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Consortia Work Group  
ANSI-NAM Chemical Regulation Network

Re: Consortium Agreements

Dear Colleagues:

On 1 June 2007 REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) came into effect. REACH is a European Union Regulation that incorporates a series of onerous and complex requirements that shifts the burden onto industry of ensuring the safety of chemicals (both on their own and in manufactured articles) manufactured, imported, and used in the European Union and the European Economic Area ("EU"). Chemicals and manufactured articles that do not meet these requirements cannot be sold in the EU, unless subject to one of the limited number of exemptions.

The "registration" component of REACH consists of the submission of a dossier on each substance to the European Chemicals Agency ("ECHA"). The REACH regime requires registrants to cooperate in the preparation of the dossier for a given substance by jointly submitting information on the hazardous properties of the substance. However, while some information must be submitted jointly, other data must be submitted individually, and on some items, there is a choice. REACH also provides for a "lead" registrant, who submits on behalf of the other registrants of such substance, classification and labeling information, study summaries and proposed testing strategies. There are also provisions for registrants to opt out of joint submission, where registrants disagree about the interpretation of information, or where disclosure of confidential information would cause substantial commercial damage. Data sharing is required for vertebrate animal testing.

REACH registration requirements apply not only to "new" chemical substances, but to so-called "existing substances," i.e., those on the EU market as of September 1981 and listed in the European Inventory of Existing Commercial Chemical Substances ("EINECS"), which were exempt under previous law from testing and notification. While new substances will need to be registered under REACH by the deadline of 1 June 2008 in order to be sold in the EU, existing substances are eligible for delayed registration requirements (and can continue to be sold in the EU) if "pre-registration" requirements are complied with ("phase-in" substances).

A Substance Information Exchange Forum (“SIEF”) will be established for each substance for the pre-registration phase in order to enable registrants to contact other registrants of the same substance and to comply with the joint data submission requirements.

Registrants of the same substance may also opt to form a consortium. A “consortium” is defined as an association of two or more persons (legal or natural), formed to pool their resources to achieve a mutual objective or a common goal. While consortia are not mentioned anywhere in the REACH regulation, they should be considered by registrants as a means of efficiently achieving compliance with REACH provisions requiring cooperation among registrants, saving money and protecting their business interests through the best possible outcome from the REACH process. Early consortium formation should allow for the optimum use of Read-Across or structure-related arguments that have the potential to significantly reduce the total cost of REACH registration.

The structure of a consortium will vary from industry to industry, and will depend in large part on the number of members and the number of substances to be covered by the consortium. Typically, but not always, a consortium will have its origin in a pre-existing European trade association or other interest group. This can have some significant advantages, including (1) expertise in the substances to be registered; (2) experience and expertise with EU regulatory issues, including REACH; (3) experience with managing competition and intellectual issues incident to a joint enterprise involving competitors; and (4) availability of trade association staff to serve as the “Secretariat” to manage the day-to-day affairs of the programs set up by the consortium and to handle all the administrative tasks incident to any organization (e.g., facilitating meetings of the “general assembly” of the consortium (consisting of each voting member), and where the membership is larger, managing “steering committee” meetings, where the members would designate a steering committee to meet regularly and make day-to-day decisions regarding preparation of registration dossiers.

There is no requirement under REACH or any other legal authority that a consortium be organized as a legal entity under the laws of a Member State of the EU. The typical vehicle for creating a consortium is an agreement among the members of the consortium, which sets forth rules and regulations of the consortium, e.g., membership, committees and other bodies of the consortium, powers granted to such bodies, confidentiality, compliance with competition law, data sharing and ownership, joint submission of data to EChA, dispute resolution, and perhaps most important, cost allocation.

Each prospective member of a consortium must therefore carefully review the terms of any such “Consortium Agreement” to see whether the advantages of participating in such a consortium outweigh any disadvantages. This review is even more important to those

prospective members which are not members of the European trade association affiliated with the consortium, or which are not even European manufacturers of the substances, such as the typical North American manufacturer of substances seeking to register them through “Only Representatives.” Given the potential for EU trade associations to draft Consortium Agreements in advance of discussions with non-EU manufacturers with provisions discriminating against new members, who typically would not own significant existing toxicity studies, it is important to review such agreements carefully to avoid such discrimination and potentially paying a disproportionately high share of future testing or other regulatory expenditure.

