

REACH – Views from a Manufacturer, Importer and Downstream User

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The REACH Regulation

“The REACH Regulation is like the National Health Service. You can never have enough resource. You must prioritise the tasks and do the best you can to meet its obligations.”

Bob Warner, Chemwise

formerly UK Health and Safety Executive lead negotiator on the REACH Regulation

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Overview

- The STERIS Corporation
- Learning about REACH
- Building and Implementing an Action Plan
- Experience So Far

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STERIS Corporation

- Manufacturer of infection prevention equipment and related products since 1987
 - HQ Mentor Ohio, USA
- Manufacturing facilities in USA, Finland, UK, Switzerland, Canada, Mexico, France



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STERIS Product Range

Healthcare Decontamination	Washers, Sterilizers, Endoscope processors
Surgical Support Systems	Operating theatre equipment
Low temperature Bio-decontamination Systems	VHP® Systems Vaporized Hydrogen Peroxide
High-Temperature Sterilization Systems	Steam sterilizers
Low temperature Sterilization Systems	Ethylene oxide
Cleaning Chemistries	Healthcare and Industrial
Disinfectants & Hand Sanitizers	Healthcare and Industrial
Pharmaceutical Processing Equipment	Water technologies: stills etc.

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Consumable Products

PRODUCT TYPES

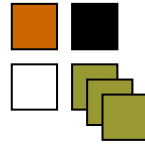
- Medical Devices
 - Detergents & Disinfectants
 - Class I and IIa
- Biocides
 - Disinfectants
 - » BPD Product type 2
 - Hand sanitizers
 - » BPD Product type 1
- Detergents
- Sterility Assurance Products
 - Chemical Indicators
 - Biological Indicators

SOURCES

- Formulate in USA and import into EU
- Manufacture in EU
- Sell own-label third party formulations
 - From Europe
 - From USA
- Distribute third party labelled products

Rest of World

Chemicals



Formulated Product



Manufactured Article



Import

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Supplier(s)

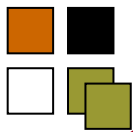


Supplier



European Union

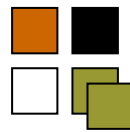
STERIS Importer



Supplier Importer



Supplier – Importer EU Manufacturer



STERIS Downstream User



STERIS Downstream User



STERIS Impact Scenarios

- STERIS as a supplier of formulated chemical products
- STERIS as a manufacturer of articles in the EU
- STERIS could be
 - Importer of Chemicals
 - Downstream User of Chemicals
 - Importer of Chemical Products
 - Downstream User of Chemical Products
 - Importer of Articles

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Learning about the REACH Regulation

- Policy Makers and Regulators
 - Meetings
 - Web sites
 - Guidance Documents
- Trade Association meetings and guidance
 - British Association of Chemical Specialities
 - Chemical Hazard Communication Society
- Other conferences, meetings, web sites, documents
 - Consultants
 - Suppliers
 - Competitors

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Sources of Information – Useful Links

Organisation	Content	Link
Chemical Watch	Briefing Business on REACH and Chemical Risks	http://chemicalwatch.com/
European Chemicals Agency	Official website for ECHA	http://ec.europa.eu/echa/home_en.html
European Chemicals Bureau	Information on REACH Implementation Projects and other technical documents	http://ecb.jrc.it/REACH/home.php?CONTENU=/REACH/RIP_PROJECTS/sommaire.php
European Commission Environment Directorate	Background policy documents on REACH	http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm
EU Member State helpdesks	Contact details for member state helpdesks	http://ec.europa.eu/echa/reach/helpdesk/nationalhelp_contact_en.html
Federal Institute for Occupational Safety and Health (BAUA)	German REACH helpdesk	http://www.reach-helpdesk.de/
UK Health & Safety Executive	UK REACH Competent Authority website	http://www.hse.gov.uk/reach/index.htm
Belgian Economic Affairs Ministry	Official Belgian REACH website including link to inventory tool	http://mineco.fgov.be/organization_market/Reach/home_fr.htm
IUCLID 5	IUCLID 5: the EU's chemical information database	http://ecbwbiu5.jrc.it/index.php?fuseaction=home.iuclidHome&type=public
European Chemical Substances Information System (ESIS)	ESIS: overarching EU inventory of substances, data, classification and labelling	http://ecb.jrc.it/esis/
OECD	eChemPortal for information on chemical substances	http://webnet3.oecd.org/echemportal/
UNECE	GHS website: Globally Harmonised System of Classification and Labelling of Chemicals	http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

