



COMMENTS OF THE

AMERICAN CHEMISTRY COUNCIL

ON THE EUROPEAN COMMISSION'S PROPOSAL
CONCERNING THE REGISTRATION, EVALUATION, AUTHORIZATION
AND RESTRICTIONS OF CHEMICALS

July 10, 2003

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EXECUTIVE SUMMARY

The American Chemistry Council (ACC) is pleased to submit the following comments on the European Commission's proposal to adopt a new European chemicals policy, known as REACH (*R*egistration, *E*valuation and *A*uthorization of *C*hemicals). ACC is concerned that despite the Commission's policy objectives for REACH, the proposed regulation is burdensome, costly and impractical. The regulation seeks considerably more information than is required to assure that chemicals are produced and used as safely as possible, and imposes a high cost on industry and governments in implementing the system.

In addition to the specific practical concerns raised by the REACH proposal, ACC has a number of general concerns:

- The proposal adopts measures inconsistent with the EU's obligations under the World Trade Organization (WTO) Agreement.
- There are significant competitive impacts on chemical manufacturers, importers, and downstream users.
- The proposed regulation is not compatible with the broader trends toward harmonization in international chemical regulation.

Throughout ACC's comments are recommendations for improvements. ACC believes that the EU's chemical regulatory system should rely in the first instance on information and data that are already available, and from that starting point assess risk management, and whether or not additional information or data is required. In brief, ACC recommends that the Commission:

- Revise the approach to registration by calling first for the submission of available hazard, use and exposure information, and existing risk management measures.
- Amend the evaluation process to assess whether existing risk management decisions are appropriate given the available information. In evaluation governments would be able to identify any gaps and consider whether any additional testing is required.
- Restructure authorization so that it relies on the data and conclusions of registration and evaluation, rather than create a separate regulatory process. This approach would assure that current uses of and exposures to chemicals considered priorities by the Commission are appropriately reviewed and managed.
- Provide more comprehensive exemptions for those substances whose chemical structures or uses pose low health and environmental risks.

If the REACH system were configured along these basic principles, the Commission would achieve its stated health and environmental protection objectives, substantially reduce the potential costs of the system (including the need for animal testing), improve the flow of information to governments and the public, and make industry a partner in meeting those goals.

In light of the significant commercial and economic implications of the proposal, both in Europe and abroad, ACC strongly recommends that the Commission consider providing an additional opportunity for comment on the draft regulation prior to making the proposal final.

I. Introduction

The American Chemistry Council (ACC) appreciates this opportunity to comment on the European Commission's proposal to adopt a new European chemicals policy, known as REACH (*Registration, Evaluation and Authorization of Chemicals*).¹

The American Chemistry Council is the non-profit trade association whose member companies represent more than 90 percent of the productive capacity for basic industrial chemicals in the United States. Council members export a significant amount of product to Europe, and in some cases manufacture, import and use chemicals in Europe themselves. In short, ACC members have a significant interest in all aspects of the proposed regulation, not just those that affect imports into Europe.

The Commission's proposal flows from a notion that the necessary predicate to effective regulation is the submission of a uniform set of data on chemical hazards, uses and exposures. This notion formed the basis for much of the European Community's existing regulations on new chemicals, which the Commission has criticized for their high cost and burden, and negative impact on innovation and the technological competitiveness of the European industry.² It is regrettable that the Commission has not used this opportunity to reorient European chemical regulation toward an approach that would provide improved protection while imposing less of a competitive handicap on European industry and downstream users.

ACC is also concerned that the REACH structure is not aligned with how the chemical industry operates in today's competitive economy. For example, the draft regulation generally requires the disclosure of more information, on very specific applications, to governments, upstream suppliers, downstream customers, and the public. Yet it is precisely those specific applications (e.g., the chemicals used to "finish" a product or article that confers a desirable characteristic) that represent the proprietary interests of companies, especially small and medium sized enterprises. The burden and cost of a "one-size-fits-all" approach like that proposed in REACH simply does not afford sufficient flexibility to account for the unique applications and diverse practices of the chemical industry and its customers.

ACC's comments address a number of general issues and concerns raised in the specific areas in which the Commission has requested comment. ACC and its members recommend that the REACH proposal be restructured to reflect the recommendations made in these comments.

¹ Consultation Document Concerning the Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH), May 7, 2003.

² Commission Communication, Strategy for a Future Chemicals Policy, COM(2001)88 final (February 27, 2001).

II. General Comments

A. The REACH Proposal is Inconsistent with the European Union's WTO Obligations

As drafted, the proposed REACH regulation discriminates against imported chemicals, and raises significant questions about how authorization decisions (particularly those affecting articles) can be applied at the border in a way that does not discriminate against imported products. REACH also appears to be more trade-restrictive than necessary to achieve the Commission's policy objectives, again in violation of the European Union's WTO obligations.

1. The Intermediates Exemption has a Discriminatory Impact

The intermediate "exemptions" provide an important illustration of the potential WTO concerns raised by the REACH proposal. Intermediates are substances solely manufactured for further chemical processing. Intermediates are the building blocks for every chemical synthesis in the chemical industry. They are already subject to environmental, occupational safety and health, and transportation regulations governing how they are used, transported and disposed. Intermediates are important in every chemical sector, particularly for plant protection, pharmaceuticals and other high value-added specialty chemicals.

REACH does not treat all intermediates the same way. The regulations as proposed set up four categories of situations that lead to different treatment, depending on whether the production chain for an intermediate starts within the EU, and depending on the intermediate's distribution network. These differences in treatment of intermediates appear to deny national treatment to imported goods, in violation of the EU's obligations under Article III:4 of the GATT 1994 and Article 2.1 of the WTO Agreement on Technical Barriers to Trade (TBT Agreement).

1. *Non-isolated intermediates*: As drafted REACH does not apply to "non-isolated intermediates" (intermediates moving within a closed-loop synthesis process). However, as soon as an intermediate is stored, it is no longer "non-isolated" and falls under REACH. Since the REACH regulation does not attempt to reach offshore manufacturing, non-isolated intermediates are by definition produced in a process that begins and ends in the EU.
2. *Isolated intermediates on site*: The draft regulation defines an isolated intermediate as "on site" when it is made and another substance or substances is synthesized from it at a single location, even if more than one company is located there. Each isolated intermediate must be registered, although with a somewhat less onerous registration requirement than other chemicals. Isolated intermediates on site are also exempted from the REACH provisions on standard and priority evaluation under Point 40a,³ authorization under Point 45.3(g), and restrictions under Point 57.1.
3. *Isolated intermediates transported under control*: The same simplified registration requirements will apply to EU manufacturers or importers of an "isolated intermediate transported." The manufacturer or importer of a chemical with such status will only be

³ However, when a risk on the level of those that would subject a chemical to authorization arises, the Member State where the site is located can demand more information and take risk reduction measures.

required to submit new test data if the amount transported exceeds 1000 tonnes per year; it generally faces the reduced registration requirements of on site intermediates. Isolated intermediates transported are also exempt from the REACH provisions on authorization under Point 45.3(g).

4. *Freely traded intermediates:* Any isolated intermediate that does not qualify for “on site” or “transported” treatment falls under the general rules of the REACH regulation, including registration and submission of toxicity and other test and safety data relating to 90% of intended uses, with requirements escalating as total tonnage imported or manufactured increases.

The treatment of isolated intermediates on site discriminates against imports and in favor of products manufactured in the EU. By definition, an isolated intermediate on site is produced in a process that begins and ends in the EU. It appears, then, that only manufacturers in the EU can register a substance as an "isolated intermediate on site" and be sure that it will be exempt from testing requirements. A user firm that imports an identical intermediate directly and uses it immediately to synthesize another substance cannot have access to this status. Further, since a “site” in the EU can include multiple operations owned by different entities, a co-located intermediates manufacturer would be able to take advantage of the limited registration procedures that apply to on site intermediates, while a non-EU manufacturer of the identical chemical could not.

The treatment of isolated intermediates transported also discriminates against imports. The draft regulation defines an isolated intermediate transported as "transported between, or supplied to, up to two other sites" under contractual control, where the intermediate is used for synthesis of another intermediate under specified conditions that minimize likely exposure. Since all isolated intermediates "on site" are by definition made in the EU, it may be inferred that a "site" for the “transported” intermediates must also be within the EU. If that is the case, then an imported intermediate cannot qualify for the status of "isolated intermediate transported," and will have to comply with the full REACH testing burden where a like EU-made intermediate would not. Again, this approach violates the EU's obligations under GATT Article III:4 and TBT Article 2.1.

The problem is exacerbated for imports of an intermediate to a terminal or distributor. If a "site" is defined as a place where chemicals are synthesized inside the EU, then an importer's terminal does not qualify as a "site," and therefore a chemical transported from an importer to an EU chemical producer can never qualify as an "isolated intermediate transported." This discriminatory limitation of the distribution options for imported intermediates, which does not apply to domestic like products, again violates the EU's WTO obligations.

Furthermore, the draft does not specify what kind of contractual control is meant, or whether the common forms of contract used for international transactions will qualify. If what is meant by “contractual control” is that the seller of the intermediate must have some kind of direct or indirect operational control over the buyer, this requirement will severely limit the availability of this option and make it practically unavailable for sellers outside the European Union. With the exception of intra-company transfers, it is highly unlikely that non-EU firms will exercise contractual operational control over EU buyers.

