

## ANALYSIS OF ALTERNATIVES: SUBSTITUTION REQUIREMENTS UNDER REACH

**Dr. Brian Magee and Dr. Chris Mackay**

AMEC Earth & Environmental, 2 Robbins Road, Westford, MA, USA

Tel: +1 978 6929090 Fax: +1 978 6926633 email: [brian.magee@amec.com](mailto:brian.magee@amec.com) [chris.mackay@amec.com](mailto:chris.mackay@amec.com)

Dr. Brian Magee is Vice President and Principal Toxicologist at AMEC Earth & Environmental's Boston-area office. Dr. Magee has over 25 years experience in performing site and product risk assessments, toxicological evaluations, and expert witness testimony. In addition to providing consulting services to private industry, he has served as consultant to the US Department of Defense, the US EPA, the Government of Canada, and various State and Canadian Provincial governments. He has also worked at the U.S. EPA Office of Prevention, Pesticide and Toxic Substances and the World Bank's Office of Science and Technology.



Dr. Chris Mackay is a Sr. Environmental Toxicologist with 14 years of expertise in product stewardship and regulatory compliance. He has worked with industrial, petrochemical, pharmaceutical, and agricultural industries in the United States, EU, Canada, Australia, and Korea. Along with providing technical guidance in product and patent development, Dr. Mackay has been involved in designing chemical, toxicological and life cycle assessments to support product development and comply with regulatory requirements under various product registration, environmental protection, and consumer safety statutes. Dr. Mackay has also provided litigation support and served as an expert witness in environmental and toxic tort as well as environmental product liability cases.



**ABSTRACT:** One of the key aims of REACH is to encourage and, in certain cases, to ensure that substances of high concern are eventually replaced by less dangerous substances. The key way that REACH will accomplish this is with the “authorisation” portion of the regulation. REACH requires that a selected number of carcinogens, mutagens, reproductive toxicants, PBT and vPvB substances, or endocrine disruptors, will be nominated for and then listed on Annex XIV of REACH as resources allow. Manufacturers, importers, or users of such listed substances of very high concern will need to apply for authorization for each chemical use. The application “should provide an analysis of alternatives considering their risks and the technical and economic feasibility of substitution, including information on

any research and development the applicant is undertaking or intends to undertake.” When widely used chemicals are listed for authorization, applications for thousands of uses will be triggered. No single substitute chemical would be a universal “alternative.” This paper explores the new field of assessment that will develop to meet the need for these “alternatives analyses.”

---

## **Introduction to the Authorisation Provision**

One of the major goals of the REACH regulation is to facilitate and accelerate the substitution of less risky substances in the European Union (EU) economy for more potentially dangerous ones. This goal is summed up by the introduction to Title VII (Authorisation).

The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution. (Article 55, Aim of authorisation and considerations for substitution)

## **Substances Subject to Authorisation**

The first question one might ask about this provision would concern the nature and identity of the substances requiring authorisation. There are currently no lists available of substances that will be subject to the authorisation provisions of REACH. The regulation did not list substances. Instead, the regulation listed criteria for substances that *may* be listed in Annex XIV in the future, and the regulation provided a process by which member states and the Agency would populate Annex XIV. The criteria by which the European Chemicals Agency (ECHA) will define a “candidate list” of substances that may require authorisation are listed in Article 57 and include:

- Category 1 or 2 carcinogenic substances
- Category 1 or 2 mutagenic substances
- Category 1 or 2 substances toxic to reproduction
- Persistent, bioaccumulative and toxic (PBTs) – persistent, bioaccumulative and toxic substances
- Very persistent and very bioaccumulative (vPvBs) - very persistent and very bioaccumulative substances
- Substances with equivalent levels of concern defined on a case-by-case basis, such as endocrine disruptors

Criteria are provided in the regulations for determining if a substance falls into one of the above categories. As stated, ECHA will develop a “candidate list” of chemicals. Member States may also submit candidates by preparing an assessment dossier in accordance with Annex XV. ECHA will prioritize the “candidate list,” using the following criteria.

