

POTS

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SEMINAR 2008

Changing Marketing Landscape - Challenges for Business Sustainability

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MANAGING THE IMPACT OF R.E.A.C.H. ON THE OILS AND FATS SUPPLY CHAIN

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SESSION 2

**POLICIES & REGULATIONS: ISSUES INFLUENCING
THE OILS & FATS DYNAMICS**

Managing the Impact of REACH on the Oils and Fats Supply Chain

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Abstract

Under the REACH (Registration, Evaluation and Authorization of Chemicals) regulation, the European Union's (EU) flagship chemicals policy, EU producers or importers are required to strictly keep track the volume of the substance produced or imported. In effect, a company will not be allowed to market or import a substance that is not registered. The big question remains, "Who will be impacted by REACH?" The short answer is all players involved in the supply chain. In reality, the impact of REACH on companies inside and outside of Europe still cannot be fully determined. However, there is no denying that compliance can be difficult. While the bulk of the administrative effort will fall upon those companies which produce or import substances into the EU, there will be consequences for "downstream users" which purchase substances from these EU Manufacturers or Importers as well as for non-EU Manufacturers. Therefore, prompt preparation is essential to ensure legal compliance, and also to win early market advantage and safeguard supplier and customer relations. This paper will explore some of the issues raised by REACH, specifically faced by the oils and fats sectors as it will not only involve environmental law, but contracts with suppliers and customers, and potential trade and customs problems.

"Managing the Impact of REACH on the Oils and Fats Supply Chain"



2nd International Oils & Fats Trade Fair & Seminar in Kuala Lumpur,
24-26 August 2008



Content of Presentation



- **REACH in Brief**
 - The Design of REACH
 - REACH: Important Timeline
- **REACH & the Supply Chain**
 - Potential issues
 - Information & position in the Supply Chain
 - Impact of REACH
 - Supply Chain Implication
 - Consequences of inaction
- **In Preparation for REACH**
 - The Oils & Fats Sector
- **In Summary**
 - Compliance may be difficult but is required

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REACH in Brief (1)

- R** *Registration (notification process)*
 - E** *Evaluation (Risk screening process)*
 - A** *Authorization (use – restriction process)*
 - Ch** *Chemicals*
- A Chemical legislation for Europe
 - Impacts the way manufacturers, importers, formulators and end users conduct business in Europe & globally
 - Industry is
 - Responsible for generating and evaluating substance data
 - Required to assess exposure associated with each identified use against the substance data
 - Appropriate Risk Management Measures (RMM) need to be agreed between Suppliers & Downstream Users (DU)

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REACH in Brief (2)

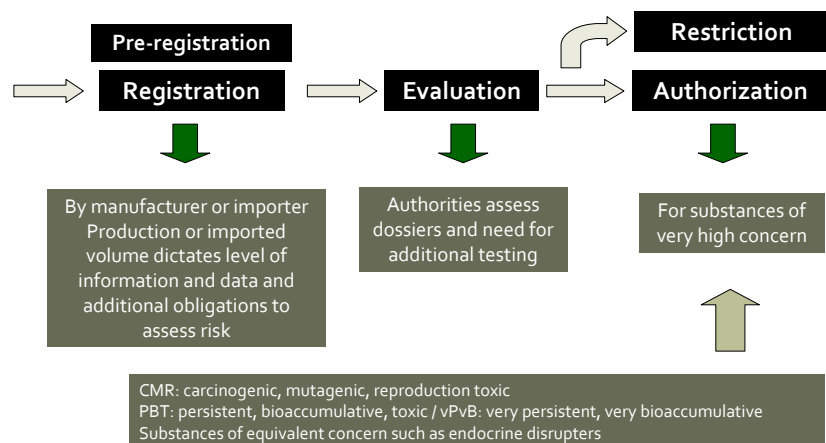
- **With the introduction of REACH:**
 - Need for a usable solution to bridge a company's current processes/systems
 - Deliverables required by REACH is created
- **DUs are required to identify use of each substance and ensure it is communicated up the supply chain**
- **Cost to Industry**
 - EU Commission estimates a cost to industry between €2.8bn to €5.2bn over 11 years.
 - Testing costs alone are estimated at €2.6bn.

