REACH Regulation

To Improve the Protection
of Human Health and the Environment

An Original Component Manufacturers
(OCM) Perspective

Presented by Thomas Culhane
tculhane@socal.rr.com

Clinic Objectives

- Receive an introduction to EU REACH regulation
- Understand why REACH is important
- Understand EU REACH requirements for substances, mixtures, and articles
- Learn about Substances of Very High Concern (SVHC)
- Understand how EU REACH affects U.S. based OCMs
- Learn how to address supply chain communication obligations
- Understand some of the first steps your organization can take to address EU REACH

What is REACH?

Registration,

Evaluation,

Authorisation, and

Restriction of CHemicals

What is REACH?

- A regulation of the European Union (EU)
  - *Regulation No (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006*
  - Entered into force on June 1, 2007
  - Replaces many of the current EU and national laws on substance registration
  - Contains 850 Pages of EU Legislation
    - Additional pages of guidance and FAQs
  - Created and administered by the European Chemical Agency (ECHA)

REACH Purpose

- To improve the previous legislative framework for chemicals of the European Union (EU) and European Economic Area (EEA) countries
- Improve the protection of human health and the environment from the risks that can be posed by chemicals
- Enhance competitiveness and innovation in the EU
- Promote alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals

Why REACH?

- Compliance to REACH regulation is mandatory for substances, mixtures, and articles produced or imported into the EU
- Because there are many other countries that have pending or similar legislation and because articles produced from non-EU manufacturers may eventually find their way in the EU, REACH compliance is having a global effect on the supply chain

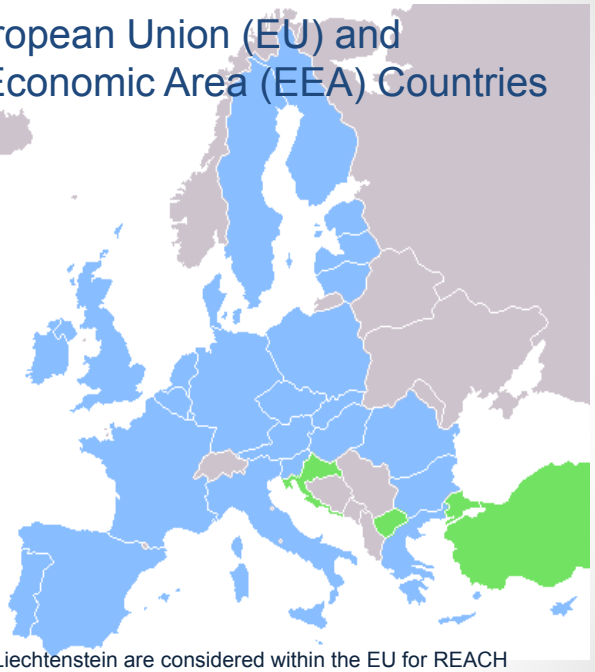
REACH Overview

- One single and coherent system for new/existing chemicals
- Shift of responsibilities from public authorities to industry
- Core elements:
  - **Registration** of substances ≥ 1 tonne/yr (staggered deadlines)
  - **Evaluation** of some substances by Member States/ECHA
  - **Authorisation** only for substances of very high concern
  - **Restrictions** - "The Safety Net"
  - **Notification and Communication** – Additional obligations for substances in Articles
- REACH Focus:
  - Substance volumes - as a proxy for potential risk
  - Greatest concern - substances and uses with risk

European Union (EU) and European Economic Area (EEA) Countries

28 Member States of the EU

Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom, Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, and Italy

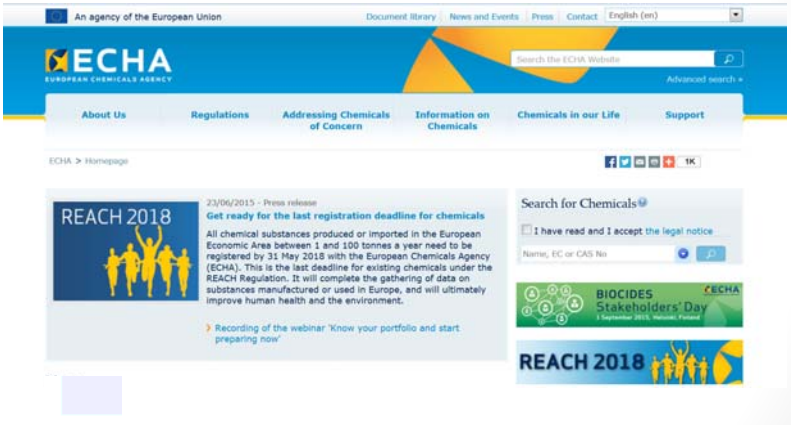


-Norway, Iceland, and Liechtenstein are considered within the EU for REACH

European Chemicals Agency (ECHA)