The following is designed to cover the key subjects in a typical REACH Consortium Agreement to help a party evaluate those terms which are crucial to that party’s determination of whether it should enter into a particular Consortium Agreement or whether it should seek other potential registrants of a particular substance to form a separate consortium, or whether it should simply participate in its assigned SIEF or SIEFs and attempt to resolve such issues at that time, either on its own, or by resorting to EChA, or depending on the nature of the issue, e.g., a competition law issue, resort to other authorities.

### **Consortium Agreement - Terms & Conditions**

1. **Preamble.** This typically sets forth the overall purpose of the parties to the Agreement with respect to REACH and may set forth historical background, names the consortium in question and specifies whether it is a separate legal entity, identifies the substance or substances (or refers to where the substances are defined), identifies the parties, identifies any trade association affiliated with the consortium.
2. **Definitions.** It is important to review these carefully and cross check them with the Agreement very carefully, since there can often be discrepancies that could be problematic later.
3. **Purpose and Scope.** This sets forth the purpose and scope of the consortium, which is important, since the purpose may be more or less expansive than a party’s interest would dictate. For example, the scope of the consortium may include only preparation of the technical dossier for the covered substances, and may not include preparation of Chemical Safety Reports or guidance on safe uses. Conversely, it may have stated purposes which go beyond REACH or even EU issues, for which a party has no interest.
4. **Substances Covered.** Substance identification is a key term, since it will determine whether a party’s substance qualifies for coverage by the consortium. This is

especially important where the substances involved are either multi-constituent substances or substances of Unknown or Variable composition, Complex reaction products or Biological materials (“UVCB substances”). Sometimes this provision will also provide for how the list of covered substances is amended; this can be extremely problematic to the extent that a simple majority of the General Assembly (or some other decision-making body formed by the consortium) has the authority to delete any substance from coverage by the consortium. It is important that a party ensures that it is comfortable with how other relevant provisions (Withdrawal of Members, Confidentiality, Data Sharing, Cost Sharing and Ownership Rights) would apply in such situation.

5. **Membership.** Consortium agreements typically provide for different categories of Members with different rights and different obligations. Typically there is a category of Associate members, which can include data holders (who seek reimbursement from Members) and users of the substance (“Downstream Users”). Some consortia may not accept as Members non-EU manufacturers who are registering substances through Only Representatives as full Members, but will accept the Only Representative for such Member. This can be highly problematic in a number of ways; first the non-EU manufacturer must find an Only Representative that is amenable to such an arrangement and successfully come to contractual terms, including compensation, indemnification, etc. Assuming this hurdle is overcome, then it is necessary to ensure that the Consortium Agreement provides for an Only Representative serving in such capacity to disclose confidential data acquired through the consortium agreement to the non-EU manufacturer, and that the ownership rights that the Only Representative has in data produced or acquired by the consortium can be assigned to the real party in interest, the non-EU manufacturer.

It is also important to review the provisions dealing with the rights granted to Affiliates of Members, especially in terms of rights to use data produced or acquired by the consortium.

There are also usually assignment provisions; typically assignment is only permitted in case of merger or acquisition with approval of General Assembly or Steering Committee. Since an asset sale involving substances covered by the consortium agreement would not satisfy this, if that is a reasonable likelihood, this provision would have to be re-negotiated.

Provisions respecting voluntary withdrawal, failure to comply with criteria for membership and assignment typically terminate all rights and obligations in the consortium, except for outstanding invoices due and payable and confidentiality obligations. The main issue here would be the loss of right to use any data produced or acquired by the consortium for which a party had paid its agreed-upon share. It should be an important consideration for any prospective Member whether it has the right to withdraw from the consortium at any time, with

no obligation to pay for any activities for which it has not agreed, with rights to use the data for which it has paid.

There are also generally provisions on expulsion or dismissal of a Member, typically for nonpayment of invoices. It is important to ensure that these provisions are reasonable, e.g., that the listed reasons for dismissal are not vague, provide for some form of due process and are otherwise reasonable in light of the remedy of expulsion or dismissal.