Similarly, the limitation of "isolated intermediates transported" to products transported between no more than two sites is arbitrary and discriminates against imports. Synthesis chains that are longer are likely to involve more international components. The discrimination is best understood with the example of an active ingredient for pharmaceuticals—in this high-value added segment of the chemical industry the synthesis chain may involve more than 10 intermediate steps.

- If all of these steps take place in one EU firm's reaction equipment, the intermediates are exempt from registration at all.
- If these steps take place on the same site within the EU, the only registration needed for all of the intermediates is a "postcard registration."
- If the steps are grouped so that 15 take place on one site and 5 on another, then the intermediates can be registered as isolated intermediates transported, and exempted from most of the test data requirements.
- If any of the intermediates are sold to more than two customers, the full requirements of REACH will apply.

This discrimination against imports violates the EU's international trade obligations under the WTO Agreement. To begin with, it is inconsistent with the EU's national treatment obligations under Article III:4 of the GATT 1994. Article III:4 provides that an imported product from any other WTO Member must be accorded treatment no less favorable than that accorded to like products of EU origin, "in respect of all laws, regulations or requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use."

Here, there is no question that the products are "like products." In terms of the criteria used by WTO panels to determine whether products are "like," an imported commodity chemical intermediate and its EU counterpart are physically identical; they meet exactly the same end-uses, are fungible means of meeting a need for a particular input for a chemical synthesis, and are perceived as identical by the consuming chemical industry; and they are classified exactly the same for tariff purposes. These are *identical* products with *identical* intrinsic characteristics, and because intermediates are used only by chemical producers for further chemical synthesis, they also have identical exposure scenarios and identical risk profiles. If the REACH regulations systematically accord imports less favorable treatment by denying imports access to the favorable status of "isolated intermediates transported," they violate Article III:4. Discrimination against imports also violates the parallel obligations of Article 2.1 of the TBT Agreement. This provision guarantees national treatment for imported products in respect of technical regulations such as the REACH scheme.

The REACH treatment of intermediates recognizes that even if a chemical is intrinsically dangerous when released, there are nevertheless situations where the risk of harm can be effectively controlled because there will be little or no exposure. Despite that recognition, however, the Commission appears to contend that imported intermediates should be denied equal treatment, in violation of the EU's WTO obligations. Imports of substances destined for intermediate uses must be equally eligible for the same exemptions as suggested for European-

sourced intermediates. The Commission should also assess how the regulation, as a whole, will affect imported substances and articles, in order to determine its compliance with Article III:4, TBT Article 2.1 and TBT Article 2.2.

2. REACH Imposes Unnecessary Barriers to Trade

Several aspects of the REACH proposal establish unnecessary barriers to international trade that may also violate TBT Article 2.2.

The REACH proposal would impose high information burdens on importers immediately after its adoption, denying any transition period. For example, the proposed regulation requires foreign producers to provide substantial information to their EU importers as a condition for access to the EU market. TBT Article 2.12 requires WTO Members to allow a reasonable interval between the publication of a technical regulation and its entry into force in order to allow importers to adapt. The WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) includes a parallel transition period requirement in its Annex B, paragraph 2. EU Commissioner Lamy and the other trade ministers at the November 2001 WTO Ministerial Meeting in Doha, Qatar formally agreed that the “reasonable interval” provided for in TBT Article 2.12 should normally be a period of not less than 6 months. It is important that the Commission provide appropriate transition periods after the publication date of the new rules.

The REACH proposal also requires manufacturers and importers to provide a detailed chemical safety report.⁴ The safety report requirement is not linked to the volume thresholds that trigger the registration requirement, and furthermore is effective with the first delivery of a substance following the entry into force of the REACH system. The absence of any transition period violates TBT Article 2.12 and the Doha “implementation agreement” provisions on minimum transition periods discussed above. Moreover, because there is no volume threshold or *de minimis* importation exemption for the requirement to provide detailed chemical safety reports, this requirement is more trade-restrictive than necessary to achieve the objectives sought, and thus has the effect of creating an unnecessary obstacle to trade in the sense of TBT Article 2.2.

Furthermore, the proposed regulation imposes a requirement on importers of any “article” to have knowledge of all chemical substances contained in the article. The importer may be required to register any unregistered substance in the articles it imports.⁵ Without proof that the article does not contain substances that may have health or environmental impacts if released, the article may not be imported. But the draft REACH regulation defines an “article” as *any* product that is composed of chemical substances or preparations, as long as its shape, surface or design is less important to its end use function than its chemical composition. “Articles” include ballpoint pens, plastic toys, automobiles, cameras, electronic equipment, and many other products used by industry and consumers. *Every* importer of *any* of these products will suddenly be subject to REACH. The broad scope of an “article” under REACH makes the proposal for substances in “articles” all the more overreaching and needlessly disruptive to trade. As discussed above, TBT Article 2.2 proscribes technical regulations that have the effect of creating unnecessary obstacles

⁴ Consultation document, Point 6.

⁵ Consultation document, Point 64.

to trade. ACC recommends that the Commission exempt substances in articles, and articles from the REACH regulation.

B. REACH Will Have Significant Competitive Impacts

The Commission's orientation paper on the draft regulation recognizes that the new chemical policy will have negative competitive impacts, even outside the European Union. In fact, the orientation paper stated that the competitive impact could only be justified if the "REACH regime is successful in establishing itself as a new international standard."⁶ In other words, even the Commission anticipates that Europe will have to convince other governments around the world that REACH is a viable approach to chemicals management.

Studies conducted in France⁷ and Germany⁸ indicate that implementing the new chemical policy will have substantial economic impacts. In France alone the policy is expected to result in an annual decrease of 1.7 to 3.2 % of GDP, cost hundreds of thousands of jobs, and eliminate many low-volume specialty and fine chemicals from the market.⁹ The Commission has estimated that the direct and indirect costs of the new system will be 18 to 32 billion Euros even without an assessment of the competitive and international implications.¹⁰ Indeed, the June 2002 study completed for the Commission on the business impact of the REACH system acknowledges that the competitive impact on Small and Medium sized Enterprises (SMEs) and downstream users could be significant as the significant costs of registration and testing could outweigh the market potential for many chemicals or chemical uses.¹¹

The direct costs of the regulation include testing and safety assessments. However, the indirect costs of the regulation, including the societal cost of chemicals that are removed from the market because their market potential is exceeded by the cost of regulation, has not been assessed. The indirect costs of the regulation are of particular importance to those who use chemicals to manufacture products that are exported to Europe. On its face the regulation imposes an obligation on European customers to request and obtain much more detailed information about the constituents in products they purchase from abroad – raising, in turn, concerns about the business impact of broader disclosures of the components present in preparations, mixtures, and articles.

The limited intermediates exemption also raises competitiveness concerns. The global competitiveness of many of Europe's own downstream industries depends on access to imported inputs. If REACH has the effect of denying downstream firms access to the full range of specialty chemicals and intermediates – and it appears likely that even the "lower" registration requirements for some intermediates will have that effect – there will be immediate and sustained impacts on the competitiveness of European industry. Where end products include small but

⁶ Chemicals Orientation Paper, Communication by Mr. Liikanen and Ms. Wallstrom, page 16 (April 1, 2003).

⁷ "Impact Study on the Future European Policy in the Area of Chemical Substances", Mercer Management Consulting (Paris, April 28, 2003).

⁸ "Economic Effects of the EU Substances Policy," Arthur D. Little GmbH (Weisbaden, Dec. 18, 2002).

⁹ Mercer Management Consulting, op cit.

¹⁰ Chemicals Orientation Paper at page 15.

¹¹ RPA and Statistics Sweden, Assessment of the Business Impact of New Regulations in the Chemicals Sector, at page xvi (June, 2002).

important amounts of unregistered substances, or the producer of an end product is unwilling to disclose trade secrets as required by REACH, European industry and consumers will similarly be denied a full range of choice, with a consequent impact on European industrial competitiveness.

C. The REACH Proposal is Not Compatible with Trends in Harmonizing International Chemical Regulation

The Commission's proposed regulation ignores in several important areas the broader trends toward harmonization in chemical regulation. For example, many other national chemical regulatory systems recognize that polymers above 1,000 Daltons molecular weight tend not to be biologically active, and thus should be exempt from major regulatory requirements. The draft proposal, however, contains a polymer definition that may have the unintended effect of increasing the number of polymers subject to the regulation.

Additionally, the advent of a REACH system would appear to provide a unique opportunity to implement the Globally Harmonized System of Classification and Labeling (GHS), yet the Commission has declined that opportunity and instead continues to rely on classification and labeling decisions made generally under Directive 67/548. In ACC's view, the decision not to pursue GHS implementation creates the potential for significant inconsistencies in classification and labeling decisions, particularly those made by commercial interests outside the EU.

The third major example of the Commission's movement away from the general trend toward harmonization is in the extensive set of technical guidelines that accompany the consultation document. For example, the protocols for acute oral studies and inhalation studies, have a number of important differences from existing protocols agreed in the Organization for Economic Cooperation and Development (OECD), such that it is not clear that the OECD version of the tests would even be acceptable under REACH. The REACH tests in some instances require more animals than the OECD protocols, and there are significant differences in test duration and dosing period. Further, three REACH health test guidelines do not correspond at all to OECD protocols, notably tests on *in vitro* mammalian cell transformation, skin corrosion, and photo toxicity¹². Those differences, of course, come at a cost – not only in expensive, duplicative testing, but also in additional animal use and the creation of potential trade barriers.