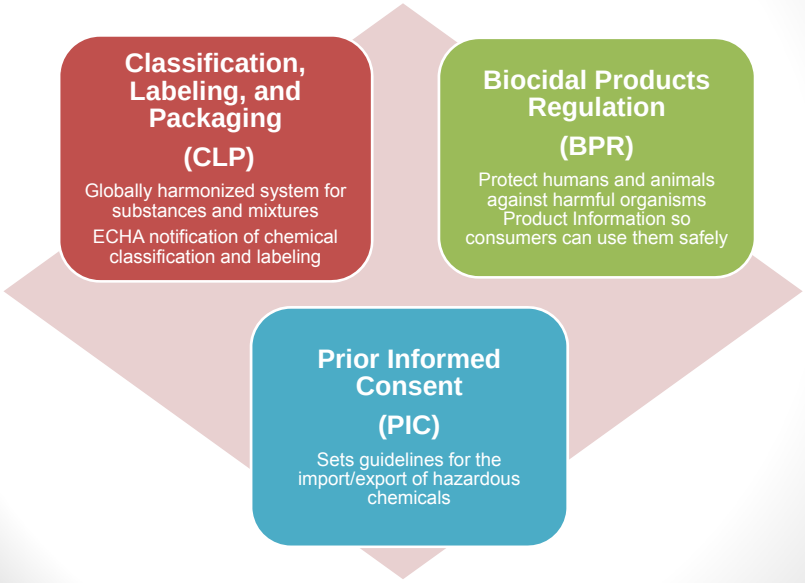
- Driving force among regulatory authorities in implementing the EU's groundbreaking chemicals legislation
  - Coordinates and implements the regulation process
  - Manages the process to ensure uniformity across the MS
  - Helps companies to comply with the legislation
  - Advances the safe use of chemicals
  - Provides information on chemicals and addresses chemicals of concern
- ECHA aspires to become the world's leading regulatory authority on the safety of chemicals

European Chemicals Agency (ECHA)



http://echa.europa.eu/

Other ECHA Regulation Oversight



REACH: Registration

- Places responsibility for risk management on the chemical producers
- Companies have the responsibility of collecting information
  - Properties and uses of substances that they manufacture or import
  - > one metric tonne per year (1Mg=1000kg=2,205lbs)
- Makes an assessment of the hazards and potential risks presented by the substance
  - Information is communicated to ECHA
  - Registration dossier containing the hazard information
  - Includes an assessment of the risks that the use of the substance may pose and how these risks should be controlled
- Registration applies to substances on their own, substances in mixtures, and certain cases of substances in articles

REACH: Registration

- Registration is based on the "one substance, one registration" principle
- This means that manufacturers and importers of the same substance have the obligation to submit their registration jointly
  - Facilitates data sharing: Substance Information Exchange Forum (SIEF)
  - Reduces amount of testing on vertebrate animals
  - Reduces financial burden on registrants
- ECHA administers the data sharing, inquiry, late pre-registration, and dispute processes
- Substances not pre-registered must begin the registration process immediately or supply will be illegal
- ECHA publishes registration dossiers on its website

REACH: Registration

Registration Dossier

- Collects all existing available information on the intrinsic properties of a substance as well as on its manufacture, uses, and exposure

Technical Dossier Contents
Identity of the substance
Information on the manufacture and use of the substance
Classification and labeling of the substance
Guidance on its safe use
Study summaries of the information on the intrinsic properties
Exposure related information (1 tpa to 10 tpa)
Chemical safety report (>10 tpa)