Basic Responsibilities of a Downstream User

- TITLE V of The REACH Regulation
- Article 37
 - Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures
- Article 38
 - Obligation for downstream users to report information
- Article 39
 - Application of downstream user obligations

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When a DSU is an importer?

- All the duties of an EU Manufacturer
 - Substances in preparations, in polymers or in articles
 - Must pre-register to take advantage of phase-in status
 - Participate in SIEFs
 - Register (dossier + CSR)
 - Communicate information on safe use
 - Substances may be authorised and restricted

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REACH Guidance Documents

- http://reach.jrc.it/guidance_en.htm
- Guidance on the different processes under REACH
 - Guidance mainly for Industry Use
 - Guidance mainly for Authorities Use
- Guidance on the different methods under REACH

Guidance on Processes for Industry – 1



Guidance on registration

- When and how to register a substance under REACH
 - » Registration tasks and obligations
 - » Preparation of the Registration Dossier
- Guidance on pre-registration – Autumn 2007
 - How to identify the substances that can be pre-registered
 - When and how to pre-register them



Guidance on data sharing

- Data sharing mechanisms for phase-in and non phase-in substances
 - » Communication within the SIEF and the cost sharing guidance
 - » Confidential Business Information and Competition Law issues related to data sharing



Guidance for intermediates

- Specific provisions for the registration of intermediates



Guidance for monomers and polymers

- Specific provisions for polymers and monomers

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Guidance on Processes for Industry – 2

-  Guidance on Scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD)
 - Specific provisions for substances manufactured, imported or used in scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD)
- Guidance on Classification and Labelling notification – ‘not yet available’
 - When and how to notify a classification and labelling for a substance
- Guidance on requirements for substances in articles – Early 2008?
 - Helps producers and importers of articles identify whether they have obligations under REACH
 - » Article 7 – registration and notification
 - » Article 33 – Article supply chain communication
- Guidance for Downstream Users – Autumn 2007?
 - Roles and obligations of downstream users
 - How to prepare for the implementation of REACH
- Guidance on the preparation of an application for authorisation – End 2007
 - How to prepare an application for authorisation
 - Analysis of the alternatives and substitution plan
 - How third parties may prepare and submit information on alternatives

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Guidance on Processes for Authorities

-  Guidance on Dossier and Substance Evaluation
-  Guidance for the preparation of an Annex XV Dossier on Harmonised Classification and Labelling
 - How to prepare an Annex XV dossier for a Harmonised Classification and Labelling proposal
-  Guidance for the preparation of an Annex XV dossier to identify substances of very high concern
 - Guidance on inclusion of substances in Annex XIV (substances subject to Authorisation)
 - Autumn 2007
 - Describes how the authorities (the Agency in co-operation with the Member States Competent Authorities) will include substances in the authorisation system
 - Elaboration of the dossier that supplements each recommendation of a substance for inclusion in Annex XIV
-  Guidance for the preparation of an Annex XV dossier to propose a restriction under REACH

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Guidance on Methods – 1

- 📄 Guidance for identification and naming of substances
 - How to name and identify a substance under REACH
- Guidance on how to comply with the provisions of the new Regulation on Classification, Packaging and Labelling of substances and mixtures - 2008
 - Help industry and authorities implement GHS criteria in the EU
- Guidance for the preparation of the Chemical Safety Report – Autumn 2007
 - Help industry conduct Chemical Safety Assessments and prepare Chemical Safety Reports, if required
 - » As part of a registration dossier (for a substance on its own or as part of a preparation or as released from an article)
 - » As part of an authorisation application
 - » As part of downstream user obligations
 - » Set out basic principles for authorities preparing a risk assessment in support of a restriction proposal, and when required as part of a Substance Evaluation