REACH thus contains several significant departures away from the overall trend toward harmonization in chemical regulation. ACC is concerned that these departures (and indeed, the REACH proposal as whole) represent a policy decision by the European Union to reject the harmonization trend. If so, that decision appears likely to have important competitive impacts, including the high cost of complying with the greater technical burden imposed by different test protocols.

¹² ACC's further detailed comments on the Technical Annexes can be found in Part III, Section G, below.

III. Comments on Specific Aspects of the REACH Regulation

The Commission has specifically requested comment on particular elements of the REACH proposal.

A. Duty of Care

The REACH proposal establishes a “duty of care” for manufacturers, importers and downstream users to assure that chemical substances do not cause adverse health and environmental impacts¹³.

The proposed regulation contains no additional definition or guidance to suggest how the duty of care might be applied. As drafted, the language suggests that any adverse impact from a chemical substance, including impacts from a substance contained in a finished good or article, is sufficient to subject the manufacturer, importer and/or downstream user to liability. In effect, the duty of care provision implies that any activity involving chemicals is so hazardous that it requires the manufacturer, importer or downstream user to ensure absolute safety or face significant consequences.

The addition of a requirement to assure absolute safety in chemical use is unduly burdensome, particularly in light of the extensive regulatory framework the Commission is attempting to construct in REACH.

The impact of the broad duty of care provisions could be mitigated somewhat if the Commission includes several other exemptions to REACH calculated to improve the practical application of the system. For example, the Commission should adopt a *de minimis* threshold for the registration requirement, and completely exempt articles and substances in articles.

B. Chemical Safety Assessment

The REACH proposal establishes a duty to assess the risks associated with manufactured and imported substances in a chemical safety assessment.¹⁴ Chemical safety assessments are a key component of registrations. Although principally applied to manufacturers and importers, the safety assessment requirement also applies to downstream users and even to substances in articles.¹⁵ Chemical safety assessments are to be in a prescribed format, covering human health and environmental assessments, exposure assessments, and risk characterization. Safety assessments are intended to be an iterative process, apparently aimed at the development of ever-more detailed and precise risk characterizations based on refined hazard or exposure assessments.

¹³ Consultation document, Title II, Point 3.

¹⁴ Consultation document, Title II, Point 4; Annex I.

¹⁵ Consultation document, Title VI, Point 32. Annex I requires that a chemical safety assessment address “. . . all intended uses . . . [and] consider the use of the substance on its own (including any major impurities and additives), in a preparation or in an article.” Annex IX describes the risk assessment requirements for downstream uses not included as part of a manufacturers’ or importers’ registration.

In ACC's view, chemical safety assessments are likely to impose significant practical problems in completing a registration. These practical problems arise in:

- Decisions on what uses to cover in a Chemical Safety Report. Fewer assessed uses conceptually means a simpler exposure and risk analysis, but there are economic and strategic implications in deciding when it becomes worthwhile to include a specific use, rather than leaving it to a downstream user. Market structure and the level of competition, and the potential conflicts between the incentives for manufacturers, importers and downstream users all factor into these decisions.¹⁶
- The desire of commercial interests to preserve proprietary data and information on specific chemical uses, process considerations and control technologies, and the like. Chemical Safety Reports will be made public. The fact that safety reports will be made public may create a disincentive for firms to join consortia, and will certainly create a disincentive to cover potential or future uses of a substance in an assessment. The mandate that chemical manufacturers and importers either join consortia and produce a Chemical Safety Report or "buy in" to existing consortia data creates significant competitive and trade secret concerns due to forced sharing of proprietary data on chemical uses, processes and technologies.
- Expanded scope of Chemical Safety Reports. Annex I apparently requires exposure scenarios for manufacturing processes, even if production does not occur in the European Union.
- Burdensome Safety Report requirements. The most open-ended and potentially difficult step in the risk assessment process set out in Annex I is the exposure assessment process. Exposure scenarios are to be developed for all intended uses and life-cycle phases of a chemical, and are to include comprehensive quantitative exposure estimates for each population and environmental media. The other requirements of a Chemical Safety Report pose similar concerns. For example, Annex I sets no bounds on downstream or life cycle assessments, and it is not clear to what extent use and exposure scenarios can be combined for the purposes of risk assessment.
- Vague or poorly described requirements for Chemical Safety Reports. It is not clear, for example, whether current toxicological criteria will be accepted as Desired No Effect Levels (DNELs) or Predicted No Effect Concentrations (PNECs). No adequacy standards are articulated to describe the level of data needed to support the derivation of DNELs or PNECs. Although safety reports can rely on "available data," unless additional guidance is provided on the interpretation of that term it is not clear what is required to support the process. As a whole, the Chemical Safety Report is a very complex process and there is a significant potential for delay and high costs if there is not sufficient flexibility in the application of the requirements.
- High costs associated with safety assessments. The cost of conducting a chemical safety assessment varies considerable depending on assumptions about the type of chemical analyzed (e.g., whether it is a new or existing chemical), the availability of data, the level of hazard, nature of the uses, level of analytical rigor and detail, etc. ACC estimates that

¹⁶ By implication, Point 38.1(b) (related to the tasks of evaluating authorities) requires that a chemical safety assessment cover at least 90 percent of the registrants' own and intended uses or risk being considered incomplete.

exposure assessments alone will average over \$6,000 per scenario.¹⁷ Many chemicals, of course, will require multiple exposure scenarios given their myriad applications. Even assuming that data gathering, analysis and documentation impose minimal demands (which ACC believes cannot be assumed based on Annex I), the average risk assessment cost estimate will be significant.

ACC strongly recommends that the Commission revisit its chemical safety assessment requirements. Safety assessment requirements should be made as flexible and as streamlined as possible. For example, *de minimis* levels should be established so that registrants can judge the need for exposure assessments related to minor uses, exposures and releases. Articles and substances in articles should be completely excluded from the safety assessment requirements. Use and exposure scenarios should be able to be combined for the purposes of risk assessments, particularly where conservative general scenarios can be used to cover multiple uses. Additional guidance and definition is required, particularly with respect to the use of existing toxicity criteria. The Commission should also consider eliminating the requirement that each registrant develop a DNEL or PNEC, and instead should permit reports to cite to existing toxicological criteria.

It is critical that decisions in the evaluation process (as well as the rest of the REACH program) be based on high quality data (e.g., data that is complete, up to date, accurate, and objective) that results from sound scientific research (e.g., is capable of being substantially reproduced). The basis for decisions in the evaluation process should be a weight of the evidence approach. However, certain provisions in Annex I (1.1.4 and 3.1.5) could be interpreted to require that total deference be given to the study “giving rise to the highest concern”, regardless of whether the study is of low quality and regardless of whether many other robust studies contradict the results.

ACC believes that the Commission should make clear in Annex I that it supports the use of high quality data and that conclusions should be based on a weight of the evidence approach. A weight-of-evidence approach provides the decision maker with a process to organize and sort through scientific findings that may appear to conflict. The weight-of-evidence approach involves careful and thorough review of study methodologies and results, as well as assessment of the relative weights that should be given to the results of individual studies or groups of studies. The importance that should be given to a particular study depends both on the quality of the study and its relevance to the issue being analyzed. Quality is assessed using principles and factors such as method accuracy, precision, and validation, quality assurance/quality control, control of experimental conditions, confounding factors and covariates, representativeness of study materials/populations, and appropriateness of statistical methodologies employed. Relevance of a study is related to the extent to which it addresses the issue under investigation.

¹⁷ ICF Consulting, Estimation of Costs for EU REACH Program Risk Assessments, at 8 (June 13, 2003). The study – which applied very conservative labor cost figures) estimated an average estimated cost for exposure estimates for downstream uses for downstream life-cycle stages (just one of the applicable life-cycle stages) to be \$6,200 per exposure scenario. Many chemicals, of course, would have require multiple exposure scenarios given their myriad applications. A copy of the ICF study is annexed as Attachment 1.

The weight of the evidence analytic approach provides an opportunity in the evaluation phase to acknowledge uncertainties and conflicts in study results, and permits all studies – not just ones favoring a particular result or position – to be taken into account.

C. Information Flow

The proposed regulation establishes a requirement that information relevant to the health and environmental effects of a substance be shared up and down the supply chain. Although in general ACC believes that improved information flow up and down the supply chain is an important element in chemicals management, the draft creates significant uncertainties for manufacturers and downstream users. For example, “any ... available and relevant information about a substance that is necessary to enable appropriate risk management measures to be identified and applied” is to be communicated.¹⁸ It is not clear how this provision could be applied with any certainty, particularly after the fact in an enforcement action. How are actors in the supply chain to know what information is “available and relevant” absent specific guidance?

ACC is particularly concerned that the information sharing requirements are so voluminous and so detailed that they may create “information overload.” ACC recommends that the Commission consider streamlining the information requirement to focus on the essential information likely to compel safe use and handling of a substance, such as Safety Data Sheets and the risk characterization components of safety assessments.

D. Registration Procedure

The Commission’s proposal sets out comprehensive registration requirements.¹⁹ In general, the regulation requires the submission of a technical dossier and a chemical safety assessment, each with mandatory requirements. ACC believes these requirements are burdensome and unworkable.