REACH: Registration

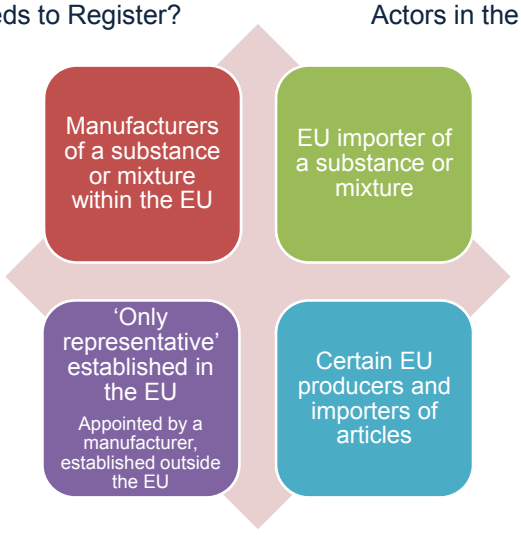
Special Transitional Regime for Substances

Type	Effective Date	Name	Substance Detail	tpa
Pre-Registration	December 2008	Phase-in Substances	Substances manufactured or imported	>1000
Registration	November 2010	Non Phase-in Substances	Substances manufactured or imported	>1000
			Carcinogenic, mutagenic, or toxic to reproduction substances	>1
			Substances dangerous to aquatic organisms or the environment	>10
Registration	May 2013	Non Phase-in Substances	Substances manufactured or imported	100 - 1000
Registration	May 2018	Non Phase-in Substances	Substances manufactured or imported	1 - 100

REACH: Registration

Who needs to Register?

Actors in the supply chain



REACH: Registration Statistics

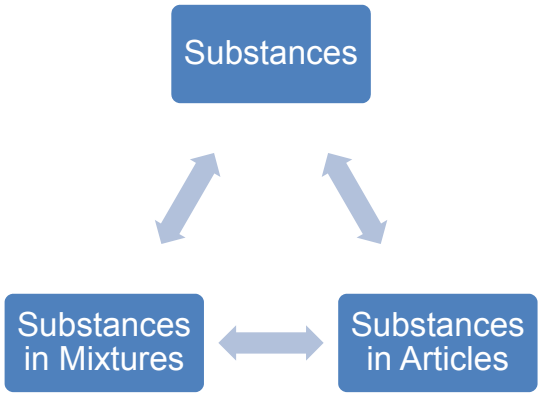
Type	Registrations*	Unique REACH Substances**
TOTAL	**41718**	**8390**
Phase-in	38741	7095
Non Phase-in	2977	1295

Company Size	Registrations*	Unique REACH Substances**
Large	35553	7814
Medium	3417	1516
Small	1811	715
Micro	937	379

*As of May 15, 2015
**Does not include an additional 5292 unique substances from Directive 67/548/EEC (prior to REACH)

Scope of REACH

Applies to all substances whether manufactured, imported, used as intermediates, or placed on the EU market either on their own or in mixtures or in articles



Scope of REACH: Substance

Substance

A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

Scope of REACH: Substance

Single chemical

- European Inventory of Existing Commercial Chemical Substances (EINECS)
- A CAS Registry Number (CASRN or CAS Number) is a unique numerical identifier assigned by Chemical Abstracts Service (CAS)

Examples:

Diethylene glycol (DEG)	CAS 111-46-6
Sodium dodecyl sulphate	CAS 151-21-3
Copper or Zinc	CAS 7440-50-8
	CAS 7440-66-6

Scope of REACH: Mixtures

Mixtures (previously called Preparation)

A mixture or solution composed of two or more substances. The function is more determined by the chemical composition than by its shape, surface, or the design.

Examples:

- Antifreeze
  - (ethylene glycol + color + scale inhibitor + other additives)
- Washing Detergent
  - (sodium dodecyl sulphate + color + fragrance + other)
- Alloy
  - (Copper + Zinc = Brass)

Scope of REACH: Article

Article

An object which during its production is given a special shape, surface, or design which determines its function to a greater degree than does its chemical composition.