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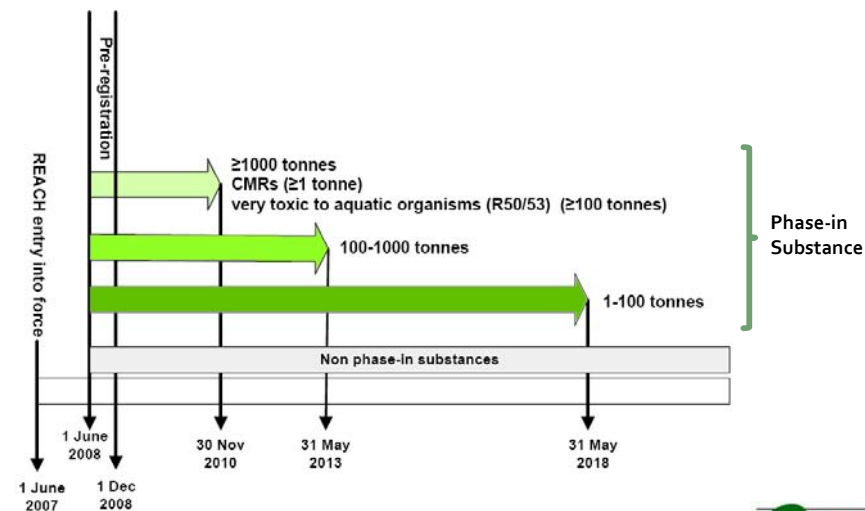
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The design of REACH



REACH: Important Timeline



REACH & the Supply Chain

- Did you know
 - Certain chemicals could be banned under REACH?
 - Your use of a chemical raw material may need to be registered under REACH?
- Companies that understand the business implications and impacts of REACH, and develop strategic action plans, will gain a competitive edge over those that do not.
- However, the inherent complexities of REACH cannot be underestimated!

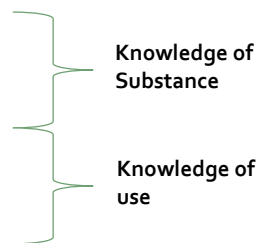
Potential Issues



- Complex Communication Networks
- Potential Rationalization of Substances
 - Loss of a supplier
 - Loss of a raw material
 - Loss of a functional element of a material / consumable
 - Loss of a product
- Loss of a customer

Information & Position in the Supply Chain (1)

- The issues to be addressed may be different depending upon your position in the supply chain
- **Manufacturers**
- **Importers**
- **Agents / Distributors**
- **Processor / Formulator**
- **Article Manufacturer**
- **Retailer**

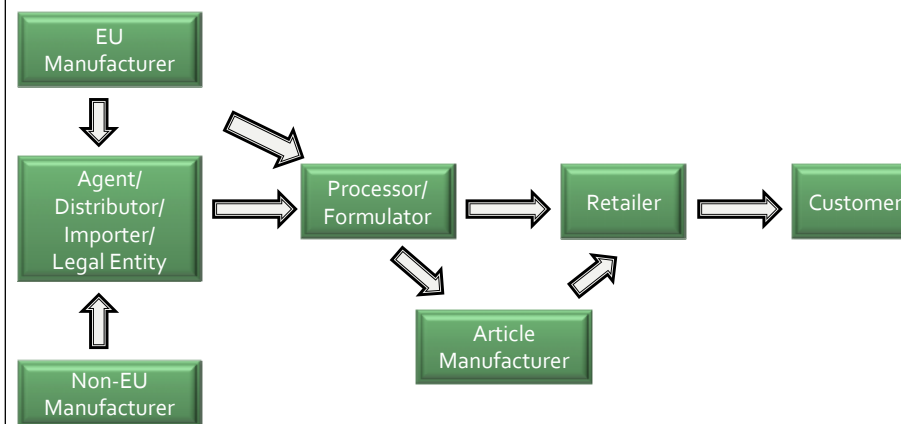


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Information & Position in the Supply Chain (2)



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Within the Supply Chain: Manufacturers



- **Pre-registration**
- **Data Evaluation**
 - Assessment of hazard data
 - Determination of value and ownership of data
 - Testing program must be initiated
- **Data Sharing**
 - Working within SIEFs
 - Must have access rights to hazard data required for volume band
- **Development of Exposure Scenarios**
 - Identification of use
 - Level of detail –specific versus generic
- **Registration**
 - Compilation of CSAs/ CSRs
 - IT tools and processes
- **Risk Assessment and Communication**
 - Risk Management Measures with Downstream Users

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Within the Supply Chain: Importers



- **Identify all substances within preparations**
 - Substance imported in quantity >1tpa must be registered
- **Understand specific requirements for imported materials**
- **Non-EU Manufacturers Nominate 'Only Representative' within EU**
 - Who will bear the costs (importer / supplier)?
- **Pre-register all substances**
 - Substances must be pre-registered to take advantage of phase-in status
- **Register with SIEF**
 - Access to the data required for a specific volume band
- **Communicate with downstream users**
 - Registration and communication issues as per manufacturers