Priority shall normally be given to substances with:

- (a) PBT or vPvB properties; or
- (b) wide dispersive use; or
- (c) high volumes.

Although the regulations state clearly that ECHA must publish its first “candidate list” by June 1, 2009, they are silent on how long it will take between this initial publication and the final listing in Annex XIV. The regulations also do not preclude the “candidate list” being published before the June 1, 2009 deadline.

## **Uses Subject to Authorisation**

Authorization will be required not only for a given listed chemical, but also for all uses for which it is to be applied, with the exception of the following.

- Categories of uses specifically exempted in Annex XIV.
- Use for scientific research and development.
- Use for product and process oriented research and development and such use has been specifically exempted in Annex XIV.
- Uses specifically exempted in Article 56 including:
  - Plant protection uses
  - Biocidal uses
  - Motor fuel uses
  - Other specified fuel uses
- For substances listed for non-environmental concerns and are whose uses are specifically exempted in Article 56 including:
  - Cosmetic uses
  - Food contact uses
- The use of the substance is as a component of a preparation at levels below certain concentration criteria specified in Article 56

ECHA is required to decide on an authorization application within 18 months of application. Failure to meet this deadline results in the use not being listed.

### **Implications of Low Production and Use Volumes**

There is no production volume exclusion for the authorisation provision. Manufacturers or importers of a substance who individually manufacture or import less than one tonne per year of a substance are not required to register the substance, so such individuals may think that they have no REACH responsibilities. This is not the case with regard to Title VII authorisation. Low volume substances and related uses are still subject to the authorisation provision, as well as any applicable restrictions, classification, and labelling provisions. Likewise, downstream users of substances that meet any of the criteria for potential listing, such as mutagenicity, must be aware of the regulatory status of chemicals they use in their business or products, regardless of how little they use. Even substances that they purchase in very low quantities from suppliers who themselves are not subject to the registration provisions will require authorisation if those substances become listed on Annex XIV.

Total production volume will be used by ECHA as one of the criteria for deciding potential listing priority on Annex XIV. So, a substance that is used in small quantities across numerous industries may escape listing. On the other hand, substances that are used in large quantities by some and in small quantities by others may still be listed early if the total aggregate production volume is large.

### **Timing Issues**

Manufacturers, importers and users of substances that meet the EU criteria as carcinogenic, mutagenic, PBT/vPvB, etc., will need to know when they might face the *de facto* banning of their substances. There is great uncertainty about this question. The regulation gives no date by which substances must be listed on Annex XI and no date after which listed substances cannot be manufactured, imported or used. However, Article 58 of REACH does present provisions that imply that affected parties may continue to manufacture, import or use a listed substance for at least 18 months after listing as follows:

(c) transitional arrangements:

- (i) the date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted (hereinafter referred to as "the sunset date") which should take into account, where appropriate, the production cycle specified for that use;

(ii) a date or dates at least 18 months before the sunset date(s) by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s); these continued uses shall be allowed after the sunset date until a decision on the application for authorisation is taken;

Thus, REACH is providing at least 18 months for its review of authorisation applications, but it is not specifying the amount of time that interested parties will have to prepare their authorisation applications after Annex XIV listing. Many questions remain. Uncertainties include the following:

- Date of the “candidate list” (must be published by June 1, 2009)
- Date of first Annex XIV listing
- Sunset dates
- Dates for submission of authorisation applications

### **Specifications for Applications for Authorisation**

According to Article 62, any manufacturer, importer or downstream user can apply for an authorisation for a substance listed in Annex XIV. The application can be made by one person or several. The application can apply to one or several substances and for one or several uses. Thus, there is flexibility in the regulation to allow applications by:

- Single manufacturers or importers
- Consortia of manufacturers and importers
- Trade groups
- Single downstream users
- Downstream user consortia
- Trade groups of downstream users

The applications, themselves, will require significant effort. According to Article 62, the application for authorisation must include the following:

- (a) the identity of the substance(s), as referred to in Section 2 of Annex VI;
- (b) the name and contact details of the person or persons making the application;
- (c) a request for authorisation, specifying for which use(s) the authorisation is sought and covering the use of the substance in preparations and/or the incorporation of the substance in articles, where this is relevant;
- (d) unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV;
- (e) an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate information about any relevant research and development activities by the applicant;
- (f) where the analysis referred to in point (e) shows that suitable alternatives are available, taking into account the elements in Article 60(5), a substitution plan including a timetable for proposed actions by the applicant.

### **Guidance for Preparing Applications for Authorisation**

No guidance is available from the Agency at this time on the preparation of applications for authorisation. However, there is a REACH Implementation Project (RIP-3.7) entitled “Guidance on preparing an Application Dossier for Authorisation.” This guidance document is being prepared by a consortium headed by Entec UK, Ltd. According to the European Chemical Bureau (ECB), the project was started in November

2006 and was due to have been finished in September 2007. The objectives of the guidance document are stated by ECB as follows:

The guidance document should provide industry all necessary guidance on the process to be followed in applying for an authorisation as well as guidance on how to prepare the application.

In particular the development and documentation of the following elements of the application will be given attention in the guidance:

- identification and analysis of alternative substances or technologies, including minimum requirements, and how to assess technical and economical feasibility of alternatives,
- preparation of a substitution plan, including e.g. actions needed and timetable.

Furthermore, guidance for third parties on how to prepare and report information on alternative substances or technologies to the Agency will be developed.

ECHA is also charged with preparing "Guidance on Socio Economic Analysis." Socio Economic Analyses may be submitted by applicants to support their requests for authorisation of substances listed in Annex XIV. According to Annex XVI, a Socio Economic Analysis may include an analysis of alternatives. Specifically, Annex XVI states that a Socio Economic Analysis may include the following element:

Availability, suitability, and technical feasibility of alternative substances and/or technologies, and economic consequences thereof, and information on the rates of, and potential for, technological change in the sector(s) concerned. In the case of an application for authorisation, the social and/or economic impacts of using any available alternatives.

The "Guidance on Socio Economic Analysis" is also not yet available. However, guidance is being developed as part of RIP 3.9 (Guidance on carrying out a Socio-Economic Analysis or input for one). The preliminary study (RIP 3.9-1), which was performed by a company named RPA and published in February 2006 (RPA, 2006), is available on the ECB website. According to the ECB, the guidance document (RIP 3.9-2) is currently being developed by Entec UK, Ltd, the same company that is developing the guidance document on authorisation applications. The project was started in November 2006.

The REACH Implementation Project 3.9-1: Preliminary Study (RPA, 2006) makes reference to alternatives in several places, but there is no explicit discussion of how alternatives can be identified. The guidance is much more focused on how one would perform a comparative analysis of one substance versus another, once alternative substances have been identified.

### **Guidance for Identifying Alternatives**

There is no specific guidance yet on the methods for identifying potential alternatives for a substance that is listed on Annex XIV. In Section 2.5.2 of REACH Implementation Project 3.9-1: Preliminary Study (RPA, 2006), the document states that the final guidance document will address this need:

The guidance will, therefore, need to provide advice on how to identify and assess the impacts of adopting alternatives, where these including [sic] substitute chemicals or processes/technologies delivering the same function as the chemical of concern or alternative risk management options able to meet the goals of a reduction in risks.