1. Mandatory Data Requirements

The REACH proposal specifies data requirements applicable to specific thresholds of production or import, with more detailed and burdensome data requirements applicable to larger thresholds. This “base set” approach to technical data ignores in the first instance that use and exposure considerations can and should drive what data is included in registration dossiers, and in the second instance that screens can indicate that further hazard testing is not needed in a particular area. Although the proposal indicates that registrants may justify not providing particular data elements in a given case, ACC is concerned that the proposal as a whole creates a bias for complete submissions of the base set.

ACC believes that the Commission could avoid many of the practical and workability problems related to registration by requiring the submission of existing, available information in technical dossiers, rather than an up front requirement to submit all required data elements.

¹⁸ Consultation document, Point 6.1(f).

¹⁹ Consultation document, Title IV.

2. Consortia Formation

The registration procedure attempts to avoid duplicate testing and registrations by requiring “pre-registration” for manufacturers and importers. The regulations assume that those pre-registering will form consortia to conduct additional testing or to share existing information. The assumed ease of forming consortia is not borne out by current experience with other testing programs.

For many years companies in the business of chemistry have come together to generate and share data in support of a variety of regulatory and voluntary initiatives. Most recently, consortia have formed to generate data for various HPV chemical assessment programs. However, few outside industry appreciate the challenges in forming these consortia, and the barriers that must be overcome for consortia to work successfully. These issues include:

- **Competition Laws.** Competition laws, including those in the European Union, restrict the type of information that can be shared among members. For example, the most equitable allocation of data development or administrative costs is a function of each company’s actual production, estimated production, or sales in a particular market. However, competition laws restrict the type of such information that can be shared, and the penalties for violating these laws can be severe. To overcome this problem, some consortia have hired independent 3rd parties to receive and “blind” this information – but the required use of such third parties necessarily drives up the cost of the registration process. Consortia must be vigilant to assure that the actions of the consortia do not violate competition laws.
- **Confidential Business Information.** Sometimes a company’s identity is considered confidential in relation to the production of a certain chemical. However, if the other non-confidential producers form a consortium there will be fewer participants, and the cost per company will be higher than if the “confidential” producer had participated.
- **Administrative overhead.** Consortia are expensive to operate. Compliance with reporting regulations and competition laws, managing funds and relationships with contractors, test labs and others, as well as the need to protect confidential or sensitive business information, require that a professional be hired to manage the consortia.
- **Determining the appropriate type of participant(s).** Who should participate? Producers, or producers plus importers? Should distributors, formulators and/or downstream users be included? What if a company only makes the product as a byproduct, or as an impurity? How should consortia address byproducts that are isolated and sold?
- **Determining the relevant period and measure of production.** Accurate and trustworthy information on when and how much of a substance was produced is essential in order to meet the REACH reporting requirements and to determine a fair and appropriate cost sharing among consortia members.
- **What chemicals are covered?** It is not clear from the draft REACH proposal that a category approach to registration will be permitted. Even if categories are permitted, it may not be easy to form consortia. For example, assume that there are 6 closely related chemicals which structurally speaking constitutes a recognized “category.” Assume further that 8 companies make one or more of the substances, but no two companies

make the same combination of chemicals. It is often extremely difficult or impossible to determine a “fair” cost allocation in this case.

- Data offsets. Should companies that have previously generated a lot of data (at a high cost) be “forced” to share that data with their competitors who did not share in the development costs, and have therefore had a competitive advantage?
- Meeting costs. Regardless of whether the meetings are in person or by conference call, forming the consortium, agreeing on structure, management and budgets consume a large amount of human and financial resources, even before the actual work of the consortia begins.
- Language, cultural and time zone barriers. Although in theory having participants from around the world will offset costs by spreading the cost burden, these offsets can easily be lost if the not insignificant language and cultural barriers are not overcome. Further, competing priorities brought on by domestic or regional authorities frequently make reaching consensus extremely difficult, if not impossible.

3. Exemptions

The few exemptions from registration are too narrowly drawn to be of widespread value to manufacturers, importers or downstream users. As indicated earlier, the intermediates exemption benefits primarily European-based registrants of those materials. The molecular weight threshold for the polymer exemption is set well above the generally recognized level at which polymers are not biologically active, and even the “reduced” registration requirements (e.g., postcard registrations) for such exempted polymers pale in comparison to the cost and burden of completing the chemical safety report.

Similarly, the exemption for process-orientated research and development (PORD)²⁰ confers a very limited benefit to the manufacturing community. By its terms the draft gives member States the authority to further regulate such research and development, which in turn raises concerns about consistency and uniformity, particularly where such research and development may span different facilities throughout the Community belonging to a single company. ACC recommends that the PORD exemption be redrafted to establish thresholds and require that the manufacturer or importer keep records that establish its compliance.

In addition, ACC believes that general registration exemptions for impurities, very small concentrations, and low volume/low exposure chemicals would improve the workability of the proposed system, principally by eliminating multiple registrations for substances unlikely to pose health or environmental risks.

²⁰ Consultation document, Point 9(f).

4. Testing Requirements

The proposed regulation adopts a “base-set” approach to testing chemicals, with data requirements increasing as production or import volume increases. ACC believes a better alternative would be to tailor testing requirements to use and exposure patterns. The prioritization approach recommended by ECETOC offers a practical approach to tailored testing, and the Commission should consider applying that type of an approach to the initial registration dossiers.

5. Definition of Use

The lack of a practical definition of “use” may make it practically impossible for manufacturers, importers or downstream users to implement major aspects of REACH. The definition of “use” in Point 2 (12) with its catchall phrase of “any other utilization” apparently proposes to define “use” broadly to capture most activities in the entire commercial chain. However, the definition provides no practical guidance on how the “use” definition will be employed for the purposes of either registration or authorization. Registration under REACH requires that the manufacturer or importer provide information on the “uses” of the substance that “shall represent at least 90% of the volume manufactured or imported. The REACH authorization process for chemicals of “high concern” requires explicit permission for each “use” of the chemical.

ACC believes the real question that should be asked is not: How is the chemical being used? Rather, the question should be: What are the exposure scenarios that a chemical manufacturer should reasonably anticipate, evaluate and report? Assuming a downstream user’s activities fall within the exposure scenarios, no further testing or analysis should be required.

Given ACC’s significant concerns about the entire approach to authorization, it is absolutely critical that the Commission’s approach to “use” in the context of registration and authorization should be refocused on exposure assumptions, with clear guidance provided to manufacturers on how those assumptions should be categorized and evaluated. This shift in focus will facilitate the development and utility of Safety Data Sheets and other related materials.

E. Polymers

The REACH proposal purports to exempt many polymers from the registration requirements.²¹ ACC is concerned that, the polymer definition creates the possibility that a significant number of new registrations, and will require the expenditure of considerable industry resources to characterize polymers and conduct the chemical safety assessments.

Polymers by their nature pose a low risk to health or the environment, and should be generally exempt from registration requirements. Polymers are not readily absorbed by biological species, and thus are relatively nontoxic. In general, polymers with a molecular weight above 1,000 Daltons are not biologically active. In those few cases where molecular weight exceeds 1,000 Daltons and where oligomer content or reactive functional groups create

²¹ Consultation document, Point 16.

special concern, other regulatory systems throughout the world have adopted safety criteria (such as limits on ionic character, functional groups, environmental stability and residual content). The REACH provisions should do the same.

The 10,000 Dalton threshold under the REACH proposal is a departure from the polymeric weight threshold adopted in several other major jurisdictions, including Canada, Australia, and the United States. Many national regulatory systems recognize that polymers with a molecular weight above 1,000 Daltons tend not to be biologically active and thus should be exempt from major regulatory requirements.²² As needed, safety criteria can be adopted for those few exceptions (e.g. high oligomer content) that may create special concern. The choice of the 10,000 Dalton threshold under the REACH proposal is a potentially important departure away from the trend in harmonizing regulatory provisions.

ACC believes that the Commission intended to create an appropriately broad exemption for polymers. However, on the basis of the draft definition, it is not clear that this objective will be achieved, and ACC requests that the Commission clarify that the intended scope and operation of the polymer exemption is at least as extensive as that available under other systems.

The REACH proposal also creates a new obligation on manufacturers and importers of polymers to submit registrations for non-registered monomers that make up more than 2% of the polymer.²³ ACC believes that this requirement would establish a regulatory requirement unique to Europe, and a further departure from generally harmonized approaches to polymer regulation.

If a European chemical company exports a new polymer to the United States, the regulatory requirement extends only to the polymer, not the new monomer. Under REACH, however, a U.S. company exporting a new polymer to Europe would be forced to register any unregistered monomer, even those the monomer itself if not placed on the European market. Further, the requirement to register monomers in polymers also raises significant concerns about the protection of confidential business information, as importers will be required to know the identity of the monomer, whether it exceeds the 2 % threshold, and indeed the exact percentage of residual monomer in the polymer in order to determine if the 1 tonne threshold is exceeded. In short, ACC believes that requiring polymer manufacturers and importers to register monomers (in some cases, a chemical they may not even manufacture) is unworkable, and imposes substantial costs and burdens.

ACC strongly recommends that the Commission revise its polymer exemption to bring it more in line with other established chemical regulatory systems. In short, the registration requirements should exempt all polymers that by their nature pose a low risk to health or the environment.