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Within the Supply Chain: Agent/Distributor



- No obligation to register
- Communication within the supply chain
 - Suppliers will require information on use and exposure scenarios
 - Customers will require confirmation suppliers will pre-register, register and support use
 - Duty to pass information on hazards & safe use down the supply chain
- Timeframes dictated by suppliers registration timeframes
 - May be higher volume and sooner than downstream users anticipate
- RMMs assessed by suppliers need agreeing with downstream users
- Potential for becoming bottleneck in communication process

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Within the Supply Chain: Processor / Formulator



- Potential for loss of raw material
 - Supplier competence
 - Costs to supplier
 - Substance properties
 - Unsupported use
- Communication through supply chain
 - Own and downstream uses to be supported by supplier
 - Suppliers may be working to different timescales
 - Consolidation of multiple suppliers
 - Customers are likely to be less aware of REACH
- Costs of raw materials may be affected

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Within the Supply Chain: Article Manufacturer



- Article is exempt from registration
 - However, substances used in its manufacture are not
- Potential for release needs to be considered
 - Substance that can be released under reasonable conditions of use needs to be treated as a preparation
 - Use of the article covered as an exposure scenario for that substance
- Availability of raw materials
- Costs of raw materials
- Variability in supplier timescales
- Standardization of exposure scenario communication to multiple suppliers of a number of substances
- Potential loss of function as forced to substitute
- Knock-on effects of substitution vs performance specifications

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Within the Supply Chain: Retailer

- Driven by
 - Price
 - Media
 - Consumer Perception
 - Consumer Purchasing Power
- Availability of substances or products



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Impact of REACH (1)



- Environmental Compliance
 - Eco-toxicity Tests
- Business Compliance
 - Companies with EU operations that consume chemicals
 - Companies elsewhere that utilize chemicals from the EU
- Manufacturers of articles to be sold in the EU, regardless of where the articles were manufactured
- Manufacturers of chemicals or preparations sold in the EU Chemical companies
- Manufacturers who sell reagents used in their products

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Impact of REACH (2)



- Suppliers may want to know how you use their substances
- Certain identified uses may not be supported
- Some substances may disappear from the EU
- There may be a need to reformulate your product or re-engineer your process
- Cost increases throughout the supply chain should be anticipated
- Possible unauthorized changes to materials

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Supply Chain Implication



- Companies can only purchase substances from a registered supplier.
- Many suppliers may not support low margin products (raw materials) resulting in supply chain disruption or cessation.
- Need to confirm that all substances in formulations are registered, (especially imported).
- New need for full disclosure of supplied formulations.



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Consequences of Inaction



- If substance is unregistered, it will be illegal to put it on the market in the EU
- Risk of disruption to raw material supply chain and manufacturing operations
- May come under increasing scrutiny by customers and non-governmental organizations
- Chemical risks and impact to company liability may not be addressed
- Companies may absorb costs they shouldn't have to bear
- Potential for fines and penalties
- Potential for product liability claims

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In Preparation for REACH: The Oils & Fats Sector (1)

- Understand how REACH applies to the company and business partners
- Identify business risks including vulnerability of supply chain to disruption
- Identify gaps in data and processes that will be needed to support REACH compliance
- Begin communicating up and down the supply chain

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In Preparation for REACH: The Oils & Fats Sector (2)

- Determine registration obligations and pre-register if applicable
 - Be aware of the timeline which is dependent on the tonnage band
 - Determine compliance dates that will drive compliance and implementation
- Understand the implications of REACH regulations in terms of:
 - Annexes IV & V & the implication of the new drafts
 - Substances excluded from REACH

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In Preparation for REACH: The Oils & Fats Sector (3)

- Prepare who is going to handle the registration of your products
 - Legal Entity
 - Only Representative or Third Party Representative
 - Importer/Agent/Distributor
- Working with respective associations or organization
- Ownership of data & test results
 - Which can be done individually
 - Which can be bought
 - Which is compulsory to share

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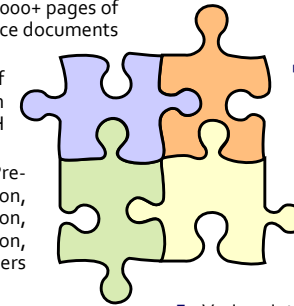
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In Summary: Compliance may be difficult but is required

Preparing for REACH is a major undertaking,

- Regulation is 800+ pages long with 2000+ pages of guidance documents
- SIEF participation of the players involved in REACH
- Multiple requirements: Pre-registration, Registration, Notification, Evaluation, Authorization, Restriction, CSAs, CSRs, Technical Dossiers
- Specific requirements for Manufacturers, Importers, Producers, Downstream Users, Distributors
- New opportunities to learn abt. new applications from customers
- Opportunities for companies that are most prepared
- Separate Responsibilities & Phased time-line which are dependent on tonnage band & hazard classification
- Various interpretations of intentional release, article, complex supply chain issues