6. **Organization of the Consortium.** Typically, a Consortium's highest decision-making body is its General Assembly, which is a group consisting of all the full members. Typically, the General Assembly will be responsible for major decisions or actions (e.g., modification of the terms of the Consortium Agreement, approval of the annual budget, approval of the annual accounts, election of Steering Committee, etc.) Typically, the Steering Committee is elected by the General Assembly, and is responsible for day-to-day decision-making respecting financial management, establishment of a Technical Committee, preparation of the registration dossiers, approval of testing programs, hiring consultants and lawyers, admitting new members, settling disputes in the Technical Committee, management and coordination of the various arms of the consortium, spending decisions, and the like. There are also typically provisions for a Secretariat, which performs administrative and staff functions; Lead Registrant (as required by REACH); and a Trustee, which is typically an independent third party responsible for receiving, recording and aggregating confidential information of the Members to ensure the confidentiality of such information, and that competition law compliance of the consortium is assured. The provisions respecting the Trustee are extremely important as part of the overall evaluation of the Consortium Agreement from a competition law perspective.

One of the most important reasons to review these provisions is ascertaining what authority is required to make decisions that would be important to the Member. For example, there is typically a provision that allows the General Assembly to change the Consortium Agreement. Depending on the percentage of Members who were non-EU manufacturers, one way to ensure that the provisions of the Consortium Agreement could not be changed to discriminate against non-EU manufacturers would be to provide that to change the Consortium Agreement would require a supermajority of 75% (assuming there were sufficient non-EU manufacturers in the General Assembly to assure a 26% voting block).

7. **Confidentiality.** Consortium Agreements will either contain a confidentiality provision or provide for a separate confidentiality agreement, all which mandate that confidential information not be disclosed to third parties. It is important that the definitions of what exactly is "confidential information," who are considered "third parties" and what entities

are entitled to access “confidential information” are acceptable. For example, it may be very important that Affiliates of a Member be entitled to have access to confidential information gained through this consortium. Also, it will be important for Members with U.S. operations to be able to disclose confidential information to U.S. EPA if required pursuant to Sections 8(d) and 8(e) of the Toxic Substances Control Act, if required pursuant to subpoena or other proper judicial process, or if otherwise legally required.

8. **Data Sharing.** These provisions generally require the Members to provide copies of existing studies, either to the Secretariat, or to the Trustee, depending on the degree of confidentiality required. There are other provisions enabling the Steering Committee to license from third parties existing studies or other information useful in satisfying registration requirements. There are also provisions authorizing the Steering Committee to develop new studies and information, which typically provide that ownership shall be shared by the Members on some agreed-upon basis, e.g., proportionate to that Member’s financial contribution toward the cost of such study or information. There are also provisions dealing with the use of such new study or information by Members, Associate members, Affiliates of Members and by third parties. It is important to ascertain that the rights and obligations afforded by these provisions are acceptable to any party considering Membership.

9. **Cost Sharing.** This may be the most important provision in the Consortium Agreement. While the REACH regulation calls for “equal” sharing of data costs from the perspective of participation in a SIEF, there is no prohibition against registrants entering into an agreement with a different formula for allocation of registration costs. Thus, there are a variety of approaches that can be used to allocate the various costs of the consortium. Some approaches call for per capita sharing of administrative costs (e.g., costs of the Secretariat and the Trustee), with a market-share basis approach used for program costs (e.g., cost of studies).

There will typically be provisions dealing with how to value existing data owned by a Member or an Associate Member relevant for registration, through the use of different models; some weight data quality; others call for compensation on the basis of the cost of creating the data. The main issue for a prospective Member to consider here is whether use of a particular model is good for that person’s situation.

These provisions may be in one place, or scattered throughout the Consortium Agreement. It is important to track them all down to calculate the potential financial impact of the Consortium Agreement.

10. **Joint Submission.** This provision will specify what information is subject to joint submission, e.g., classification and labeling and (robust) study summaries. A consortium

may decide to include Chemical Safety Reports (CSRs) and guidance on safe use, as well. It is important to determine the extent of the consortium's commitment to provide CSRs; for example, a consortium may only agree to put together CSRs for uses of a substance which are common to all Members.