²² See, e.g., Toxic Substances Control Act (TSCA) Premanufacture Notification Exemptions, 40 C.F.R. § 723.250(b)(1998)(also exempting polymers with a molecular weight greater than 1,000 Daltons and less than 10,000 Daltons, with oligomer content less than 10 percent below 500 molecular weight and less than 25 percent below 1,000 molecular weight, and limited reactive functional groups).

²³ Consultation document, Point 15.

F. Intermediates

In addition to ACC's previous comments related to the WTO implications of the draft's treatment of intermediates, ACC recommends that the Commission improve the workability of the intermediate-related regulations by exempting downstream users of an intermediate from any further notification or assessment requirements if the intermediate in question is exempt from registration or is subject to limited registration requirements. This exemption for users would be consistent with the low risk/low exposure scenarios likely for most intermediates.

G. Data Requirements

ACC has conducted a review of the REACH methods for determining toxicity and other health effects, and the test methods for determining ecological toxicity. ACC assessed each REACH guideline and the corresponding guideline established by the Organization for Economic Cooperation and Development (OECD). ACC identified the similarities and differences between the tests, and made a preliminary determination about whether a study conducted according to OECD guidelines is likely to be adequate for REACH purposes. On the basis of this review, ACC believes it is critical that the Commission provide clear and unambiguous guidance that tests conducted according to the OECD guidelines are acceptable for the purposes of REACH. Where the Commission chooses to depart from the accepted, harmonized approach in the OECD guidelines, the Commission should explain why the departure is necessary.

Overall, ACC's analysis demonstrated that the majority of REACH health guidelines differ only slightly from the OECD guidelines. However, where there are differences (such as the protocols for acute oral studies and inhalation studies), there are sufficient differences that it is unclear whether the OECD versions would be acceptable under REACH. One of the fundamental principles that industry and governments around the globe support is that testing results need to be harmonized so that data generated for one region are applicable and acceptable to all regions. Without internationally harmonized and validated test methods, additional laboratory animal studies could proliferate and international trade negatively affected. It is vitally important that the OECD test methods are adopted under REACH and that the Commission promote the mutual acceptance of data.

Three REACH health guidelines do not have a corresponding OECD guideline: the *in vitro* mammalian cell transformation tests (B.21), skin corrosion (B. 40), and *in vitro* photo toxicity (B.41).

On the ecotoxicity tests, most of the REACH guidelines are consistent with the relevant OECD guidelines. However, for REACH guideline C.7 (investigation of abiotic degradation hydrolysis as a function of pH) the differences are noteworthy. Specifically, the REACH guideline specifies that up to three tests be performed depending on the outcome of the preliminary test, where the OECD guideline includes a preliminary test and only one follow up. Some other specific differences were identified in the ACC study such that ACC was unable to determine whether or not OECD guidelines would be sufficient for the tests under C.1 to C.3, and C.8 to C.10. It is not clear to ACC how the differences might affect the stringency of the

Commission's review of test data. The Commission should provide clear guidance – well in advance of the registration requirements – to provide some certainty for commercial interests conducting, or proposing to conduct, the relevant tests.

In the interest of global harmonization and avoidance of duplicative testing and its consequent use of additional animals, ACC urges the Commission to fully accept OECD protocols.

ACC's review of the health and ecotoxicity test guidelines is annexed as Attachments 2 and 3.

H. Data Sharing/Consortia Formation

The Commission has attempted to outline data sharing requirements in the draft proposal, principally in creating exchange mechanisms such as a Substance Information Exchange Forum (SIEF).²⁴ In ACC's view, the SIEF have the potential to raise the same problems identified for consortia in registration, particularly as the details necessary to assess the effect of SIEFs are not addressed in the proposal. In effect, the SIEF attempts to force cooperation among commercial organizations with intense competitive interests. The implications for a company refusing to share data with other SIEF participants²⁵ are not clear. ACC believes a better approach would be to create appropriate incentives for the creation of consortia and operation, but leave their actual use and operations to the decisions of commercial interests.

I. Procedures for Downstream Users

The Commission's proposed regulations impose a general duty of care that the manufacture and use of chemicals and chemical products not adversely affect health and the environment.²⁶ In addition, downstream users have an obligation to register substances not otherwise registered by the manufacturer or importer, to conduct chemical safety assessments,²⁷ to report relevant information to both the central Agency and up and down the supply chain,²⁸ to notify the Agency of their use of authorized substances,²⁹ and, in cases where the manufacturer or supplier has not done so, to apply for authorizations.³⁰

As drafted, the regulation applies to a wide range of industrial processing, consumption, formulation, and manufacturing activities. It has the effect of imposing on downstream users a significant burden, principally in producing safety assessments and in notifying the Agency of their specific uses of registered substances. In some cases, the downstream user may have more or better information on the ultimate use of given product, including disposal, compared to the

²⁴ Consultation document, Point 30.

²⁵ For example, is the refusal to share data and costs a violation that subjects a SEIF participant to a civil penalty for a violation, up to the 10 percent of worldwide turnover limit established in Point 108.3?

²⁶ Consultation document, Point 3.

²⁷ Consultation document, Point 32.

²⁸ Consultation document, Point 33.

²⁹ Consultation document, Point 55.

³⁰ Consultation document, Point 45.

manufacturer or importer. Thus, downstream users may have an additional, significantly increased burden in understanding and assessing the “end” of the product cycle.

The problems created by the downstream user requirements are exacerbated for the users and producers of articles that themselves contain many different parts and components made with chemicals (e.g., automobiles and electronic equipment). At a minimum, the regulation imposes on commercial interests the obligation to know about the exact content of each of their component parts – a huge undertaking, particularly given experience to date in implementing the End-of-Life Vehicle Directive. ACC also understands that some customer companies are looking to REACH to justify full formulation disclosure – a prospect that raises significant concerns about the protection of confidential information.

In purpose and effect, the regulation appears to impose on downstream users the obligation to create a “mass balance” view of the chemicals processed and used throughout the Community. This approach may well compromise confidential business information, particularly since the simple use of a chemical may constitute a trade secret in a downstream users’ process.

The proposal requires downstream users to complete their chemical safety assessments for their own uses and subsequent downstream uses within 18 months after the effective date of the regulation.³¹ As the first *tranche* of registrations are not due until 36 months after the effective date of the regulation, this means that downstream users must complete a safety assessment even before registrations are filed! The assessment requirements also create the possibility that different downstream users will reach significantly different conclusions about a particular chemical or application, in turn raising market uncertainties about those uses or applications.

The Agency is tasked to receive registrations, facilitate the information and data exchange processes, conduct assessments and analyses under the authorization and restrictions provisions, and provide the myriad guidance required under the proposal. As a result, the task of monitoring downstream user notifications is simply another burden that consumes scarce industry and government resources. ACC recommends that Commission take steps to relieve the burden imposed on downstream users. The Commission should consider raising the threshold for chemical safety assessments from 250 kg to a higher level, or eliminating the requirement altogether. Indeed, eliminating the requirement is warranted because a substance not otherwise exempt cannot be used unless registered, and the chemical safety assessment to be provided by the manufacturer or importer is required to address at least 90% of the intended uses.

Some of the negative impacts on downstream users could be mitigated if the Commission adopts some practical, reasonable limitations and exemptions from the notification requirements for downstream users. For example, articles should be completely exempt as they pose low risks, and low volume/low risk chemicals should not require subsequent notifications by downstream users to the Agency.

³¹ Consultation document, Point 34.

J. Evaluation Procedure

The draft regulation generally assigns responsibility for the review of registration dossiers to the member States of the European Union.³² As drafted, however, the proposal contains no detailed guidance for the member States in making those evaluations, and creates the potential for inconsistencies in interpretation and non-uniform decisions on related substances. ACC recommends that evaluations be conducted by the Agency to assure uniformity and consistency.

The draft also gives evaluating authorities the ability to aggregate the production and/or import volume of different registrants for the purposes of requiring the additional test data otherwise required at higher volume thresholds.³³ Under this approach, a registrant of a substance between 10 and 100 tonnes may find that, as a consequence of the aggregation during the evaluation phase, he will be required to provide the data otherwise associated with the 1,000 tonne threshold. A consequence of the aggregation authority is that the testing obligations (and potentially, data sharing or cost sharing responsibilities) of those manufacturing or importing relatively smaller amounts of a substance may be significantly more costly and burdensome testing, at the discretion of a Member State authority that in some instances may be under political pressure to request additional data.

ACC recommends that the Commission consider restructuring the evaluation phase to place authority in the Agency for evaluation. In addition, the evaluation phase should be restructured to serve first as a means of assessing the adequacy of available information (submitted in registration dossiers) as the basis for risk management decisions. The Agency can determine if the use and exposure information submitted with a registration indicates data or information gaps for which additional testing must be required, and indeed whether or not additional risk management measures should be recommended.

In other words, the REACH proposal establishes evaluation as a means of checking whether all the required information has been provided in a registration. In ACC's view, evaluation can be better directed to more efficiently and effectively allocate industry and government resources in assessing information gaps and obtaining required data. ACC also recommends that the Commission consider appropriate exemptions from detailed evaluations (e.g., for low risk or low exposure applications) or expedited evaluation procedures.

K. Authorization Procedure

The REACH proposal focuses on the inherent hazardous properties of a substance as the key criteria for authorization. ACC strongly believes that candidates for authorization should be identified on the basis of concerns about the risk they pose, not inherent hazard.