Examples:

- Battery (or any electronic component)
- Printed circuit board or a computer
- Tire
- Dress shirt

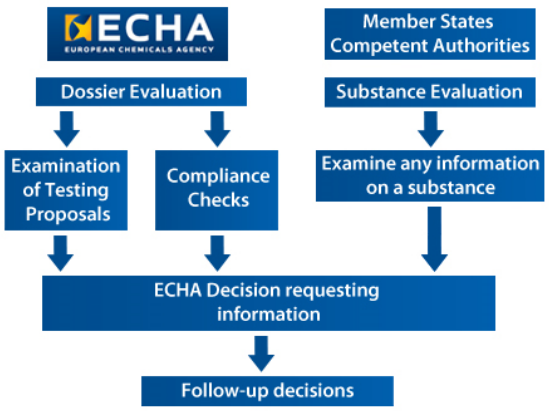
REACH: Evaluation

Evaluation Process Objectives

ECHA and the Member States evaluate the information submitted by companies to examine the quality of the registration dossiers and the testing proposals and to clarify if a given substance constitutes a risk to human health or the environment

- Examine the quality of the testing proposals
- Examine the quality of the registration dossiers
- Evaluate the substance information submitted by companies/registrants

REACH: Evaluation



Evaluation Process Outcome:

Clarify if a given substance constitutes a risk to human health or the environment

REACH: Evaluation

- **Examination of Testing Proposals**
  - Conducted by ECHA - Result: reliable and adequate data
  - Prevent unnecessary animal testing
  - Invites third parties input
- The options for the draft decision area:
  - Acceptance of the testing proposal
  - Acceptance of the testing with modifications
  - Rejection of the testing proposal
- ECHA adopts the decision based on the proposal and the information submitted by third parties

REACH: Evaluation

- **Compliance Check of the Dossiers**
  - Conducted by ECHA
  - Examination of the registration dossier
  - Checks compliance with the legal requirements
- Possible Outcomes
  - No action toward the registrant
  - Quality observation letter – ECHA identifies shortcomings
  - Decisions to request additional information

REACH: Evaluation

- **Substance Evaluation**
  - Conducted by Member States
  - Evaluation of certain substances
  - Clarify if substances pose a risk to human health or the environment

- Possible Outcomes
  - Risks are sufficiently under control (measures already in place)
  - Additional risk management measures are required
    - Restrictions
    - Identification of substances of very high concern (SVHC)

REACH: Authorisation

Authorisation Process Objectives

Identify those Substances of Very High Concern (SVHC) that may have serious effects on human health or the environment

Assure risks resulting from SVHC use are properly controlled

Assure SVHC are progressively replaced by suitable alternatives

REACH: Authorisation

Substances of Very High Concern (SVHC) Hazard Properties

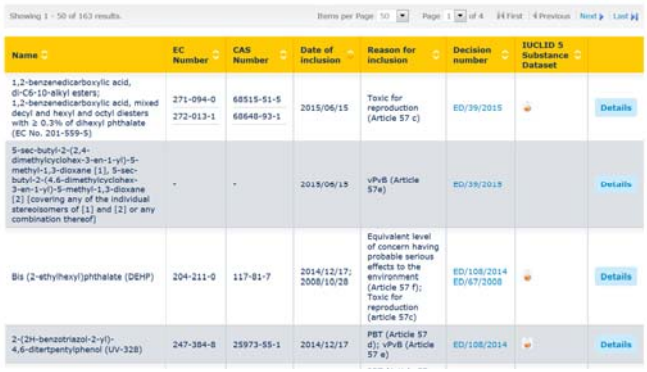
Hazard Properties	Type
Carcinogenic, mutagenic, or toxic to reproduction (Commission Regulation (EC) No 1272/2008)	CMR Cat.1 or 2
Persistent, bioaccumulative, and toxic (REACH Annex XIII)	PBT
Very persistent and very bioaccumulative (REACH Annex XIII)	vP and vB
Substances with an equivalent level of concern (Case by Case)	Endocrine bydisruptors

REACH: Authorisation

The Candidate List
• ECHA or MS proposes a substance to be identified as a SVHC
• If identified, the substance may be added to the Candidate List
• Prepare a dossier in accordance with the requirements in Annex XV
• Identification process includes a period of public consultation
• Substances typically added twice per year
• Inclusion may create Notification and Communication obligations for companies manufacturing, importing, or using such substances in articles