A clue to the upcoming guidance can be obtained by evaluating a recent document on the same topic prepared by Entec UK, who is currently charged to prepare the two relevant guidance manuals for ECHA. In a recent document prepared for Defra entitled "Sustainable Consumption and Production of Chemicals in the UK: Encouraging More Sustainable and Safer Alternatives" (Entec, 2007), Entec states that there are considerable barriers to shifting to safer and more sustainable alternatives. These include:

- Lack of availability of alternatives
- Lack of awareness of alternatives
- Lack of demand for alternatives from users/consumers

- Costs of implementation of alternatives
- Fear of loss of competitiveness through the use of alternatives

Entec (2007) concluded that identifying alternatives is a challenge. Specifically, they stated:

Companies in the chemicals supply sector may believe there are no alternatives to hazardous or less sustainable chemicals currently in use, or they may not be aware of alternatives, or of how to obtain information on alternatives.

It does not appear as if any soon-to-be released guidance will offer an easy approach for identifying potential alternatives to any substances that will be listed on Annex XIV. Much guidance is available to assist the applicant in evaluating or assessing any alternatives that are already identified. Such guidance will be discussed in another section of this paper.

### **Challenges in Identifying Alternatives**

Clearly, no one alternative substance can be defined as a substitute for a substance that has wide usage throughout industry. For instance, the ATSDR (2006) Toxicological Profile for Formaldehyde lists the following uses for formaldehyde in industry, among others.

- Preservative/Biocide/Disinfectant
- Tanning agent
- Chemical Intermediate
- Anticorrosive for metals
- Chelating agent
- Coagulation agent for rubber latex
- Treatment chemical for textiles
- Additive for adhesives
- Anti-oxidant for synthetic rubber
- Modifier for starch

Similarly, if substances, such as benzene, phenol, coal tar, sodium dichromate, etc. were listed on Annex XIV, there would be a need to identify a whole suite of alternative substances depending on the specifics of the use. As a simple example, one might easily identify a potential alternative for phenol's use as a disinfectant in mouthwash, but identifying an alternative for phenol in the production of formaldehyde-phenol resins is a more difficult task. In that case, it is possible that one might consider other substances with a phenolic moiety, such as naturally occurring phenolic substances as alternatives to phenol, but the processing cost associated with producing a product of similar quality from such alternatives will be significantly higher. One might also consider alternatives for the formaldehyde-phenol resins in their end-use, but again to find an alternative of comparable specifications at equivalent cost will be a mammoth undertaking.

### **Identification of Alternatives**

It is unlikely that there will be any specific guidance regarding how to identify alternative substances. Effort in the recognition of feedstocks likely to be listed and the identification of potential alternatives will become a part of the cost of doing business. For specific substances and end uses, various substitution initiatives have been recently undertaken or are underway. Entities seeking to identify alternatives to evaluate against the substance for which authorisation is sought can consult various existing organizations.

One useful source of information in the search for alternatives to potentially hazardous constituents is the Toxics Use Reduction Institute (TURI) at the University of Massachusetts in Lowell, MA (<http://www.turi.org>). The TURI was established by law in Massachusetts under the Massachusetts Toxics Use Reduction Act of 1989. The goal of this statute was to encourage the reduction in the amount of toxic substances used and the amount of toxic byproducts generated by industries in Massachusetts .

Another potential resource in the quest for less risky alternatives is the U.S. EPA's Design for the Environment (DfE) Program (<http://www.epa.gov/dfe/>). According to EPA, the DfE program "focuses on industries that combine the potential for chemical risk reduction and improvements in energy efficiency

with a strong motivation to make lasting, positive changes.” The DfE website provides documents on alternative substances and processes for the following categories of industries:

- Automotive Refinishing
- Electronics
- Cleaning Formulations
- Furniture and Flame Retardents
- Garment and Textile Care
- Industrial and Institutional Laundries
- Nail Salons
- Printing
- Wire and Cables

In addition, the DfE program has developed a process, called a Cleaner Technologies Substitutes Assessment (CTSA), which is “a methodology for evaluating the comparative risk, performance, cost, and resource conservation of alternatives to chemicals currently used by specific industry sectors.” With regard to the identification of alternative substances, the CTSA merely states that project team members should identify a preliminary list of substitutes. They do not specify how this should be done, but rather outline a general approach to the identification of potential replacements as follows;

