



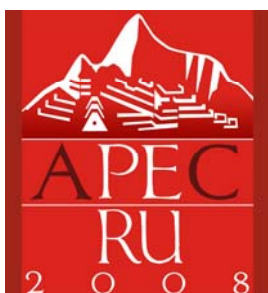
**Asia-Pacific
Economic Cooperation**

2008/SOM1/SCSC/TFTF/005

Agenda Item: 5

GE Healthcare Approach to REACH

Purpose: Information
Submitted by: GE Healthcare



**Sub-Committee on Standards and
Conformance Trade Facilitation Task Force
Meeting
Lima, Peru
23 February 2008**



GE Healthcare Approach to REACH

“Registration, Evaluation & Authorization of Chemicals”

February 2007
APEC, Peru

Tayyeb Mirza
GE Healthcare
Global Chemical Leader
REACH Program Manager

Beth A. Hulse
GE Healthcare
Global Regulatory Manager
Environmental Products



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A global company

GE is a family of businesses aligned with our customers' needs.

Operations in
over
100+ countries

300,000+
employees
worldwide

Manufacturing
facilities
in **40+** countries



Commercial Finance



Infrastructure



Industrial



Healthcare

NBC Universal



Consumer Finance

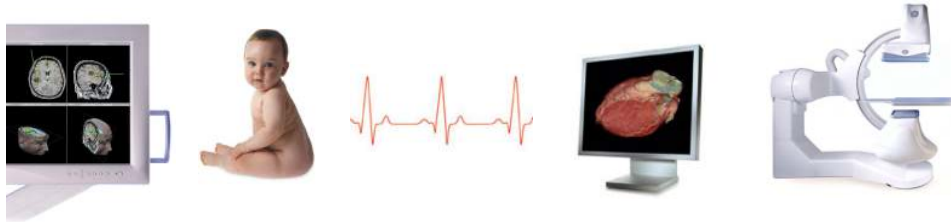


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GE Healthcare

GE Healthcare brings the world medical science and technologies that are helping to transform healthcare. We are working with our partners in healthcare to help them predict, diagnose, inform, and treat disease earlier than ever.

\$15B business, 42,000 employees



Diagnostic Imaging • Interventional Cardiology & Surgery • Clinical Systems
Healthcare Information Technologies • Services • Bio-Sciences

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EU REACH...the Requirements



Registration, Evaluation & Authorization of Chemicals

REACH... a very complex comprehensive chemical management regime

- Managed by New European Chemicals Agency (ECHA)
- Impacts the entire supply chain in EU and across the globe
- Information gathering & reporting for next 10 years
- To effectively manage...must focus on immediate critical time frames

Purpose of REACH

- 1) Protection of human health & environment
- 2) Substitute substances of high concern
- 3) Focus on risk management
- 4) Single chemical system for existing and new substances
- 5) Shift responsibility from authorities to industry and downstream users

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EU REACH...1st Deliverables

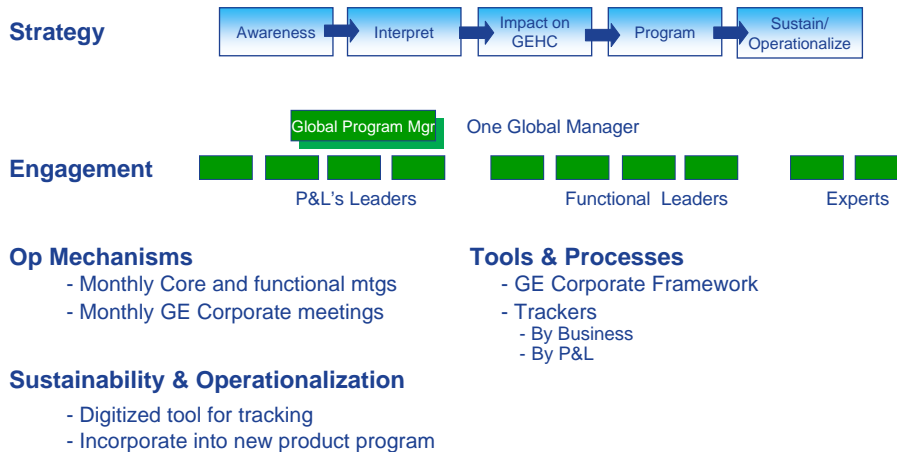


Critical timing:

- **May 16 2008:** PPORD notifications, Product and Process Oriented Development
- **June 1 – November 30, 2008:** GE and or suppliers have obligations to submit pre-registrations
 - Registration tasks and obligations
 - Preparation of Registration Dossier
- **June 1 2008,** Provide SDS's in REACH format
- If manufacturing or importing more than 10 tons per year, must also provide:
 - Chemical safety assessment & chemical safety report
 - Customer must communicate to GE how will utilize chemical.

