory and legal/policy guidance. The expansive talent pools at BCCM, B&C, and Acta allow for all-inclusive, comprehensive services in management, regulatory, and scientific efforts for a wide range of global chemical management systems and the business and legal issues these systems invite. Our team is deeply experienced in multiple scientific arenas, including food regulations, pesticides, risk assessment, computer modeling, chemical control efforts, nanotechnology, synthetic biology, and biofuels/biochemicals. Access to this pool of talent has proven to be an essential element in the success of BCCM's groups.

## ADMINISTRATIVE SERVICES

BCCM's key management objective is to protect and immunize each consortium's interests from antitrust concerns, thereby allowing individual members to promote the consortium's goals. BCCM staff has more than 30 years of experience in managing and providing antitrust protection to various trade groups.

While antitrust protection is an important focus, BCCM provides comprehensive administrative, accounting, and communication support services that are necessary for a consortium's success, including coordination of all meetings/conference calls; maintenance of e-mail lists; collection and maintenance of confidential production or market share information for cost allocation purposes; providing for the amal-

gamation and protection of competitively sensitive information; membership recruitment; and website design and maintenance.

## REGULATORY ADVOCACY

BCCM's goal is to ensure each consortium's voice is heard on regulatory, scientific, legal, and related advocacy issues of interest to consortium members. BCCM often serves as the consortium's liaison with pertinent domestic and international regulatory agencies central to the consortium's issues. BCCM addresses regulatory advocacy needs for its clients, such as updating membership on significant regulatory, scientific, and legal issues relevant to the consortium's issues; engaging with regulatory groups to identify opportunities for coordination; networking with other groups on common areas of interest; preparing regulatory comments; and building and maintaining positive relationships with key state, federal, or international agencies/organizations, such as the EPA, the Occupational Safety and Health Administration (OSHA), Congress, the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA), and related entities.

## ROUND-ROBIN TESTING

BCCM has developed and executed round-robin analysis of consortia members' products in response to regulatory agency requests. These projects included obtaining and recording members' samples, blending those samples, coordinating with third parties for sample analysis, and developing final reports that



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provided relevant information while maintaining confidential business information. BCCM staff has also coordinated with B&C attorneys in the compilation and submission of market data to various agencies to demonstrate potential commercial impacts of proposed government actions.

In activities related to collection of sensitive business data, BCCM utilizes the B&C law firm's standard operating procedures (SOP) for protection of client records and information that specify locked files and disposal via shredding. BCCM staff engages B&C legal counsel in assessing, designing, and implementing identified data collection exercises to ensure they are compliant with all antitrust and competition sensitivities. In coordination with B&C attorneys, or a group's outside legal counsel and consortium representatives, BCCM staff works to identify the goal of the collection exercise, as well as the cohorts and timeframes, and assists in the preparation of surveys or other collection mechanisms. When information is submitted, BCCM staff follows established protocols and procedures on how to maintain the information, and engage in data analysis and aggregation suitable for public advocacy needs.

### **RESEARCH/TESTING PROGRAMS**

For groups wishing to engage in research or regulatory testing programs, BCCM can provide services associated with preparation of requests for proposals; negotiation of contracts with laboratories/testing facilities; provision of scientific counsel on test protocols and draft reports; regulatory and/or legal counsel on reporting obligations; and coordination and monitoring of testing activities, including updates to membership on key milestones and reporting obligations.

Often times, a consortium may undertake a research/testing program in response to regulatory

requirements. Some consortia, however, elect to develop a voluntary research program. This may be done in support of product stewardship goals or to "get a jump" ahead of an anticipated, but not yet implemented, regulatory requirement. Such voluntary work can at times help guide a regulatory agency as it considers data that are important to its goal.

"Research work" is not completed simply because a final study report has been issued. BCCM also works with consortium members to manage the archival of important study materials to ensure all regulatory requirements are satisfied.

### **COMMUNICATIONS**

Many BCCM consortia engage in various public communication activities, ranging from developing and maintaining websites to creating a vibrant social media presence, to preparing press releases. As requested by the individual consortium, BCCM can provide membership updates on issues of concern; lists of chemical lists, summarizing all federal, state, and international lists on which chemicals of interest are included; alerts to consortium members of relevant industry/government developments; design and maintenance of public and private websites; development of professional brochures, advertising, promotional, and other informational materials (*i.e.*, position statements, best practice guides); and development of product defense strategies, including draft press releases and related documents, formulated responses to media and other inquiries, and prepared question and answer documents.

In some instances, a consortium may wish to develop a communications program to respond to a significant advocacy need. In these cases, BCCM relies on past experiences with specialized communications firms to identify the most appropriate consultant to address



*Our management approach is and always has been that a consortium should sunset when its goals are achieved.*

the needs of the consortium. BCCM works with these firms to obtain focused and cost-effective proposals for the consortium members to review. Once a communications firm is selected, BCCM works to ensure all interests identified and public communication and outreach are managed effectively to leverage the group's investment in issue management and public outreach.

#### **FINANCIAL MANAGEMENT SUPPORT**

An often overlooked but critical service for industry groups is financial management. BCCM offers comprehensive and timely financial management support, which we believe is second to none. BCCM provides its consortia clients with a full line of accounting services, including preparing tax filings in all relevant jurisdictions; preparing financial statements; assisting with budgeting; invoicing member companies for annual fees, disbursements, and other expenses; remitting payments to contract laboratories, consultants, or other service providers as approved by the membership under contractually agreed upon conditions and schedules; maintaining consortium funds in a separate bank account; and collecting member payments and processing accounts payable.

All BCCM financial and tax preparation materials are prepared by a Certified Public Accountant (CPA).

#### **TECHNOLOGY**

BCCM groups enjoy the very latest in communication, meeting, and file management technology. Conferencing features are state of the art and include services

ranging from basic audio teleconferences allowing for the participation of international callers to web-based meetings and video conferences. SharePoint sites are available and can be established to manage the development of complex documents requiring group input and review. When desired, websites are created quickly and managed efficiently using the latest software tools and resources. List serves are created and managed to optimize work flow and enhance communications with consortium members.

#### **MISSION FOCUSED**

BCCM management recognizes concerns with the "Hotel California" phenomena often associated with consortia groups. Once a group is formed, it often remains in existence, whether it is actively engaged in work, or not. That is not BCCM's philosophy. Our management approach is and always has been that a consortium should sunset when its goals are achieved. While some BCCM groups have long-term goals that may take years to achieve, others have very specific, very narrow program goals to achieve and will disband following that work. These groups have a beginning, a middle, and an end

Examples of BCCM consortia that have sunset include the **California Nano Industry Network (CalNIN)** and the ICEMN. While these consortia sunset upon achieving their goals, the networks and relationships remain in place and could easily be reactivated should an issue arise in the future for which the industry wishes or needs to collaborate.

## B&C CONSORTIA MANAGEMENT

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