Once a project team is assembled, the team members develop an Industry and Use Cluster profile document and a Regulatory Profile document to help define the project focus. An Industry and Use Cluster Profile gives market data for the industry, describes technological trends, and presents a summary of key industry processes, individual steps within processes, chemicals typically used in each step, and a preliminary list of substitutes for each step. These sets of substitutes make up the *use clusters* for the industry. A *use cluster* is a product- or process specific application in which a set of chemical products, technologies, or processes can substitute for one another to perform a particular function.

Additional substitutes are identified as a CTSA progresses and more information is gained about the characteristics of the use cluster and of the industry. All stakeholder groups are potential sources of information about additional substitutes. For example, manufacturers and suppliers of chemical products and technologies play an important role in substitute identification, since they frequently have an up-to-date understanding of current industry trends, and emerging products or technologies. Also, the participation of suppliers in the CTSA process is essential to developing information on chemical product formulations, which is used in the risk characterization

Trade associations frequently track new developments; universities and other research organizations may be involved in applied or basic research on new alternatives. Public-interest groups concerned about human health risk or other environmental impacts may have independently searched for options to prevent pollution. DfE project teams use all of these resources to develop a *substitutes tree*. A *substitutes tree* is a graphical depiction of the substitute or alternative chemical products, technologies, or processes that form the use cluster and their relationship to each other within the functional category defined by the use cluster. In a DfE project, the terms *substitute* and *alternative* are used interchangeably to mean any traditional or novel chemical product, technology, or process that can be used to perform a particular function.

It can be expected that gaining ECHA acceptance of a finding of no adequate alternative is going to be difficult. Furthermore, subsequent regulatory requirements for use-specific authorization will prove arduous for both producers and downstream users thus further reducing the substance’s market appeal.

Identifying alternatives will require an initial recognition of the marketable properties of the listed material, and then finding comparable replacements. In some cases this will be reasonably straight forward, where one solvent may be replaced with another. An example of this is the replacement of perfluorooctylsulfate with the less environmentally stable perfluororbutane sulfonates. In other cases a substitution may not affect the product’s properties, but will increase its cost of production. This was seen in the replacement

of the polybromodiphenyls with the more difficult-to-handle phosphorus ester flame retardants. The loss of a listed material may result in a rethink with regards to an entire process unit. For example, the desire to reduce the need for hazardous solvents has spurred the development of the new ionic-based and supercritical process procedures. So identification of alternatives will need to be broad and rely on new ways of thinking to meld economics and efficiency with these new regulatory requirements.

### **Guidance for Evaluating Alternatives**

Once alternative substances have been identified, applicants will need to perform an analysis of alternatives considering the technical and economic feasibility as well as the regulatory and environmental risks associated with the potential substitution. As noted above, specific ECHA guidance for preparing applications for authorisation and for performing socio-economic analyses are not yet available. There are, however, other guidance documents that potential applicants can evaluate if they wish to perform advanced planning on the future work that may be required by ECHA.

For instance, the OECD Framework For Integrating Socio-Economic Analysis In Chemical Risk Management Decision Making (OECD, 2000) states that the European Commission has identified the following questions regarding the assessment of the impacts of substitute substances:

- What substances might be used in place of the substance in question? What are their market situations?
- Do these substitutes present a new set of risks? If so, what is the nature of these risks?
- Are the substitutes effective for all of the same situations as the original substance? Will new technology, equipment or processes be required by industry to achieve the required results using the substitutes? What are the associated costs?
- Will there be a loss of production facilities and other specialised capital and technology which was used in the manufacture of the restricted chemicals or products?
- What research and development is necessary in order to switch to the substitutes? Will such activities require significant expenditure? Will retraining of personnel on use of the substitutes be required?
- Will the consumer have the same level of satisfaction with the substitute? and
- Will some products disappear due to a lack of substitutes?