³² Consultation document, Title VII.

³³ Consultation document, Point 38.1(d).

1. The Authorization Procedure should be Streamlined.

ACC believes that the authorization process suggested for REACH could be substantially more reasonable, and effective, if authorizations focus primarily on a substance's potential human and environmental exposures. This approach would assure that only the uses of chemicals of concern that are significant risks are subject to authorization. To that end, ACC recommends that the authorization procedure be integrated into the registration and evaluation phases of REACH. The data that will be made available at registration and reviewed at evaluation are directly relevant to the authorization process and will be needed to properly identify and prioritize uses of the highest concerns, as well as those uses that qualify for exemptions.

Implementation of a practical approach to authorization will promote an effective process, and should yield substantial benefits in the efficient application of both industry and government resources. Moreover, a streamlined approach will achieve the health and environmental protection objectives set out in the White Paper, while avoiding adverse effects on international trade and commerce. Under this approach, the Commission would identify the substances requiring authorization upon the completion of the registration and evaluation phases, and would have the opportunity to address priority concerns and set appropriate deadlines for applications.

ACC first recommended to the Commission a streamlined approach to authorization in August 2002, and provided specific recommendations on creating a "single track" approach to authorization. A copy of that paper is appended to these comments as Attachment 4.

2. Authorization Substances should not be Identified on the Basis of Hazard Characteristic.

The authorization procedure has been expanded from the focus on carcinogens, mutagens, and reproductive toxins (CMRs) first articulated in the White Paper. Authorization is now proposed to also extend to persistent, bioaccumulative and toxic (PBT) substances, as well as very persistent or very bioaccumulative (vPvB) substances. ACC is concerned that the extension to other categories raises the threat that substances will be banned or restricted according to arbitrary criteria, and undermines the risk-based approach initially suggested by the registration and evaluation phases. ACC recommends that hazard characteristic not be used as the basis for identifying authorization substances, but rather that risk (identified through registration and evaluation) be the basis for identifying substances subject to authorization.

ACC understands that the Commission has assigned a high priority to certain categories of chemicals, including CMRs, PBTs, and vPvBs. As currently structured, however, the REACH authorization procedure has the potential to quickly become overloaded. The Commission has estimated that there will be some 1,300 CMR substances subject to authorization,³⁴ all of which will be the subject of registrations beginning with the third year after entry into force. The Commission has only been able to complete risk assessments for a small number of priority substances under the current system – and even the modifications

³⁴ Commission Communication, Strategy on a Future Chemicals Policy, COM(2001)88 final.

resulting from REACH will not create the necessary increase in the capacity to review authorization applications and make the necessary decisions.

ACC believes a better approach is to limit authorization to those priority chemicals identified in the registration and evaluation phases. In other words, substances would be subject to authorization if the use and exposure pattern, and risks, warrant. This approach would result in a more efficient and effective application of industry and government resources in addressing authorization substances.

3. Endocrine Disruption is not an Appropriate Basis for Authorization.

The same concerns outlined above with respect to the authorization process apply equally to the proposal to include endocrine disrupters. In addition, ACC maintains that endocrine disruption is not an appropriate basis for authorization.

A. Endocrine Disruption is a Mode of Action, not a Health Effect

Endocrine disruption is a mode of action not a health effect. Classification or labeling is not needed as the adverse effects caused by putative 'endocrine disrupters' will be identified as C (carcinogen), M (mutagen) or R(reproductive toxicant, at least for human health concerns.

The EU currently has appropriate measures in place for reproductive and developmental toxicities. A subset of these covered reproductive and developmental toxicities are endocrine-mediated (e.g., thyroid, estrogen, and androgen). The proposal to create a separate endocrine toxicity authorization would therefore duplicate existing systems that are already in-place and function. Creating a new and separate system would likely lead to confusion and possibly conflicting assessment outcomes. Additionally, the criteria for "equivalent level of concern" must recognize that endocrine is a mechanism, not a health endpoint, and that an "adverse effect" must be scientifically demonstrated before a substance can be labeled an "endocrine substance of concern."

For human safety, endpoints for thyroid-, estrogen-, and androgen-mediated reproductive and developmental toxicities are either present in current testing guidelines or can be incorporated as enhancements into the current testing guidelines, as is being done by the OECD. Endocrine-mediated cancer mechanisms are also well known, and endpoints for these mechanisms are included in current cancer bioassays. It is important to recognize that some of the endocrine-related cancers elicited in laboratory animals, e.g., thyroid and Leydig cell cancers of the testes, are not applicable to human risk assessment.

B. No Scientific Criteria for Endocrine Disruption have been Adopted

ACC is particularly concerned that neither the Commission, nor other governments, have formally adopted science-based criteria for categorizing a substance as an "endocrine disrupter". Therefore, before the EU can propose a substance be listed as an endocrine disrupter, the criteria for such a categorization must be very clearly specified.

It is generally understood that the definition of "endocrine disruption" encompasses both the endocrine mechanism of action and adverse health effects. For example, the widely cited

Weybridge definition, with which we concur, has two parts: 1) the substance acts through an endocrine mechanism, and 2) there is a demonstration of harmful effects caused by alteration of endocrine system function.³⁵ In the context of public health and environmental protection, it is essential that the Weybridge concept of “adverse effects” be the focus of public policy decision-making.

The Weybridge-type definition is consistent with our understanding of the science in that it implicitly recognizes that while substances may interact with the endocrine system, they may not adversely affect human health or the ecosystem. Within endocrine systems, natural variations in hormone levels and reversible or transient changes that are not considered adverse have been well documented. The endocrine system is complex and seeks to maintain homeostasis in a continually variable and fluctuating natural environment. Substances can interact with the endocrine system by a variety of mechanisms, including direct effects on hormone dependent or producing tissues, on enzymes involved in the excretion of a hormone, on enzymes for hormone synthesis and through agonistic or antagonistic hormone receptor binding. Evidence that a substance interacts with a component of the endocrine system through one of those demonstrated mechanisms in short-term *in vivo* or *in vitro* screening assays (e.g., *in vitro* receptor binding and transcriptional activation assays or *in vivo* short-term assays such as the uterotrophic assay, that are designed to determine if a substance interacts with a component of the endocrine system), however, does not provide any information on whether that substance causes other biological changes, which may, in turn, cause adverse health effects. Potential for adverse health effects can only be determined by long-term whole animal studies that specifically focus on endocrine responsive endpoints. Only by adopting a definition of endocrine disruption that includes evidence of adverse effects and not just evidence of endocrine activity, can the Commission focus on understanding what is needed to protect public health and the environment.

In the near future, indications of potential endocrine activity from short-term screening assays will identify chemicals for further testing; however, screening results alone are inadequate and inappropriate for hazard characterization or risk assessment. As noted earlier, the endocrine system is complex with natural variations in hormone levels and reversible or transient changes that are not considered adverse. If results from short-term assays suggest the potential for endocrine activity, longer term *in vivo* studies, in which exposures are evaluated in the complete and intact endocrine system and encompass critical life stages and processes, are necessary to fully characterize potential endocrine mediated adverse health effects upon the endocrine system and in other tissues or organs. If validated long-term whole animal tests determine that these chemicals produce adverse effects (e.g., birth or developmental defects, adverse neurological effects, cancer, or reproductive dysfunctions), we support classification under existing internationally accepted regulatory classification standards.

³⁵ In addition to the Weybridge definition above, see the discussions at the International Programme on Chemical Safety, http://www.who.int/pcs/emerging_issues/end_disrupt.htm; and in Environment Canada, “Establishing a National Agenda on the Scientific Assessment of Endocrine Disrupting Substances,” February, 2000.

Chemicals should be considered for formal regulatory classification and labelling only after they have been subjected to validated tests. Classification and labelling should be based on a weight-of-evidence evaluation³⁶ of hazard data and integration of exposure information.

C. A Focus on Endocrine Disruption in Authorization is Premature

The EU's action is premature since OECD must complete validation of screens and tests needed to adequately evaluate substances.

Even prior to the development of harmonized screens and tests for endocrine activity, however, chemicals have been, and continue to be, tested for adverse health effects of concern under current chemical regulation laws, the high production volume chemical testing program and pursuant to product stewardship activities of individual companies.

The Organisation for Economic Cooperation and Development (OECD) is engaged in developing and validating endocrine screens and tests.³⁷ ACC believes that the EU should lend additional support to the OECD Task Force on Endocrine Disrupter Testing and Assessment's on-going efforts to standardise and validate the globally harmonised test guidelines prior to initiating new, routine screening and testing procedures for endocrine disruption. The OECD EDTA has made considerable progress in development of a framework for evaluating substances based on proposed or existing screening and testing assays.³⁸ Further, the requirement for internationally accepted standardized and validated assays for classifying a substance as an endocrine disruptor must be clearly stated in Point 47.

Internationally harmonised procedures are needed to prioritise substances efficiently, to screen for endocrine activity, and to test for adverse effects in the framework of a coherent chemicals policy. These procedures should be implemented in a tiered, hierarchical scientific framework in which validated screening assays are used to identify substances with endocrine activity in order to prioritise substances for further, more definitive testing. Definitive testing, using validated, harmonised protocols, is necessary to identify adverse effects caused by alterations to endocrine system function. Using a tiered approach, results from definitive tests must outweigh or supersede results from screening assays in guiding policy and management in both the public and private sectors.