Ongoing supply chain obligation - Modify registration to account for new uses as
 Long as not represent huge risk to human health & environment

GEHC REACH Program Strategy



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Global REACH Organization...by Business & function

Global Leader

GEHC Global REACH Leader

Core Team

REACH Business Leaders

Diagnostic Imaging	Clinical Systems	Life Sciences
Medical Diagnostics	Surgery	IITS

Functional Leaders

Sourcing	Materials	Environment Health Safety
Service Parts	Operations	

Experts

Corporate/GEHC legal	Consultants	Corporate/GEHC EHS
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Program consistency across GEHC ...common timing, tools, org structure, op mechanisms

Beth A. Hulse, GEHC - Shanghai 7 /

Internal Communication & Operating Mechanisms

- Communication of regulation to stakeholders
- Training on the regulation
- Monthly operating mechanisms for affected functions
- GE Corporate & business programs on how to comply
- Roll out of Company wide tools
- Communication with suppliers & customers
- Business and leadership reviews
- Trackers for Compliance

<p>Monthly GEHC REACH Meetings</p> <ul style="list-style-type: none"> Sourcing EHS Operations Materials Service Parts
<p>Monthly GE Corporate</p> <ul style="list-style-type: none"> Businesses Functions Corporate Consultants

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Supplier Communication & Compliance

- Education of suppliers on REACH
- Letters to suppliers
- REACH in supplier contracts
- Track pre-registration compliance
- New supplier if not compliant

...Enhance processes for change control & new product programs

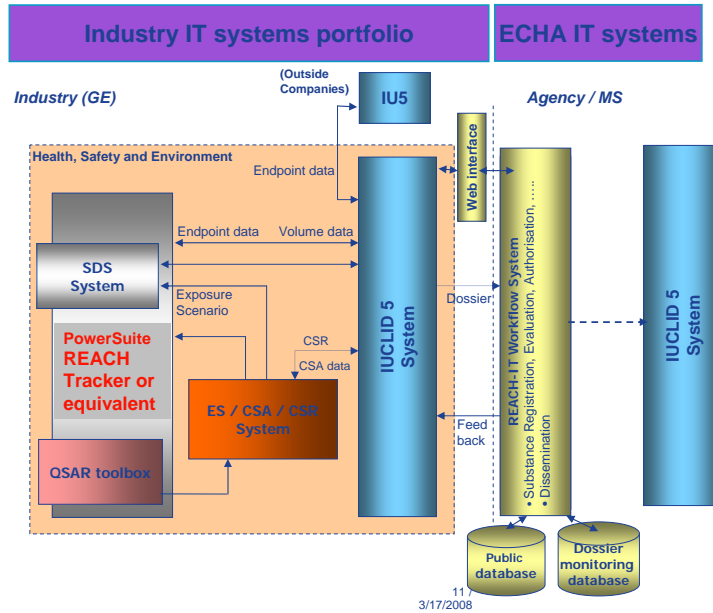
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Ensuring Compliance - Tracking Key Milestones

Pre-registration Complete 30/09/2008					
Pre-Registration substance list produced 31/05/2008					
Pre-Registration program Developed 30/04/2008					
Exposure Scenarios developed for relevant GEHC products 31/10/2008					
GEHC Customers contacted re:use of our materials 31/10/2008					
Confirmation of support for all Critical Chemicals 30/04/2008					
Suppliers contacted re: priority & critical chemicals 30/04/2008					
List of Articles requiring notification produced 30/04/2008					
Articles reviewed for items that may release > 1 tonne 30/04/2008					
Critical Chemicals Identified 29/02/2008					
Criticality Review of all CSI performed. 29/02/2008					
Priority (> 1 tonne) materials Identified 29/02/2008					
Chemical Inventory Produced					
REACH Team Formed					
REACH Leader Assigned					
Businesses					
Lifesciences					
Medical Diagnostics					
Clinical Systems					
Diagnostic Imaging					

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GE Process and Integration with ECHA System



GE Tool- REACH Tracker

Interface for GE businesses & sites to create & manage tracking, building chemical substance inventories, & facilitating REACH compliance activities

- Create, manage, and assign ownership for REACH tracking
- Integrated data mining
- Build CSIs using the web-based interface or Excel based upload template
- Facilitate REACH compliance activities and supplier/customer communications
- Track pre-registration/registration targets, ownership, and followup
- Data mine and analyze across and within business units and compare tonnages against thresholds

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GE Healthcare Areas of Risk... Requiring Greatest Focus



- ...Complete list pre-registered
- ...No impact on supply chain
- ...Registration completed by GEHC or suppliers...accuracy/timely/complete
- ...Cost for registration & testing reflected in price of supplied parts
- ...Compliance...far the biggest risk is suppliers
 - If not in EU, not familiar with REACH
- ...Time & effort to convert MSDS into REACH format

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Where to find more information: ECHA



- <http://echa.europa.eu/>
 - Guidance updated
 - Software tools: IUCLID 5
 - REACH Navigator → REACH Status
 - REACH FAQs
 - Helpdesks (REACH, ECHA & IUCLID)

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Thank You

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