More importantly, the REACH Implementation Project 3.9-1: Preliminary Study (RPA, 2006) discusses Assessment of Alternatives in Section 2.5.2. This document indicates that there is still a good deal of uncertainty regarding the comprehensiveness of the Alternatives Analysis that REACH will require, but the draft framework presented there is helpful. Specifically, this document states:

Ideally, an analysis of potential alternatives would consider the full range of impacts associated with their adoption. Under the Existing Substances Regulation (EEC 793/93), for example, the TGD on risk reduction strategies (RRSs) suggests the assessment of:

- the costs (or savings) of adopting any alternative, for example as a result of the need to make process changes or due to increased input prices;
- the availability of alternatives in the short-term;
- impacts on the efficacy or technical performance of the substances or products; and
- any changes in risks to the environment and human health associated with the move to the alternative process or substance.

Such analyses have rarely been comprehensive due to a lack of information on what the alternatives would be for commercial sensitivity reasons and due to a lack of comparable data on the health or environmental risks. REACH should address this situation as a greater level of information will become available, particularly on the health and environmental risks associated with the use of a substance.

However, it could be argued that even such analyses are not comprehensive enough. They fail to consider the wider environmental (or health) implications associated with increasing levels of control; for example, the degree to which changes in processes or inputs would lead to increased energy consumption, increased waste arisings, increased demand for other scarce resources, etc.

This raises questions over what the scope should be of any analysis of alternatives in terms of the impacts considered as part of any authorisation application or restrictions proposal. Should the boundaries be kept fairly tight, aimed at discussing whether or not a move to alternatives would result in a shift in risks (for example, from the environment to workers, or vice versa)? Or should the scope be such that all significant impacts of adopting an alternative are discussed at least qualitatively, and potentially quantitatively. For example, should a more life-cycle analysis based approach be promoted, which would encourage a fuller assessment of impacts to better reflect wider sustainability concerns? Again, this issue was discussed by the SEG and the conclusion was that those preparing submissions should be encouraged through the use of, for example, checklists to consider impacts from a more life-cycle based perspective than a more narrow perspective.

As another example, the United Nations Institute for Training and Research in conjunction with the International Programme on Chemical Safety (UNITAR, 1999) had developed a document entitled "Development Of Risk Reduction Strategies For Priority Chemicals A Guidance Document." They have stated that analyzing alternative substances should involve an assessment of the following criteria:

- risks of the substance to human health and the environment;
- risks of the substitute(s) to human health and the environment;
- costs and benefits to the producer of the substance;
- costs and benefits to the producer of the substitute;
- costs and benefits to the user or other stakeholders; and
- other factors, such as administrative burden, employment, etc.

The details of the type of analysis that ECHA will require in an "alternatives analysis" are not yet known, but performing such an analysis appears to be more manageable than identifying the substances to include in the analysis. There is ample precedent for comparing risks of several alternative substances in a specific end use situation and assessing the technical and economic feasibility of substituting one substance for another in a specified end use. The tools of risk assessment can be brought to bear as can the numerous risk-based prioritization protocols that have been developed over the years to rank substances for regulatory testing and to rank waste sites for investigation. In addition, applicants can gain relevant information by evaluating the tools of Life Cycle Analysis, the TURI's Toxic Use Reduction strategies, EPA's Cleaner Technologies Substitutes Assessment approach, and countless other recent initiatives such as green labelling programs.

### **Comparative Risk Assessment**

The evaluation of an alternative substance and a listed substance based on risk will be a very important component of the "alternatives analysis." And while this will likely be considered the cornerstone of the alternatives assessment, there will likely be significant pressure on the part of ECHA to streamline this process so that it can be done quickly and efficiently. This does not mean that care and comprehensive consideration should be sacrificed for immediate expediency. An assessment that does not recognize the critical potential hazards does not serve the public interest. This should be of paramount concern to the manufacturer since it is almost always the manufacturer who will be held ultimately responsible for any damages resulting from a poor substitution. This responsibility could range from being forced to repeat the substitution, to being held liable, or even criminally responsible, for incurred damages.