The EU should recognize the benefits of international cooperation among all stakeholders in the validation and harmonization of screening and testing methods, particularly for those substances considered to be potential endocrine disruptors. This is important to ensure the most efficient use of existing resources, to avoid unnecessary duplication of effort, to minimize the use

³⁶ This approach is best described as an objective and balanced interpretation of the totality of scientific evidence regarding endocrine disruption as a mechanism of action whereby a substance may lead to adverse effects.

³⁷ The OECD Task Force is engaged in evaluating, standardizing & validating several screening assays, for both mammalian & wildlife species.

³⁸ The OECD EDTA issued a revised "Conceptual Framework for the Testing & Assessment of Endocrine Disrupting Chemicals" in June 2002 which describes the types of assays and distinguishes the different purposes of the various assays, differentiating those focused on assessing potential endocrine activity from those which provide information on dose-response and adverse effects for use in risk assessment.

of laboratory animals, and to help promote mutual acceptance of data that is essential to avoid trade barriers.

D. A more considered, fair and open process is needed for deciding a substance has endocrine disrupting properties.

If the decision is made to potentially subject substances with endocrine disrupting properties to authorization under REACH, the legislation should include fair and open procedures for allowing stakeholder and scientific input and for allowing appeals from listing decisions. The process itself also needs to allow for more time for thoughtful consideration and should require an affirmative decision among member states before a substance is included in the list for authorization.

The system described in Article 47 of the legislation for identifying a substance for inclusion on the authorization list contains a bias toward inclusion. Once a substance is nominated by a member state, there is no way to stop its inclusion, save a decision of the Commission to the contrary. Under Article 47, there is at most 75 days between nomination of a substance by a member state and referral to the Commission for decision, offering little time for meaningful analysis and comment by other member states or their scientific communities. This process, coupled with the fact that there are no scientific criteria for identifying substances having endocrine disrupting properties of an equivalent level of concern, virtually guarantees that any listing decision will be arbitrary and politically, rather than scientifically, driven. The economic, social and environmental impacts of subjecting a substance to authorization are considerable. It seems reasonable that more time should be taken to make sure the decision is an appropriate one and that greater consensus among member states should be required to assure that all consequences are taken into account in making the decision.

The legislation also does not provide for any procedure for soliciting, accepting or responding to information or comments from the scientific community, the public or affected parties. At a minimum, affected industries, including the downstream users, should be given a meaningful opportunity to be heard before a decision to identify a substance for authorization is made. Finally, the legislation does not provide any opportunity to appeal a decision that a substance should be subject to authorization. Particularly with the rapid pace at which the legislation contemplates a decision will be made, a mechanism for challenging a decision should be added. In an area like endocrine disruption, where the science is uncertain and the testing protocols not validated, there needs to be more, not less, public scrutiny and opportunity for scientific input. The legislation should guarantee the public a right to participate in these high consequence decisions.

4. Authorization Applications

The authorization application process permits, but does not require, applicants for authorization to submit socio-economic and substitution studies in support of an application for authorization.³⁹ Although this provision is drafted as permissive, ACC believes the actual effect will be to force commercial interests to develop and submit socio-economic and substitution

³⁹ Consultation document, Point 50.5.

studies for consideration, if for no other reason that commercial interests have by definition a vested interest in seeking such an authorization.

In an effort to understand the potential burden of the socio-economic analysis under Annex XV of the proposed regulation, ACC has attempted to estimate the level of associated effort by developing a profile of the types of analyses that might be of interest to EU regulators. On the basis of the profiles, ACC established an estimated reasonable mid-range value level of effort, and subsequently estimated the total cost of completing each type of analysis. ACC's effort did not include the general use and substitutes analysis or economic impacts analysis because the requirements are too general.

On the basis of ACC's study, which is appended as Attachment 5, ACC believes that a comprehensive socio-economic analysis (covering three tiers of analysis) could cost well over \$800,000. Even assuming the Commission receives applications on only half of the 1,300 CMR chemicals requiring authorization, the costs of conducting comprehensive socio-economic analyses could be well over \$500 million.

The Commission must recognize that the socio-economic and substitutes analyses will drive up the cost of authorization applications significantly, for both industry and the Agency. The Commission should account for that added cost in its estimate of the burden and impact of the draft regulation.

L. Restrictions Procedure

ACC is concerned about the Commission's explicit rejection of a risk-based approach to regulation for Class 1 and 2 CMRs used in consumer products.⁴⁰ Under this approach, the Commission will not apply the procedure identified for other proposed restrictions, including developing risk assessments, socio-economic analyses, and a hearing process) to CMRs.

ACC understands the Commission's considerable interest in protecting public health from potential exposure to CMRs. However, there are a number of consumer applications in which CMRs are used but which are not likely to cause any exposures to the substance in question. For example, one consumer product – gasoline – contains known carcinogens, but by any reasonable socio-economic analysis could not be easily removed from the European market. Presumably the EU does not intend to ban the carcinogens in gasoline, but absent the application of the full restrictions procedure, there would be no opportunity to address the considerable socio-economic benefits of gasoline.

In addition, the "unacceptable risk" basis for proposed restrictions is not defined, and could lead to circumstances in which individual EU member State governments make restrictions proposals that are not grounded in sound science and objective criteria.

In general, the restrictions provision duplicates the authorization procedure. In ACC's view, the Commission could substantially improve the workability of the REACH system by integrating elements of the restrictions proposal into a streamlined and enhanced authorization

⁴⁰ Consultation document, Point 57.2.

system. For example, if authorization is the consequence of registration and evaluation, the information necessary for the Commission or member State governments to consider in recommending additional restrictions would already be available, and would provide a basis for work on risk assessment and socio-economic assessments to begin. In order to have a “safety net” to cover otherwise unreasonable risk situations, the Commission and member States could propose to accelerate authorization reviews in appropriate circumstances.

M. The Agency

Although ACC believes the concept of a central European Chemicals Agency has a great deal of merit, ACC is concerned that the Agency will not have the authority or resources necessary to administer the program effectively. For example, Point 80 appears to indicate that fees charged for registration, evaluation and authorization would provide the bulk of the Agency’s budget. Given the level of activity and number of tasks charged to the Agency, fees will need to be set at a significant level in order to provide the necessary resources to hire, train and manage a large staff. Those fee levels, in turn, may create disincentives to register or apply for authorization of certain substances.

ACC is also concerned that the interaction between the Agency and the member State governments will create substantial bureaucratic delays and inefficiencies, particularly because organizational responsibilities are spread across the Commission, the Agency, and Member State governments. If the REACH structure is simplified, as suggested in these comments, the Agency’s tasks will become proportionately more manageable. Moreover, if functions are centralized within the Agency, appropriate expertise will be developed as the staff gains experience.

N. Other

1. Confidential Information

The draft regulation allows EU member governments to protect certain information as confidential upon request of the submitter. However, the regulation fails to provide uniform criteria on what shall be considered confidential, imposes no requirements on governments to adequately protect confidential information, and imposes no sanctions for wrongful disclosures of such information. In addition, there is no appeal mechanism if the Agency or a Member State should disagree with a manufacturer, importer or downstream user that their information should be considered CBI. Instead, the proposal presumes that information will be released to the public without an opportunity for a manufacturer, importer or downstream user to protest or obtain court protection of its CBI, and to have that dispute decided by a neutral party in a timely fashion.

Although the REACH proposal is clear that all member governments of the European Union are to respect confidentiality decisions,⁴¹ the draft creates the potential that different governments will apply different standards (and perhaps processes) for confidentiality claims. Further, the proposal suggests that non-EU governments may access some confidential

⁴¹ Consultation document, Point 102.

information,⁴² and it is not clear how the Commission will protect against disclosures of confidential information. ACC recognizes that the Agency will be tasked to develop appropriate guidance on confidentiality procedures. However, the issue of protecting confidential business information is so fundamental to the efficient and effective operation of the system that ACC recommends the Commission include specific, detailed confidentiality provisions in its draft regulations. Those provisions should create a legal obligation to protect designated confidential business information, establish sanctions for wrongful disclosures, and outline the specific areas in which claims of confidentiality can and cannot be made.

As the Commission is no doubt aware, the competitive advantage of many firms is built on the ability to maintain the confidentiality of the component elements of preparations and formulations. Industry's competitive edge will certainly be lost if information on the constituent elements of a given preparation (or article, for that matter) becomes widely known as a result of REACH. Indeed, the lack of adequate protection for proprietary information threatens to jeopardize innovation in the very industry that epitomizes technological innovation.

REACH requires that detailed information on the constituent elements of a preparation be disclosed to governments and included in chemical safety reports. The safety reports will certainly become available to competitors. Similarly, registration dossiers will include information that in many instances will have significant proprietary implications, including the identity of the manufacturer or importer, information on manufacturing and use, information on the process used to manufacture or use a substance, and the concentration of the constituent elements of a preparation. REACH even requires the subsequent user or manufacturer of a registered substance to effectively provide notice that he is entering the market – a requirement that has significant anticompetitive implications. Under the terms of the proposal, however, most of the information cannot be claimed confidential.