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Guidance on Methods – 2

- Guidance on information requirements under REACH – Autumn 2007
 - How to collect and assess available information
 - » Intrinsic properties of the substances to be registered
 - » Requirements specified by REACH
 - Identifying data gaps
 - Generating additional information required to comply with the Regulation
- Guidance on Socio Economic Analysis – 2008
 - How to prepare a socio-economic analysis or input for one as part of Authorisation and Restriction procedures
- Guidance on priority setting for evaluation – Autumn 2007
 - Different priority setting methods to prioritise dossiers, testing proposals or substances for evaluation
 - Guide the Agency and Member States Competent Authorities on the application of these methods
-  Guidance on IUCLID
 - How to use IUCLID 5
 - Preparing dossiers for different REACH requirements
 - 15.8 MB 2044 pages

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Build an Action Plan

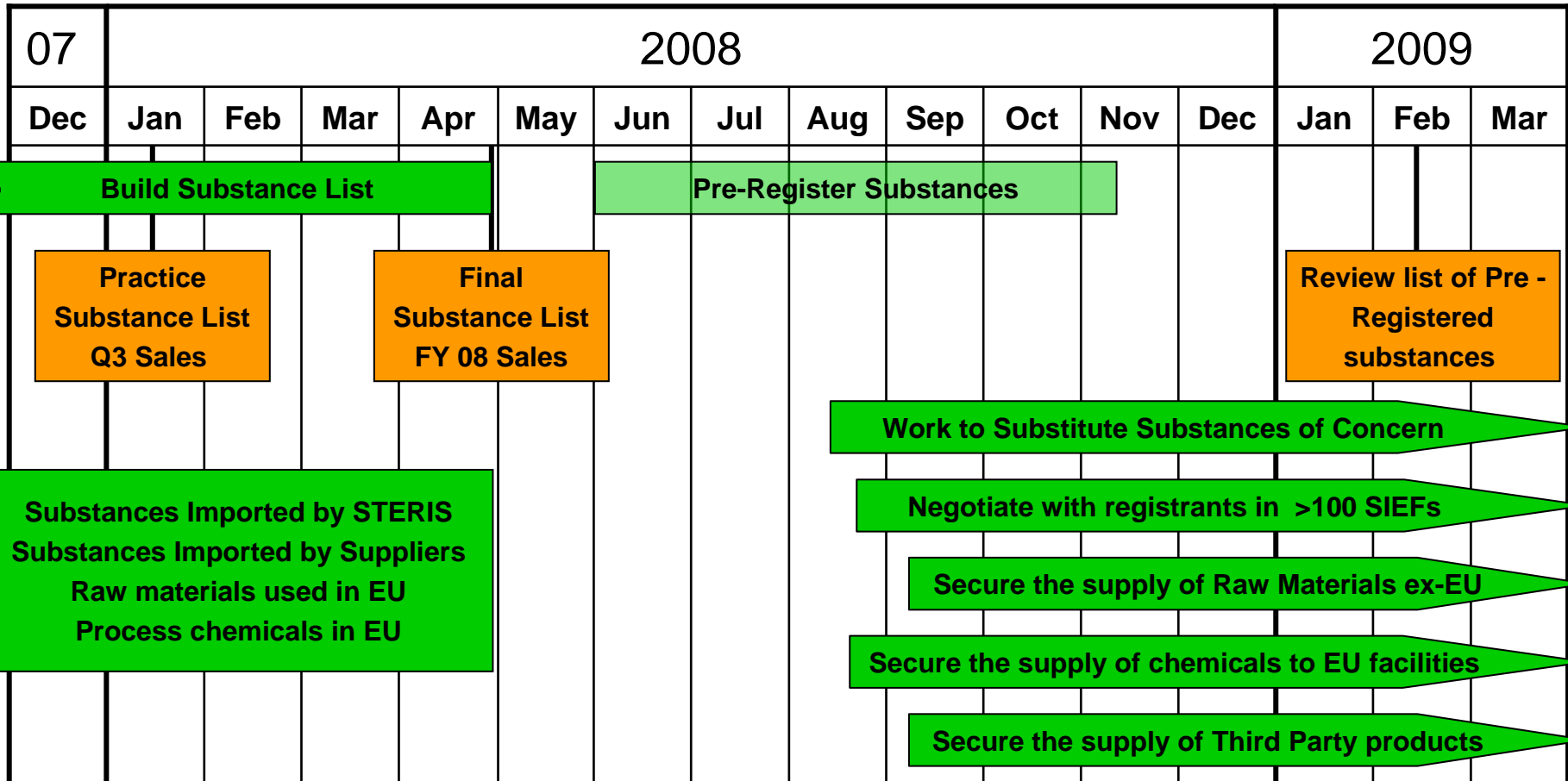
- Understand the Regulatory Timetable
- Collect and collate the information required pre-register the chemicals
 1. Identify the chemical substances that fall within the scope of the Regulation
 2. Identify the products in which the raw materials are used
 3. Identify the location of manufacture of each product
 - a. Internal – which facility
 - b. External
 4. For each chemical substance
 - a. Identify the manufacturer(s)
 - b. Establish whether the manufacturer or STERIS is responsible for registering the chemical
 - c. Establish the quantity imported by STERIS into the European Union
- Prepare a data sheet for each relevant chemical substance, in order to pre-register the substance on the European Chemical Agency data base within the deadline set in the Regulation
- Work with the European Facilities to establish the security of the their chemical supply chain