Even when simply comparing hazard potential, there is significant effort required to make comparisons that are meaningful. Some examples are given below of circumstances where considerable input from a trained toxicologist is required to make determinations that are truly protective of human health and the environment.

#### DIFFICULT COMPARISONS OF HAZARD POTENTIAL

Currently Used Substance	Potential Alternative
Listed Carcinogen	Unclassified substance with little or no toxicity data available
Listed Carcinogen	Unclassified substance with little or no toxicity data available, but with structural similarities to other listed carcinogens
Listed Category 1 Carcinogen	Category 2 Carcinogen
Listed Category 2 Carcinogen with on-going research regarding the relevance of the animal mode of action to humans	Unclassified substance with little or no toxicity data available
Listed Mutagen with negative human carcinogenicity studies	Unclassified substance with little or no toxicity data available
Listed Mutagen with no animal or human carcinogenicity studies	Listed Mutagen with negative human carcinogenicity studies
Listed PBT	Substance not yet assessed for PBT

The assessment of potential alternatives cannot only consider the comparative hazards of the replacement materials or processes, but also the potential for risk associated with the replacement. Risk differs from hazard in that it not only considers the inherent threat of the substance, but also the potential to represent the hazard based on use or exposure. Risk assessment in alternatives analysis should begin broadly and consider all aspects of the substitution, both upstream and downstream, as well as with regard to occupational, consumer, and environmental risk. It is important that all significant risks be included in such analyses, such as:

- Risks of the substance during manufacture, formulation and end use
- Risks of the other substances used during manufacture, formulation and end use
- Risks of the wastes produced during manufacture, formulation and end use

As these potential problems are screened out, the assessment can identify and concentrate on those issues most likely to represent a potential threat and provide the quantitative basis upon which control and mitigation measures can be developed.

#### Conclusions

At some point in the future, selected substances that meet the criteria listed in Article 57 of the REACH regulations will be listed in Annex XIV and as such manufacture, importation, and use will be prohibited without use-specific authorisation. The criteria for listing unfortunately apply to many substances in use today. Hence the number listed substances could potentially be very large.

As part of the authorization process, "alternatives analyses" will need to be submitted to ECHA. No guidance is currently available regarding the preparation of applications for authorisation, although ECHA states that such guidance will be published in the future. Little, if any, guidance and few standardized methods are currently available for identifying the potential alternatives that would be the subject of the "alternatives analyses." A review of the literature indicates that identifying alternatives will most likely be done via *ad hoc* processes that rely heavily on in-house research and professional expertise.

Comparative risk assessment evaluations of alternative substances are clearly among the analyses that will be required to be submitted to ECHA as part of the alternatives analyses. Experts in risk assessment

techniques and trained toxicologists must be involved when comparing the hazards and risks posed by alternative substances to make meaningful comparisons that are truly protective of human health and the environment.

## References

Entec UK Limited. 2007. Sustainable Consumption and Production of Chemicals in the UK: Encouraging More Sustainable and Safer Alternatives.

RPA. 2006. Reach Implementation Project 3.9-1: Preliminary Study For a Technical Guidance Document on Carrying Out a SEA or Input for One. Service Contract Number: CCR.IHCP.C430310.X0

OECD. 2000. Framework For Integrating Socio-Economic Analysis In Chemical Risk Management Decision Making

EC (1997): Working Paper on *Risk Management*, (Doc.97/RiMa02), Directorate General III, European Commission, Brussels.

UNITAR. 1999. Development Of Risk Reduction Strategies For Priority Chemicals A Guidance Document (Pilot Version) January 1999.