This provision may also include the designation of the lead registrant, or identification of the process for designating the lead registrant. There will need to be provisions dealing with the responsibilities of the lead registrant, along with provisions dealing with its withdrawal, dismissal and replacement of the lead registration.

This provision should also include provisions dealing with individual Members' right to "opt out" of joint submissions, and impact, if any on cost allocation issues.

11. **Budget and Finances.** The total budget (by year) may be set forth in the Consortium Agreement; there may be provisions in the Consortium Agreement delegating the responsibility to prepare such a budget to the Steering Committee, with approval reserved to the General Assembly. This section may also address the way the consortium has decided to allocate various expenses. This section may also address how the addition of a new Member may affect the cost allocation formula, and also provide for a premium payable by any new Member. It will also contain provisions on invoicing and payment.

12. **Ownership Rights; Right to Use Information.** As indicated above, it is essential for any prospective Member to ensure that the rights to use studies and information acquired through the consortium be adequate to meet that party's business needs. For example, many Consortium Agreements will limit Members' rights to use data and studies generated by the consortium for REACH compliance purposes only. As indicated above, for a multi-national corporation manufacturing and selling the substance in markets around the world, it would be imperative that it be able to use any studies or data generated by the consortium to comply with the notification and disclosure requirements of other governments. For example, new hazard information gained about a particular use of a substance through the Consortium Agreement would clearly need to be added to the Material Safety Data Sheet for the substance as well as disclosed to U.S. EPA pursuant to Section 8(e) of TSCA (see Section 7 above).

These provisions also typically contain a provision that there is no right to transfer these ownership rights, or rights to use these studies and information; this may be a significant problem in the event of an asset sale involving a substance covered by the Consortium Agreement.

13. **Liability of Consortium Members.** There are typically provisions indicating that the liabilities of each Member for the expenses of the consortium are several and not joint, and that the Members shall exercise due care and diligence vis-à-vis other Members in observing the rights and obligations relating to the Consortium Agreement. There are generally also provisions that each Member is solely liable to third parties and shall indemnify other consortium Members against all liabilities and claims in connection with any loss, damage or injury to third parties resulting from its own fault or negligence.

14. **Compliance with Competition Laws** While it is important to have such a clause, it is probably more important to ensure that the Consortium has the following in place:

Prohibitions on members sharing information on prices, production capacities, sales or import volumes, market share, or indicators of market behavior (e.g., precise chemical composition information or tonnage information);

Prohibitions on allocation of markets or customers;

Consortium Agreement has clear scope and transparent and uniform membership criteria for current and potential members;

Consortium has adopted a formal, written competition law compliance program;  
and

Consortium has appointed an independent third party (“Trustee”) to handle Members’ confidential information and to otherwise insure compliance with competition law (monitor and control discussions at meetings of Members).

15. **General Provisions.** There are typically a variety of other clauses addressing miscellaneous issues. There is typically a Duration clause, which is usually tied to the completion of the stated purposes of the agreement. There is also typically a Dissolution provision, a choice of law provision, choice of jurisdiction provision, arbitration or other dispute resolution provision, a limited representations and warranties provision, a severability clause, a notices clause, and an “Entire Agreement” clause. These provisions, while not unimportant, are straight forward and should not require additional explanation.

Clearly there are advantages inherent to participation in a consortium pursuant to a written Consortium Agreement. Clearly, REACH obligations for joint submission and data sharing make it clear that cooperation among manufacturers and importers is essential to successful compliance. A Consortium Agreement which establishes well-defined membership





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rules, clear rules for allocation of costs, clear project management rules and procedures, organized programs for preparing registration dossiers, clear rules for protecting confidential data and compliance with competition law provides Members with the opportunity to reduce registration costs through better cost control and by sharing the costs. However, it is essential to ensure for any potential Member of a consortium that the agreement actually accomplishes the foregoing while safeguarding the business interest of such Member at a cost to such Member which is the same or less than the cost of registration without the consortium. I hope that this paper will assist in that analysis.

Very truly yours,

HUNTON & WILLIAMS LLP

A handwritten signature in black ink that reads "Daniel E. Uyesato". The signature is written in a cursive, flowing style.

Daniel E. Uyesato

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