ACC is particularly concerned that the information provided in registration dossiers, chemical safety reports, and information required to be provided up and down the supply chain will allow competitors to identify exact formulations and/or process technology. For example, the use of a particular substance as a catalyst in itself conveys important information about the chemical reaction being used, and its advantages and disadvantages – but the use of that catalyst may be the innovative application that merits protection as a trade secret or proprietary information.

REACH may also force the disclosure of confidential business information in pre-registration, throughout the evaluation and authorization processes (when information is made publicly available or decisions made), and in the linkage of manufacturers, importers and downstream users to specific substances or preparations. REACH must provide appropriate protection of confidential business information.

ACC believes that detailed, specific component information is not generally necessary for hazard, exposure and risk assessments, and indeed would be of little use to generally public. Yet in requiring a high level of detail in disclosures, the practical, efficient implementation of REACH is threatened.

⁴² Consultation document, Point 90.

2. Benefits

The Commission estimates that the REACH system will produce 54 Billion Euros in occupational safety and health benefits alone, outweighing the estimated costs of 18 to 32 Billion Euros.

The Commission's reliance on improvements in occupational safety and health due to REACH are misplaced. Employees in chemical manufacturing and downstream industries tend to 1) be more highly educated, 2) be better protected and 3) have fewer health and safety related incidents than employees in other industries. Particularly once occupational cancers due to asbestos exposures are taken into account, the fact is that there may not be as much room for improvement in occupational safety and health, and certainly not the level of benefit suggested by the Commission. Indeed, the occupational benefit cited by the Commission for REACH would seem to imply that workers in the European chemical industry are among the least protected in the world – a conclusion that would not be appropriate given the world-class occupational standards in effect in Europe.

The Commission recently completed an assessment of the occupational health benefits of REACH.⁴³ The assumptions that underlie the analysis raise important questions about the ability to rely on the results, however. For example, the report assumes that the REACH system will result in the identification of all chemicals that will be carcinogenic in the work place. Further, the report assumes that the risk management measures identified under REACH will have an immediate impact on occupational cancers, when it is well known that cancers have long latency periods. And finally, the report assumes there are no adverse implications of removing a CMR substance from the work place, either for health or the environment. In brief, the RPA report on the occupational safety and health benefits that accrue from REACH are optimistic at best.

ACC recommends that the Commission substantially revise its estimate of the occupational benefits from REACH to better reflect standard operating procedures, training, and education within the chemical industry, as well as the substantial protection already afforded by existing law.

3. Substances in Articles

Producers and importers of articles containing more than 1 tonne of a chemical substance must register the substance if during reasonable and foreseeable use and disposal “sufficiently high amounts” of the substance will be released.⁴⁴ This provision raises the most direct potential threat for regulatory decisions made on the basis of process and production method (PPM) considerations in violation of WTO decisions.

⁴³ The European Commission (RPA) Final Report – Assessment of the Impact of the New Chemicals Policy on Occupational Health (March 2003).

⁴⁴ Consultation document, Point 64.

The proposal to include substances in articles (and in some cases, articles themselves) in the scope of the REACH program is focused on the hazard created by the release of substance in an article, rather than the exposure or risk. Since REACH is intended to apply to the full life cycle of a product, including disposal, it is apparent that the “release” of a substance after disposal of an article could trigger a registration requirement. The definition of the term “article”⁴⁵ is also unclear, as the requirement to register an article depends on an interpretation of the extent to which chemical composition “determines . . . end use.” For example, does the use of a particular chemical that extends the durability of a polymeric substance used for floor treatments “determine” its end use?

Similarly, the regulations do not detail how the provision on releases from articles or finished goods will be applied. Although the regulation contemplates that guidance to apply this provision will be developed in the future, it is not clear whether the “sufficiently high” release limit will be applied across categories of chemicals, articles or uses, a combination of all three, or considered on a case-by-case basis.

Although the proposed regulation notes that guidance will have to be developed on this element of the proposal, the guidance is to be developed at least 3 months before the first registration deadline established under Point 22 (e.g., no later than 33 months following the entry into force of the regulation). Even on that schedule, the guidance may not come in time to take account of longer product development cycles, such as those in the automobile industry and industries that rely on significant number of component parts. The provisions related to substances in articles threaten a significant impact not only on the chemical industry, but also on every industry that uses chemical substances or products made with chemical substances.

ACC recommends that the Commission provide a general exemption of articles from the REACH system. The cost and burden of addressing substances in articles far outweighs the potential health and environmental benefit of such a regulation. ACC believes that existing consumer product legislation provides appropriate protection against potential risks caused by substances in articles. Further, by creating appropriate revisions in the authorization program along the lines suggested in these comments, the Commission would still be able to act on unreasonable risks to health and the environment posed by particular uses.

4. Enforcement

The proposed regulation establishes a maximum civil penalty for violations at 10 percent of worldwide turnover (sales) of the violating party.⁴⁶ All other sanctions for violations would be developed by the individual member governments of the European Union, and, subject to the maximum fine level, governments are to set fines at a level “which ensures that it has a deterrent effect.”

ACC is concerned that this approach to developing a system of appropriate penalties for violations of REACH is fundamentally unfair. Where the EU market represents only a small part of a firm’s global turnover, a maximum fine calculated on total world sales is clearly

⁴⁵ Consultation document, Point 2.3.

⁴⁶ Consultation document, Point 108.

disproportionate. Further, as ACC has identified in other areas of the proposal, the practice of allowing the development of national penalty systems can create inconsistencies and non-uniform results (e.g., where behavior similar to that sanctioned by one member State results in a different or no penalty in another country).

Further, the major obligations of commercial interests under the regulation are to provide test data, conduct safety assessments, and make reports to governmental authorities. It is unclear how the enforcement provisions of the proposed REACH system will handle relatively minor infractions (e.g., reporting violations) compared to willful refusals to comply with a regulatory mandate. ACC recommends that the Commission revisit the question of appropriate sanctions for violations. In particular, if the Commission nevertheless believes that a percentage of sales penalty is appropriate it should be limited to that portion of a firm's turnover attributable to the EU market.

5. Remedies

There are no provisions in the entire proposal that would provide an applicant or other stakeholder with the opportunity for independent review of any level of decision-making in the REACH process. Given the significant impact this legislation may have on the European economy and its competitiveness, we believe it is absolutely critical to provide a *full and fair* hearing before an *impartial tribunal* in a meaningful manner at each *meaningful time in the process*. All decisions should be well explained, well reasoned so that there can be effective administrative review of decisions before they become final, and effective judicial review once the decisions are finalized.

6. Additional Clarifications

As the Commission can no doubt understand, the relatively short comment period has made it difficult to identify and address each and every component that warrants comment. In light of the significant commercial and economic implications of the proposal, both in Europe and abroad, ACC strongly recommends that the Commission consider providing an additional opportunity for comment on the draft regulation prior to making the proposal final.

IV. The Commission Should Consider an Alternative Approach to REACH

The length and complexity of the draft REACH proposal make it difficult to recommend specific text for changes in any one title that will completely address the range of concerns that have been raised. However, ACC believes that the Commission could more readily achieve its policy objectives, at a much lower cost, by considering an alternative approach to REACH. This alternative approach – summarized here but reflected throughout these comments -- relies more heavily on a risk-based approach.

The alternative recommended by ACC would focus on registration by the submission of available hazard, use and exposure information, and information on existing risk management practices. Such a registration system would avoid the need to conduct additional testing in the first instance. A more flexible risk assessment requirement (Chemical Safety Report) would allow manufacturers and importers to put the available information into the context of known

uses and exposures. Under this approach, pre-registration would not be necessary. The Commission could include all submitted registrations on an inventory (organized, for example, by CAS number); subsequent manufacture and import of that substance could then refer to the appropriate registration number.

The registration requirements should exempt all polymers and intermediates that by their nature pose a low risk to health or the environment, as well as impurities, *de minimis* concentrations, and very low volumes or low exposure chemicals. Articles, and substances in articles, should also be exempt as posing negligible risk to human health or the environment. ACC assumes that the Commission will wish to retain a “safety net” that provides the authority for the Agency and/or national governments to expedite actions when serious threats to health and the environment are identified, and that “safety net” should provide appropriate coverage for substances otherwise exempted from registration.

Evaluation under ACC’s recommended alternative would identify any particular data gaps or needs and assess whether the available information supports the risk management practices already in place. The evaluation phase could conclude with a requirement to submit further test data, or a decision that the data, information and risk management practices in effect were adequate. In the interim, those registering a particular substance would know who else had submitted a registration and could begin to take appropriate steps to consider forming testing consortia.

Where risks are identified, authorization should be the logical consequence of registration and evaluation, rather than a separate regulatory procedure. Chemicals to be authorized should be identified on the basis of risk, not inherent hazardous properties. This would assure that all relevant information developed during the registration and evaluation process is considered before additional testing is mandated, and would further assure that risk elements are the basis for authorization decisions.

Further, the Commission could conform this system more closely to the trends in international chemical management, by adopting the Globally Harmonized System for Classification and Labeling and conforming all test protocols to the validated OECD standard.

ATTACHMENTS

Attachment 1: Estimation of Costs for EU REACH Program Risk Assessments

Attachment 2: Health Effects Test Guidelines Analysis

Attachment 3: Ecotoxicity Effects Test Guidelines Analysis

Attachment 4: ACC Comments on Authorization, August 29, 2002

Attachment 5: Potential Burden Associated with Socioeconomic Analysis Related to REACH provisions