REACH: Authorisation

Candidate List of Substances of Very High Concern



Name	EC Number	CAS Number	Date of inclusion	Reason for inclusion	Decision number	IUCLID 5 Substance Dataset	
1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)	271-094-0 272-013-1	68515-51-5 68648-93-1	2015/06/15	Toxic for reproduction (Article 57 c)	ED/39/2015		Details
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof]	-	-	2015/06/15	vPvB (Article 57e)	ED/39/2015		Details
Bis (2-ethylhexyl)phthalate (DEHP)	204-211-0	117-81-7	2014/12/17; 2008/10/28	Equivalent level of concern having probable serious effects to the environment (Article 57 f); Toxic for reproduction (article 57c)	ED/108/2014 ED/67/2008		Details
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	247-384-8	25973-55-1	2014/12/17	PBT (Article 57 d); vPvB (Article 57 e)	ED/108/2014		Details

Number of substances on the Candidate List: 163 (06/15/2015)

Source: http://echa.europa.eu

REACH: Authorisation

The Candidate List - Process to Authorisation

- Consists of candidate substances for possible inclusion in the Authorisation List
- ECHA regularly assesses the substances from the Candidate List
- Determine which substances should be included in the Authorisation List
- Prioritization based on information on the uses and volumes of the substances on the EU market
- Process includes a period of public consultation prior to recommendation

REACH: Authorisation

Authorisation List of Substances (Annex XIV of REACH)

Name	EC Number	CAS Number	Sunset date	Latest application date	Exempted (categories of) uses	
1,2-Dichloroethane (EDC)	203-458-1	107-06-2	22/11/2017	22/05/2016		Details
2,2'-dichloro-4,4'-methylenedianiline (MOCA)	202-918-9	101-14-4	22/11/2017	22/05/2016		Details
2,4 – Dinitrotoluene (2,4-DNT)	204-450-0	121-14-2	21/08/2015	21/02/2014		Details
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	101-77-9	21/08/2014	21/02/2013		Details
5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	201-329-4	81-15-2	21/08/2014	21/02/2013		Details
Acids generated from chromium trioxide and their oligomers. Group containing: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid	231-801-5 236-881-5	13530-68-2 7738-94-5	21/09/2017	21/03/2016		Details
Ammonium dichromate	232-143-1	7789-09-5	21/09/2017	21/03/2016		Details
Arsenic acid	231-901-9	7778-39-4	22/08/2017	22/02/2016		Details
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7	21/02/2015	21/08/2013	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC.	Details

Number of substances on the list: 31 (July 10, 2015)

Source: http://echa.europa.eu

REACH: Authorisation

- Substances on the Candidate List are subject to Authorisation
- Manufacturers, importers, or downstream users
  - Need to submit an application to ECHA
  - Requests the Authorisation for specific uses
  - Must receive Authorization to continue using these substances
  - Substances prohibited after the “Sunset Date”
- Inclusion creates legal obligations to companies manufacturing, importing, or using such substances, whether on their own, in preparations, or in articles

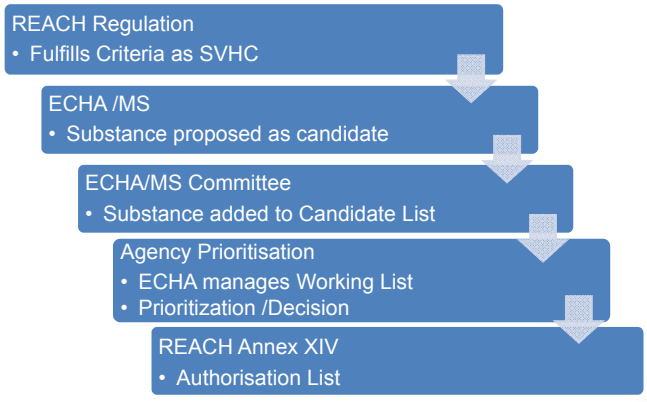
REACH: Authorisation

Applications for Authorisation

- Authorisation - Granted by ECHA
  - Risk assessment route
    - The applicant can demonstrate that the risk from the use of the substance is adequately controlled
  - Socio-economic route
    - The socio-economic benefits of using the substance outweigh the risks and there are no suitable alternative substances or technologies

