

## REACH - Authorisation Applications & Socio-Economic Analysis (SEA)

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### Why SEA Matters – Making the Most of Your Authorisation Application

According to the REACH regulation, certain *substances of very high concern* (SVHC) will be banned unless an Authorisation is granted for a continued and specific use. The applicant of an Authorisation must demonstrate that the health and environmental risks associated with the specific use of an SVHC substance either can be adequately controlled or give evidence that the risks are significantly outweighed by the substance's benefit to society and that suitable alternatives are not available.

While there are many similarities between REACH Registration and the Authorisation process, there are key distinctions. There is no volume threshold in the Authorisation process—meaning Authorisation requirements may apply to substances exempted from Registration requirements. Also, beyond the typical requirements for a Registration dossier, the Authorisation application includes what is called an Analysis of Alternatives—and if suitable alternatives exist, a Substitution Plan.

If the risks of the substance in question cannot be adequately controlled, then a socio-economic analysis (SEA) is required to demonstrate how other benefits may outweigh health and environmental risks. Additionally, the SEA can be a strategic

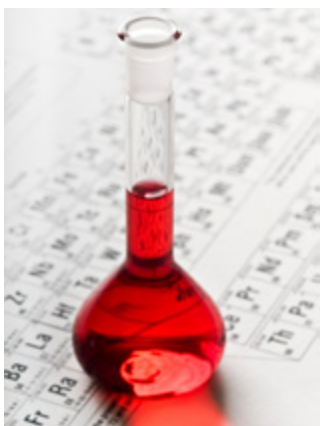
component of the Authorisation application's Analysis of Alternatives by supporting specific proposals of the applicant's Substitution Plan. Ultimately, evidence from a socio-economic analysis (both positive and negative effects) is critical to the application process and the EU Commission's final decision in granting or denying Authorisation.

### Why Cardno ENTRIX?

We are uniquely positioned to help with all facets of the REACH Authorisation process, including:

- Socio-Economic Analysis (SEA)
- Economic Analysis of Alternatives and Replacement Products
- Substitution Plan Development
- Toxicology and Risk Assessment

In addition to providing all the scientific, technical and chemical expertise required for the Authorisation process, Cardno ENTRIX also has a team of economists on staff with deep experience in conducting thorough, accurate and credible socio-economic analyses for a range of clients. Our scientists and economists are experienced in working side-by-side with clients on the identification of available potential alternatives, and the socio-economic implications of replacing chemicals with new compounds or formulations.





## Representative Experts

### John Phillips

**Vice President and Technical Director/  
Product Safety & Compliance**

*989 839 2355*



Mr. Phillips leads our global Product Safety & Compliance practice and oversees Cardno ENTRIX consulting services in regulatory compliance, chemical registration, and product stewardship. He also actively consults to our global chemical and consumer product company clients. Prior to joining the firm, Mr. Phillips spent 30 years with The Dow Chemical Company, most recently as Global Director of Chemical Policy, Chemicals & Health Issues.

### Tom Grumbles

**Senior Consultant  
Product Safety & Compliance**

*713 662 1991*



Mr. Grumbles has over 30 years experience in industrial hygiene and product safety compliance across the chemical industry. He has led compliance under REACH, TSCA, state regulations such as California Proposition 65, and multiple Global Chemical regulatory schemes. He has experience in evaluating the potential impact of inadvertent contaminants in surfactant products that can present potential consumer and environmental exposure concerns. Additionally, he has expertise in toxic tort litigation support.

### Wim Jetten

**Senior Advisor  
Product Safety & Compliance**

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Mr. Jetten leads our European-based efforts in REACH consulting and other EU regulations. Previously, he spent an impressive 30-year career at The Dow Chemical Company. While there, he provided critical industry input during all stages of REACH regulation development and the subsequent implementation guidance materials. His breadth of experience includes advocacy on chemical policy including REACH, chemical product compliance and stewardship, and manufacturing site EH&S programs.

### John M. Urbanchuk

**Technical Director  
Environmental Economics**

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Mr. Urbanchuk is a senior economist with more than 30 years experience in conducting socio-economic impact analyses. He is thoroughly acquainted with use reviews, and the incorporation of chemical exposure on human, mammalian, avian, aquatic and non-target species into economic cost-benefit analysis. He is also experienced with the identification of available potential alternatives, and the socio-economic implications of replacing existing substances with new compounds or formulations.

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# Relevant Socio-Economic Analysis Examples

## Public Interest Document for Cyhexatin.

Prepared a socio-economic analysis of the acaricide Cyhexatin (tricyclohexyl tin hydroxide) for use on pome fruits, strawberries, grapes, hops, almonds, walnuts and ornamental plants for submission to the US EPA in support of registration for use. Cyhexatin is used to control mite populations on a variety of agricultural crops and ornamental plants. The product provides excellent control of phytophagous mites (mites that feed on plants), and extensive field trials have demonstrated Cyhexatin is mild to beneficial insects, including predatory mite species. Our analysis combined scientific efficacy and risk exposure data with price and volume estimates to evaluate potential impacts of registration and use on producers, users (growers), and end-use consumers of products on which Cyhexatin would be used. A detailed evaluation of alternatives including abamectin, hexythiazox, clofentezine, pyridaben, and fenbutatin-oxide was integral to the study. Alternatives were evaluated on the basis of price, efficacy, formulation, exposure risk, and economic impact.

## Socio-Economic Analysis of an MTBE Ban and Replacement with Ethanol

Prepared a socio-economic analysis for a State Attorney General and Joint Defense Group regarding the impact on producers, gasoline blenders, and consumers of a ban on the oxygenate methyl tertiary butyl ether (MTBE) and its replacement with ethanol. Oxygenates are added to fuel to increase its oxygen content and improve the combustion process. In 1979, as lead was being phased out of gasoline, oxygenates became a new octane enhancer. MTBE was

used in gasoline throughout the U.S to reduce carbon monoxide and ozone levels caused by auto emissions. MTBE was widely detected in drinking water in major U.S. metropolitan areas and alleged to be a potential carcinogen. The primary alternative to MTBE is ethanol, an alcohol produced primarily from the conversion of starches to sugars, fermentation, and distillation. Other alternatives evaluated included ethyl tertiary butyl ether (ETBE), tertiary amyl methyl ether (TAME), and diisopropyl ether (DIPE). The study evaluated the impact of MTBE removal on refinery costs, infrastructure (transportation and storage issues associated primarily with alternatives), gasoline prices, and consumer welfare.

## Socio-Economic Analysis of Herbicide Cancellation

For a global pesticide manufacturer, prepared an analysis of the impacts on farmers, consumers, and the environment of the potential cancellation of the herbicide cyanazine for use on corn, soybeans, and cotton. The analysis was submitted to the US EPA in support of notice to cancel registration.

Cyanazine is a member of the triazine family of herbicides which also includes atrazine, simazine, and propazine. Atrazine was introduced in 1958 and provided farmers the first effective alternative to cultivation and 2,4-D for the control of grasses and weeds. Atrazine quickly became the leading herbicide applied on corn but was classified as a restricted use product over concerns regarding water quality and impact on plant and aquatic life. This study evaluated the use of cyanazine as an alternative to atrazine, and examined the impact of other alternatives including Acetanilides (pre-emergence grass herbicides alachlor and metolachlor) and ALS inhibitors such as sulfonyleureas and imidazilones.

Cardno ENTRIX is committed to conserving and restoring our natural resources and the environment. We practice stewardship through the conduct of our business, the development of our staff, and the services we provide our clients.

### For More Information:

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