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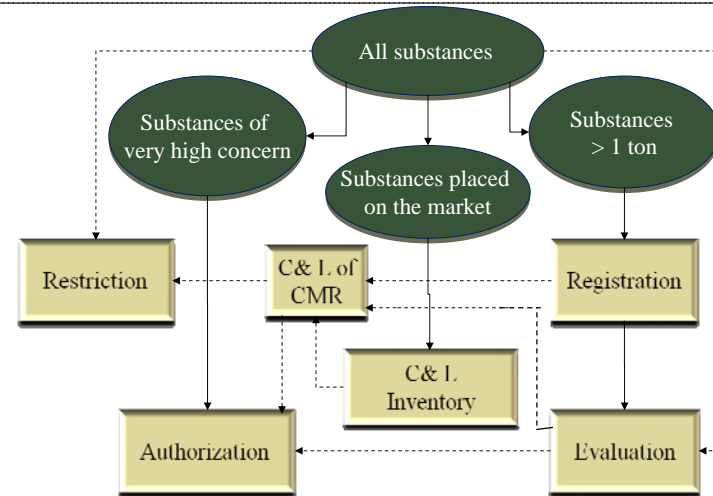


Thank you for your attention

By : Surina Ismail, Ph.D.



The Structure of the REACH Processes



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Pre-Registration and Registration

- *Pre-registration - 2008*
 - Applicable to phase-in substances
 - Manufacturers, importers and only-representatives submit substance identification information and tonnage band
 - Allows delayed registration timelines
- **Registration – 2010+**
 - Manufacturers and importers must register substances manufactured or imported into the EU of at least 1 tpa
 - Requires technical dossier
 - 10tpa or greater also requires a chemical safety report, which includes information from the chemical safety assessment



Evaluation, Authorization, Restriction

- **Evaluation**
 - Registration dossiers will be evaluated for content and completion
 - Substances will be evaluated on their particular risk to human health and the environment.
- **Authorization**
 - Applies to substances of very high concern (SVHC)
 - Includes carcinogens, mutagens, reproductive toxins, persistent bio-accumulative toxins (PBTs), and very persistent, very bio-accumulative substances (vPvBs) and endocrine disrupters
 - Manufacturers, importers and downstream users will be required to apply for authorization to manufacture, import or use a SVHC
- **Restriction**
 - Applies to chemicals posing unacceptable risk
 - Restriction may be placed on certain uses of the substance or a complete ban of the substance



Summary of REACH impact on the

- Direct legal obligations only on EU entities
 - EU manufacturers
 - EU importers
 - EU Downstream Users
- BUT impact on supply chain will be significant
 - Similar to other EU product regulation
 - Responsibilities will be pushed down the supply chain
 - EU customers expect products to comply

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Getting started on implementation (1)

- Applicability assessment:
 - High level determination of how REACH affects your business and your partners (chemical suppliers, importers, downstream users, components suppliers)
 - Identify key criteria that will determine specific responsibilities for your company
 - Define timeframes for compliance
 - Determine high-level estimate of potential costs
 - Define the business case for REACH and being proactive
 - REACH may result in disruptions of availability of chemicals
 - Could result in need to find and qualify substitute chemicals, which could take 1-2 years
 - Being proactive, costs can be contained and disruptions minimized
 - Communicate results within your organization and build support

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Getting started on implementation (2)

- Assessing vulnerability of supply chain
 - List your inventory of chemicals utilized in manufacturing
 - Determine supply chain partners and ultimate source of chemicals
 - Review for presence of SVHCs
 - Identify substances that are likely to be withdrawn due to REACH
 - Communicate with suppliers on their plans for supporting your chemicals through REACH
 - Initiate chemical substitution and qualification where risk of disruption is significant
 - Develop a REACH strategy
 - Proportionate to applicability and potential business risk
 - Detailed action plan based on applicability assessment and supply chain vulnerability
 - Internal, external resources and expertise

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Not Included in REACH

- **Excluded from the registration obligation:**
 - Radioactive substances,
 - Non-isolated intermediates,
 - Waste,
 - Substances under customs supervision,
 - Substances for plant protection and biocides,
 - Substances for following applications: medicinal products for human or veterinary use, food and feeding stuffs (**Note: quantities of such substances which are used for other applications have to be registered**)
- **Annex IV + Annex V.**