REACH: Authorisation

Applications for Authorisation Process



REACH: Restriction

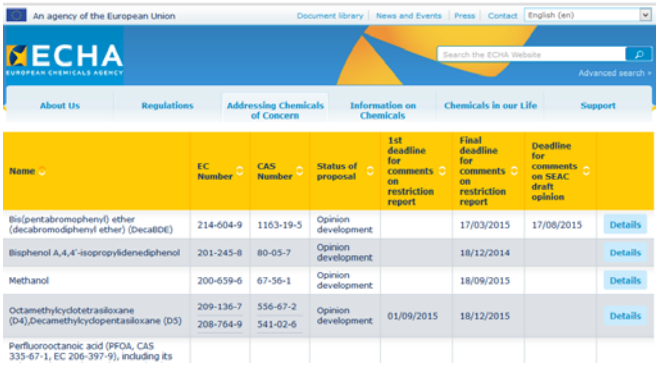
- Tool used to protect human health and the environment from unacceptable risks posed by chemicals
- May limit or ban the manufacture, placing on the market, or use of a substance
- Applies to any substance on its own, in a mixture, or in an article, including those that do not require registration ("The Safety Net")
- ECHA can propose restrictions if they find that the risks need to be addressed on an union-wide basis

REACH: Restriction

- ECHA can also propose a restriction on articles containing substances that are on the Authorisation List
- The list of the restricted substances and the conditions of restriction are available on Annex XVII of REACH
- Once the substance restriction has been adopted, industry must comply: manufacturers, importers, distributors, downstream users, and retailers
- The Competent Authorities in the Member States are responsible for enforcing the restriction

REACH: Restriction

Restrictions Under Consideration



http://echa.europa.eu/ July 10, 2015

REACH : Notification

Notification of Substances in Articles

- Producers and importers have to notify to ECHA of the substances listed on the Candidate list which are present in their articles, if **both** the following conditions are met:
  - The substance is present in their relevant articles above a concentration of 0.1% weight by weight (1000 ppm)
  - The substance is present in these relevant articles in quantities totaling over 1 tpa (per producer or importer)
- Notify no later than six months after the inclusion of the substance in the Candidate List

REACH : Notification

Notification of Substances in Articles

- The information to be notified includes the following:
  - The identity and contact details of the producer of article
  - The registration number for the SVHC
  - The identity of the SVHC (CAS, EINECS)
  - The classification of the SVHC
  - A brief description of the use of the SVHC in the article and of the uses of the article

REACH : Notification

Notification of Substances in Articles - Exemptions

- There are two cases when a notification is **not** required:
  - The producer or importer of an article can exclude the exposure of humans and the environment to the substance during normal or reasonably foreseeable conditions of use of the article, including its disposal.
    - In these cases, the producers and importers will give appropriate instructions to the recipient of the article
  - The substance has already been registered by a manufacturer or importer in the EU for that use

REACH : Communication

Communication in the Supply Chain – Substances in Articles

- Directly after a substance is included in the Candidate List, suppliers of articles which contain such a substance in a concentration above 0.1% (weight by weight) have to provide enough information to allow the safe use of the article to the recipients of the article
  - Recipients: industrial or professional users and distributors, but not consumers
    - As a minimum, the name of the substance in question has to be communicated
    - Provide this information within 45 days, free of charge

Substances in Articles

Obligation	Registration of Substances in Articles	Notification of Substances in Articles	Communication of Information on Substances in Articles
Legal basis in REACH regulation	Article 7(1)	Article 7(2)	Article 33
Actors concerned	Article producers Article importers	Article producers Article importers	Article suppliers
Substances concerned	Substances intended for release	Substances on Candidate List for Authorisation	Substances on Candidate List for Authorisation
Tonnage threshold	1 tonne per year	1 tonne per year	-
Concentration in article threshold	-	0.1% (w/w)	0.1% (w/w)
Exemption from obligation possible on basis of:			
Substance already registered for that use	Yes	Yes	No
Exposure can be excluded	No	Yes	No

Note. Adapted from Guidance on Requirements for Substance in Articles (ECHA)

Who Has Responsibility?

Three distinct types of article actors in the supply chain:

Article importers - as outlined in Article 3(11)

Any company located inside the EEA that imports articles from countries that are located outside the EEA. Importers supply articles directly to their customers or they may incorporate these articles into the production of new articles

Article producers - as defined in Article 3(4)

A company that produces an article within the EEA, regardless of how the article is produced and where it is placed on the market

Article supplier - as defined in Article 3(33)

Producer or importer of an article, distributor, or other actor in the supply chain placing an article on the EU market

What is needed by an OCM to meet your customer REACH requirements?