Key REACH Milestones

1 June 2008	Pre-registration for existing substances starts Registration for new substances starts
30 November 2008	Pre-registration for existing substances ends
1 December 2008	Registrations for existing substances starts (those substances that were not pre-registered)
1 January 2009	List of pre-registered substances published (Substance Information Exchange Forums – SIEFS – created)
1 June 2009	First recommendation of priority substances to be considered for authorisation published
30 November 2010	Deadline for registration of substances supplied at or above: <ul style="list-style-type: none"> • 1000 tonnes per annum (tpa) per manufacturer or importer • 100 tpa and classified as very toxic to aquatic organisms • 1 tpa and classified as Category 1 or 2 carcinogens, mutagens or reproductive toxicants
31 May 2013	Deadline for registration of substances supplied at 100 tpa or above
31 May 2018	Deadline for registration of substances supplied at 1 tpa or above

Crucial
To
Pre-
Register

Pre-registration Activities



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Experience So Far

- Waiting for Definitive word on Substances in Articles
- Main US Manufacturing Facilities
 - Actively engaged with R&D and Supply Chain
- European Facilities
 - Identified some chemical supply uncertainties
- European Third Party Products
 - A mixed response

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Asked four product suppliers about REACH Obligations

- Are you an EU Manufacturer, Importer or Downstream User of the chemicals in the products you supply to STERIS?
- Is STERIS the Importer or Downstream User of the chemicals in the products you supply?
- Please explain your rationale

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Supplier Responses

- Supplier 1
 - We are importers and will set up a legal entity to take on obligations so our customers are Downstream Users – here is our position paper
- Supplier 2
 - It doesn't apply to us because the product is a medical device
 - Really?
 - Yes, our American parent company says so
- Supplier 3
 - We buy raw ingredients that will be registered from EU manufacturers, formulate and re-import so we are Downstream Users
 - Emails from regulators to confirm this position
- Supplier 4
 - No response

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Where is it best to be?

<p>Downstream Users of Clean Chemicals</p> <p>Supplier does the work (make sure he does)</p>	<p>Downstream Users of Bad Actors</p> <p>Beware, supplier may pull out Threat to product Action: Substitute safe chemistry?</p>
<p>Importers of Clean Chemicals</p> <p>Task force management Information management Action: become Downstream User? (change supplier)</p>	<p>Importers of Bad Actors</p> <p>Task force management Expert Resource Intensive Threat to product Action: Substitute safe chemistry</p>

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