- A sustainable and comprehensive REACH strategy is needed:
  - To maintain global market access - at minimal costs
  - To minimize business disruptions
  - To minimize liabilities and other obligations
  - To maximize on-time delivery of products
  - To improve time-to-market for new product development

REACH: What First Steps Should an OCM Take?

Step 1: Initiate the Project
- Project Team Formation
- Problem Definition Statement

Step 2: Create the Project Charter
- Determine Project Team Members/Resources
- Define the Business Case/Project Scope
- Project Milestone Summary
- Project Objectives and Goals
- Charter Approval

Step 3: Development of the Project Plan
- Communication Plan
- Multi-Generation Plan
- Project Management Plan

A U.S.-Based Original Component Manufacturer's (OCMs) Perspective

Is REACH applicable to you?

Yes
- EU based company producing products in EU for sale in EU
- EU based company Exporting products globally
- EU based company Importing products
- Non EU based company Shipping products into the EU

No
- Non EU based company Shipping products into USA
- Non EU based company Shipping products into non EU country

Component = Product = Article

U.S. companies exporting Articles into EU have no direct legal liability but will have customer requirements for the communication of SVHC in Articles

A U.S.-Based Original Component Manufacturer's (OCMs) Perspective

Customer Driven Need - REACH compliance certifications

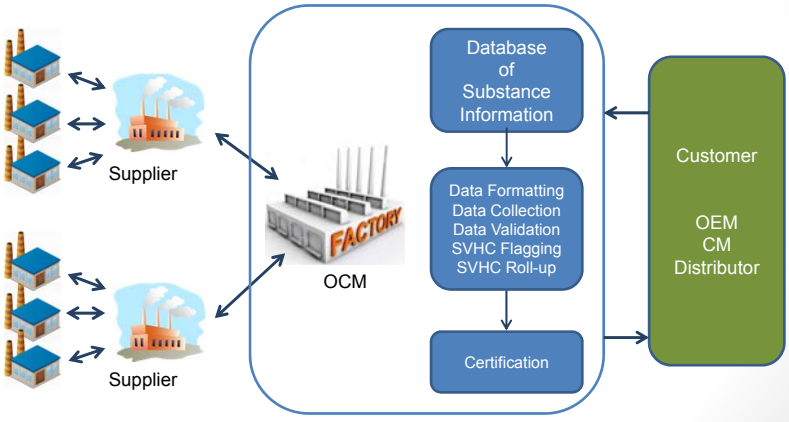
- OCMs receive REACH compliance certification requests
  - Original equipment manufacturers (OEMs), distributors, and contact manufacturers (CMs) located in the EU
  - OEMs, distributors, and CMs located outside the EU, but export to the EU
- REACH Compliance Certification:
  - Statement:
    - Product (Article) contains < 0.1% w/w of SVHC on CL

    or
    - Product (Article) contains > 0.1% w/w of SVHC on CL
      - Provide SVHC name and amount

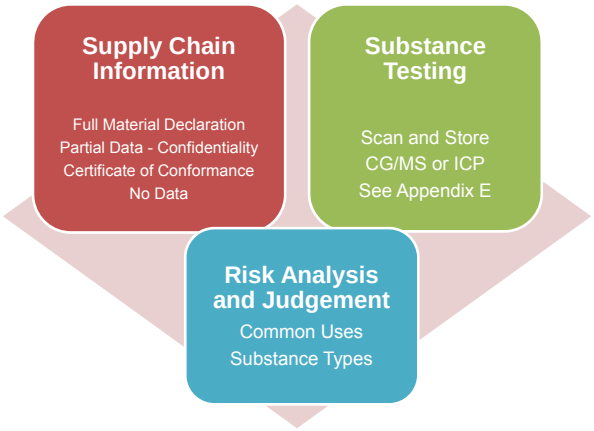
REACH: OCM Supply Chain

Data requests sent upstream from OCM
REACH data sent downstream from Supplier

Certification request from Customer
REACH Certification from OCM



REACH: SVHCs in Articles



The need to strike an effective balance between compliance assurance and costs!

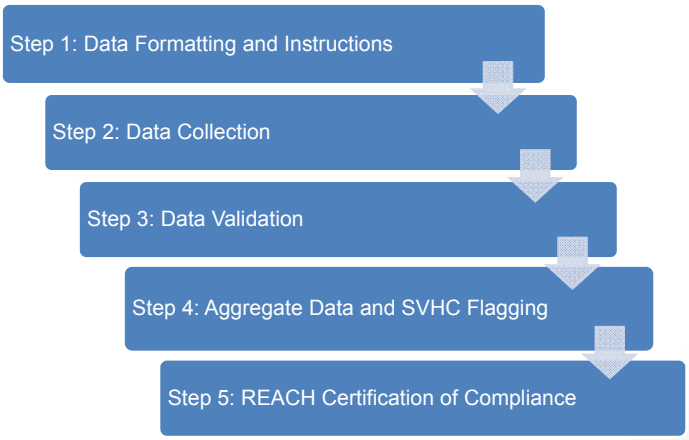
Candidate List: A "Moving Target"

- SVHC: Currently 163 SVHC on Candidate List
  New substances added twice per year
  Year 2020 goal - hundred's more to be added
- Recommend: Product-Level Substance Disclosure
- Vehicle: Full Material Declaration (FMD) or
  Full Material Composition Declaration

- Full Material Declarations contain:
  - Substance information on materials used in Articles
    - Substance Name
    - Substance CAS Number
    - Weight (and % or ppm) of each substance
      - Article level
      - Homogeneous material level

REACH Compliance Certification Process

Five Step Process to Generate a Certificate of Compliance



REACH Compliance Certification Process

Step 1: Data Formatting and Supplier Instructions

- Unify substance data format
  - Request compliance information in the form of a FMD
  - Select an industry standard tool for formatting
    - IPC-1752A, IEC 62474, Excel, PDF, or similar
- Suppliers often do not understand all aspects of REACH
  - Educate your customer on REACH
  - Provide clear and concise instructions/expectations/response date
- Send FMD requests to your suppliers
- Create records (Config Management or REACH Database System)

REACH Compliance Certification Process

Step 2: Data Collection

- Collect the FMD from your supplier(s)
- Update records (Config Management or REACH Database System)
- Inventory the supplier responses:
  - Suppliers unwilling to share any substance information
    - Educate your supplier on REACH and readdress
  - Some suppliers will consider their material composition information confidential and will not provide a FMD or will only provide partial material composition Information and consider other portions confidential
    - An alternate approach is to collect a product level Certificate of Compliance (CoC) per the latest CL of SVHC

REACH Compliance Certification Process

Step 3: Data Validation

- Validate Supplier FMD (or material composition Information)
  - Establish a rigorous review process
  - Resource-intensive task
  - Correct errors, duplicate, incomplete, and incorrect data
  - Ensure data consistency and accuracy of all line item information
  - Follow-up with supplier, as required
- A combination of automated tools and personnel validate your data
- Update records (Config management or REACH database)

REACH Compliance Certification Process

Step 4: Aggregate Data and SVHC Flagging

Aggregate the supplier data:

- Convert the information into other data formats, if required
- Standardize and validate the data against the database information
  - Part number, substance name, CAS number, and substance weight
- Include all suppliers data from all sources
- Update records (Config management or REACH database)

Flag SVHC:

- Update flag to reflect changes in REACH regulations
  - Additions to Candidate List of SVHC
- Update records (Config management or REACH database)

REACH Compliance Certification Process

Step 5: REACH Certification of Compliance

- Generate a Product-Level REACH Certification of Compliance
- Analyzing compliance status based on aggregated supplier data (flagged SVHC) and SVHC on Candidate List
- Certification of Compliance to include:
  - Certification statement
  - Applicable part number
  - Reference to REACH Regulation
  - Reference to SVHC on Candidate List
  - Authorizing signature, title, and date
- Update records (Config management or REACH database)

Help!

- The European Chemicals Agency website
  - Check the legislation
  - Check the Guidance sections
  - Check the Frequently Asked Questions
  - Contact the national helpdesk
- Talk to colleagues and business/trade associations
- Consultants, third party's….many!
- Knowledgeable companies in the supply chain

References

- European Chemicals Agency (ECHA)

http://echa.europa.eu/web/guest/regulations/reach/

http://echa.europa.eu/documents/10162/19126370/svhc_roadmap_2015_en.pdf

http://echa.europa.eu/documents/10162/13632/articles_en.pdf

- EUR-Lex: Access to European Union law

http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=OJ:L:2006:396:TOC

- European Commission

http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm