

Global Chemical Regulatory Changes

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- Introduction
- International Regulatory Changes
 - U.S. Department of Homeland Security (DHS) (Chemical Facility Anti-Terrorism Standards (CFATS))
 - GHS
 - REACH
- Conclusion

International Regulatory Changes

- Multilingual
- Complexity
- Expertise
- Compliance

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DHS Chemical Facility Anti-Terrorism Standard (CFATS)

- Establishing “risk-based performance standards” for the security of chemical facilities (Oct. 2006)
- CFATS Interim Final Rule (6 C.F.R. Part 27)
 - Promulgated: April 9, 2007
 - Effective: June 8, 2007 (except Appendix A)

- Appendix A to CFATS: Final Rule
 - Essential part of the IFR
 - “Tentative list” of Chemical of Interest (COI)
 - “Revised list” (Final Rule)*

* Adds provision: How to calculate the quantities of COI (in possession)



Appendix A – Chemicals of Interest (COI)

- Approx. 300 hazardous chemicals
- Screening Threshold Quantities (STQs)
- Security hazard classifications for each chemical
 - “Release (Toxic, Flammable, Explosives)”
 - “Theft or Diversion (Chemical Weapons/Chemical Weapons Precursors, Weapons of Mass Effect, Explosives/Improvised Explosive Device Precursors)”
 - “Sabotage or Contamination”

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DHS CFATS

- Purpose
 - To ensure the security of facilities storing potentially dangerous chemicals
- Who is impacted?
 - Any business/ facility that uses or possesses (or later comes into possession of) the COI in quantities that meet or exceed the STQs
 - **ALL** chemical facilities must complete and submit “Top-Screen”
 - Except (Statutory exemption)
 - Facilities under the Maritime Transportation Security Act
 - Public Water Systems (Safe Drinking Water Act)
 - Treatment Works (Federal Water Pollution Control Act)
 - Any facility owned/operated by the Dept. of Defense or the Dept.. of Energy
 - Any facilities subject to Nuclear Regulatory Commission regulation



DHS CFATS

- “Top-Screen” procedures
 - All chemical facilities submit “Top-Screen” to DHS
 - No minimum time limit for how long the COI are at the facility
 - Includes chemicals routinely stored in storage tanks or in warehouses (e.g. propane, ammonium nitrate)
 - Chemicals delivered on site for immediate consumption
 - DHS determines “whether a facility is a ‘high-risk’ which will then be considered as a ‘covered facility’”
 - DHS notifies the facility
 - What must the facility do?

“Top Screen” Procedures

- What must the facility do?
 - Complete “Top-Screen” questionnaires based on the corresponding Screening Threshold Quantities (STQs) of the COI (Appendix A)
 - STQs – NOT threshold quantities
 - Must submit “Top-Screen” notice to DHS
 - November 20, 2007 starts the clock for Top Screen Submission (Deadline: Jan. 22, 2008)
 - If facility comes into possession of the COI after Nov. 20, 2007, the facility must submit the Top Screen within 60 calendar days of coming into possession of the chemical
 - DHS will determine & notify the high risk “covered” facility

“Top Screen” Procedures

- Must prepare the followings:
 - Security Vulnerability Assessments (SVAs) within 90 days of receiving written notice from DHS
 - Asset characterization, threat assessment, security vulnerability, risk assessment & countermeasure analysis
 - Site Security Plans (SSPs) within 120 days of receiving notice from DHS
 - Address each security vulnerability addressed in SVAs and identify measures to address each vulnerability
 - Address as many as 19 categories of risk-based performance standards (e.g. securing the facility’s perimeter; site assets; screening and controlling access to the facility; deterring theft and diversion of potentially dangerous chemicals; training; etc.)
 - Alternative Security Programs (ASPs)
 - Chemical-terrorism Vulnerability Information (CVI)



“Top Screen” Procedures

- Must prepare the followings:
 - Alternative Security Programs (ASPs)
 - Not a substitute for the required SVAs
 - Chemical-terrorism Vulnerability Information (CVI)
 - Protected information

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Conclusion (DHS – CFATS)

- For ANY FACILITY that manufactures, uses, stores, or distributes certain chemicals (COI) at or above a specified quantity.
 - Be familiar with the procedures & substantive security performance standards
 - Have sufficient technical & legal expertise
- Penalties: up to \$25,000 for each day

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http://www.unece.org/trans/danger/publi/ghs/ghs_rev02/02files_e.html



GHS (Rev. 2) 2007

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- UN Purple Book
- U.S.
- Europe
- Asia-Pacific
- Latin America
- Middle-East & Africa

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Scope

Classifying substances and mixtures

- Health and Environmental effects
- Physical hazards

Hazard communication requirements

- MSDSs
- Labels

Countries can choose to implement GHS in its entirety or implement only certain parts (building block approach)

Classifying Substances and Mixtures - Health and Environment Hazards

- Acute toxicity
- Skin corrosion/irritation
- Severe eye damage/eye irritation
- Respiratory sensitizer
- Skin sensitizer
- Germ cell mutagenicity
- Carcinogenicity
- Toxic to reproduction
- Specific Target Organ Toxicity following Single Exposure
- Specific Target Organ Toxicity following Repeated Exposure
- Aspiration hazard
- Hazardous to the Aquatic Environment (Acute; Chronic)

Classifying Substances and Mixtures - Physical Hazards

- Explosives
- Flammable Gases
- Flammable Aerosols
- Oxidizing Gases
- Gases under Pressure
- Flammable Liquids
- Flammable Solids
- Self-Reactive Substances
- Pyrophoric Liquids
- Pyrophoric Solids
- Self-Heating Substances
- Substances which on contact with water emit flammable gases
- Oxidizing Liquids
- Oxidizing Solids
- Organic Peroxides
- Substances Corrosive to Metal

Hazard Communication – MSDS

Sixteen section MSDS required

- Substance identity and company contact information
- Hazards identification
- Chemical composition and data on components
- First aid measures
- Fire-fighting measures
- Accidental release measures
- Handling and storage
- Exposure controls and personal protection
- Physical and chemical properties
- Stability and reactivity
- Toxicological information
- Ecological information
- Disposal considerations
- Transport information
- Regulations
- Other information

Four independent regulatory authorities

- Occupational Safety and Health Administration (OSHA)
- Environmental Protection Agency – Federal Insecticide Fungicide and Rodenticide Act (EPA FIFRA)
- Consumer Products Safety Commission (CPSC)
- Department of Transportation (DOT)

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Current:

Hazard Communication Standard (HCS)

Addresses:

- Health hazards
- Physical hazards
- Label requirements
- MSDS requirements

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COMPARISON – HCS V GHS

	HCS	GHS
<i>Health Hazards</i>	Firm cutoffs	Cut offs vary by endpoint
<i>Physical Hazards</i>	Several physical hazard endpoints	Multiple categories within an endpoint; leads to signal words, hazard phrases, and pictograms
<i>Label Requirements</i>	Performance oriented Different placement of information on the label	Specific requirements (signal words, hazard statements, pictograms) Different placement of information on the label
<i>MSDS Elements</i>	8 section MSDS required	16 section MSDS required; more extensive information required than ANSI and ISO MSDS standards



Label requirements

Classification schemes impacted

- Physical properties
- Chemical properties
- Toxicology endpoints

Adoption of GHS requires rule-making

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CPSC operates under the Federal Hazardous Substances Act (FHSA)

COMPARISON – FHSA V GHS

FHSA	GHS
Risk-based	Hazard-based
Likelihood or probability of something happening	Absolute, not taking probability into consideration
	Classification and labeling includes more categories and different criteria
	Format and placement of label information are different
Generally, symbols are not used	Use of symbols

- DOT classifications are impacted
 - Physical hazards (consistent with International transport requirements: “United Nations Recommendations on the Transport of Dangerous Goods”)

EU Proposed Regulation

- Issued by European Commission Council (June 27, 2007)
 - Revised in June 2008 (corrections, deletion of text, new text)
 - Directive 67/548/EEC & Directive 1999/45/EC repealed (June 1, 2015)
- Classification, packaging and labeling (June 1, 2015)
- The Safety Data Sheet Directive (91/155/EEC) has been taken up by REACH (Regulation No. 1907/2006)

Transitional Periods

- Substances: December 1, 2010.
- Mixtures: June 1, 2015.
- Between December 1, 2010 and June 1, 2015 (Substances):
 - Classification (Directive 67/548/EEC & proposed Regulation)
 - Packaging and labeling (Proposed Regulation)

Transitional Periods (new draft)

- Substances classified, labeled and packaged according to Directive 67/548/EEC & placed on the market before Dec. 1, 2010
 - Not required to be re-labeled and re-packaged according to this Regulation until Dec. 1, 2012
- Mixtures classified, labeled and packaged according to Directive 1999/45/EC & placed on the market before June 1, 2015
 - Not required to be re-labeled and re-packaged according to this Regulation until June 1, 2017

Proposed Regulation (Classification)

- Adopted GHS Physical, Health & Environmental Hazard Classes
- Differences (not adopted):
 - Flammable liquids (Cat. 4)
 - Skin corrosion/irritation (Cat. 3)
 - Aspiration hazard (Cat. 2)
 - Acute aquatic (Cat. 2 and Cat. 3)
 - Acute toxicity (Cat. 5)
- Additional EU hazard class (i.e. Hazardous for the Ozone Layer)

Proposed Regulation (Label)

- Name, address and telephone number of the supplier
- Nominal quantity of a substance or mixture
- Product identifiers
- Hazard pictograms
- Signal words
- Hazard statements
- Precautionary statements
- [Supplemental information on hazards]

GHS Implementation

- Japan
- New Zealand

GHS Implementation Status

- Korea
- Taiwan
- China

GHS Activities in Other Countries (in-progress)

- Australia
- Malaysia
- Indonesia
- Singapore
- Thailand
- Vietnam

GHS Implementation – Japan

- Industrial Safety & Health Law (ISHL)(Dec. 1, 2006)
- MSDS & Label
- ISHL listed substances (non-listed substances)

GHS Implementation – Japan

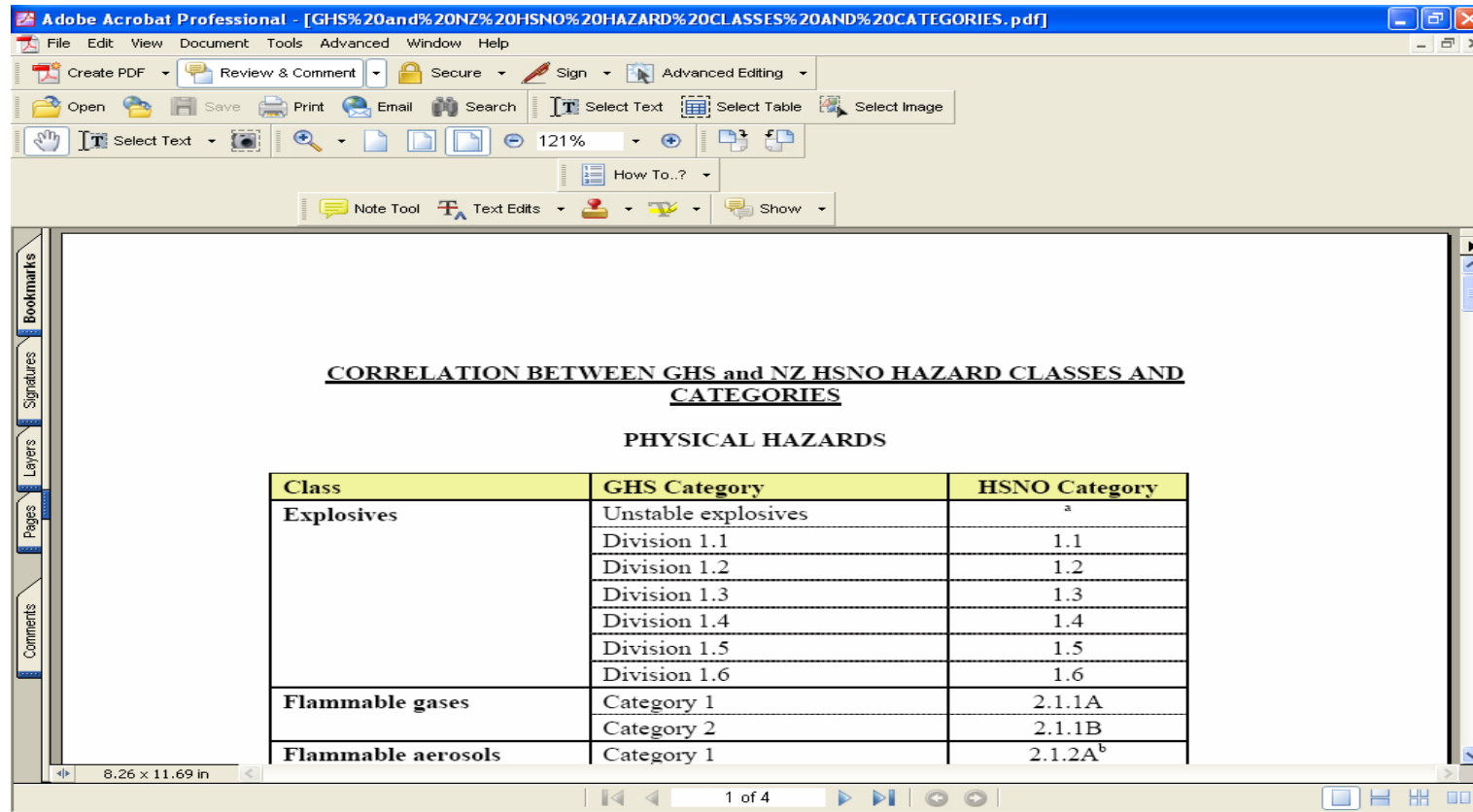
- Classification Results List (1,500 regulated chemicals) (<http://www.nite.go.jp/>)
- Label & MSDS (Japanese Industrial Standard (JIS))
 - JIS Z 7251:2006 (Label)
 - JIS Z 7250:2005 (SDS) (December 31, 2010)

New Zealand

- Hazardous Substances and New Organisms Act 1996
- Hazardous Substances (Classification) Regulations 2001
- Hazardous Substance (Chemicals) Transfer Notice 2006
- Code of Practice for the Preparation of Safety Data Sheets (SDS) (Sept. 2006)
- Code of Practice for Labeling of Hazardous Substances (Aug. 2007)
- HSNO Hazard Classification System (based on UN GHS with few differences)

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GHS Implementation – New Zealand



CORRELATION BETWEEN GHS and NZ HSNO HAZARD CLASSES AND CATEGORIES

PHYSICAL HAZARDS

Class	GHS Category	HSNO Category
Explosives	Unstable explosives	^a
	Division 1.1	1.1
	Division 1.2	1.2
	Division 1.3	1.3
	Division 1.4	1.4
	Division 1.5	1.5
	Division 1.6	1.6
Flammable gases	Category 1	2.1.1A
	Category 2	2.1.1B
Flammable aerosols	Category 1	2.1.2A ^b

Korea

- Ministry of Environment (MOE)
 - Toxic Chemical Control Law (TCCL)
 - Final Draft of full adoption of GHS from July 1, 2008
 - Latest: Draft amendment to TCCL by NIER (Notice 2008-183, May 2008)
- Ministry of Labor (MOL)
 - Standards for Classification and Labeling of Chemical Substances and Material Safety Data Sheet (MSDS) (Revised Jan. 1, 2008)

Korea

Ministry of Labor – Classification, Label & MSDS

- Physical hazards, health hazards & environmental hazards
- July 1, 2008 (pure substance & mixtures)
- Extension dates:
 - Substances: July 1, 2010
 - Mixtures: Jan. 1, 2015 (draft amendment on May 2008)
→ July 1, 2013 (MOL Decree No. 303, June 27, 2008)

Korea

Ministry of Environment – TCCL Chemical List

- Toxic chemical classification (expected to be publicly available after 2010)
- Single toxic chemical: July 1, 2011
- Mixtures: July 1, 2013
- Exception: “New single toxic chemical” after July 1, 2008 must comply with GHS standards



GHS – Asia Pacific



Classifications	UN	Korea MoL	Korea MoE (Draft)
FLAMMABLE GASES	Category 1 - 2	Category 1	Category 1 - 2
FLAMMABLE LIQUIDS	Category 1 - 4	Category 1 - 3	Category 1 - 3
ACUTE TOXICITY	Category 1 - 5	Category 1 - 4	Category 1 - 4
SKIN CORROSION / IRRITATION	Category 1 - 3	Category 1 - 2	Category 1 - 2
SERIOUS EYE DAMAGE / EYE IRRITATION	Category 1, 2A, 2B	Category 1, 2A	Category 1, 2
AQUATIC TOXICITY (ACUTE)	Category 1 - 3	Category 1	Category 1 - 3



- Fully adopts the 16 sections of the UN Purple Book
- Must comply with the GHS standards
 - Pure substances: July 1, 2010
 - Mixtures: July 1, 2013
- Should be prepared in the Korean language
- The test data conducted in compliance with GLP (Good Laboratory Practice).
- Should be prepared for all substances and mixtures containing more than 1% of physical, health, and environmental hazards.

Taiwan

- Rules on Hazard Communication and Labeling of Hazardous Substances
(Council of Labor Affairs - CLA)
 - Issued in Oct. 2007
 - Effective: Dec. 31, 2008
 - Classification: No Environmental Hazards
- Environmental Protection Agency (EPA) GHS Regulation
 - Issued in Dec. 2007 (No effective date)
 - Classification (Health, Physical & Environmental Hazards)

China

- Safety Regulation on Chemicals Classification and Labeling (direct translation of GHS Recommendation)
- 26 GB Standards (GHS Classification & labeling of chemicals)
 - Issued in 2006 (effective date: Jan. 1, 2008)
[transitional period]
 - Current MSDS and classification & labeling regulations are still valid
 - Draft Regulation (expected)

Singapore

- Singapore Standard 286 –Caution Labeling for Hazardous Substances (SS 286 Part 2)
- Issued for public comment in 2007 (Draft)

Australia

- Draft National Standard for the Control of Workplace Hazardous Chemicals
- Draft National Code of Practice for Control of Workplace Hazardous Chemicals
- Will follow EU's date (supposed to be 2008)

Thailand

- Timetable (Phased-in approach)
 - Phase 1 (2007): GHS Hazard Statements (all physical hazards, and some health and environmental hazards) for single substances
 - Phase 2 (2008): All health hazards, environmental hazards, and physical hazards for single substances & mixtures
 - Feb. 2009 for pure substances; Feb. 2010 for mixtures

Thailand

- Classification (Hazardous Substances Act B.E. 2535)
 - Ministry Notification (Guideline for GHS classification, labeling & SDS) [No Draft yet]
- MSDS (ISO 11014-1(1994)) – to be revised
 - Hazardous Substances Act & Factory Act
(GHS hazard and precautionary statements)
- Labeling – to be revised
 - Hazardous Substances Act, Factory Act & regulations
(Hazard symbols not standardized)

Malaysia

- Department of Health & Safety (DOHS)
 - CLASS (Classification, Labeling and Safety Data Sheets) Regulations (Draft) [2009]
 - Grace period: 1 year
- Ministry of Environment (MOE)
 - EHS Notification and Registration System (Voluntary)
 - Regulation not in place yet
 - 2010 (Notification required)
 - Grace period (TBD); gradual phase-in (1 ton)
 - Environmental Quality Act (to be amended this year)

Scope

- All “Environmentally Hazardous Substances” (according to GHS criteria or Annex 1)
 - Out of scope: Pesticides Act 197; Poisons Act 1952; and Chemical Weapons Convention Act 2005
- Manufacturers & Importers of pure substances
- Importers of Chemical mixtures/Finished Products

Types of Notifications

- Basic Notification: Substance on Annex 1 → basic data
- Full/Detailed Notification: Substance Not on Annex 1 → evaluation according to GHS

Indonesia

- Presidential Regulation (Draft) [Sept. 2006; 3rd Revision]
 - GHS Pictograms and MSDS
- Ministry of Environment Regulation No. 3 of 2008 (Permen LH No. 3 tahun 2008)
- Government Regulation No. 74 of 2001 (to be amended)

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The Philippines

- Consultations, workshops, roundtable discussions
- Revisions to be made into the existing legislations

Vietnam

- Chemical Law (New)
- Legal obligations on classification, labeling and SDS
- Indication of the Government Body responsible for GHS implementation (Ministry of Industry and Trade)

Latin America

- Chile, Argentina, Brazil and Peru

Middle East

- Awareness

South Africa

- Classification, Packaging & Labeling Standard

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Companies will need to re-evaluate how their substances and mixtures are classified for each regulatory entity, country and/or region

- Health and Environmental effects
- Physical hazards

and will likely need to re-issue several

- MSDSs
- Labels

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Various GHS implementation scenarios globally →
GHS is not plug and play

Compliance will be:

- Labor intensive, costly & time consuming especially initially (home-grown system v. ERP)
- Confusing (conflicting regulatory approach among governmental agencies/ministries)
- Transitional (occurring over period of months/years)

R – Registration

E – Evaluation

A – Authorization

C – Restriction

H – Chemicals

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- Regulation (EC) No 1907/2006 (December 2006)
 - Entered into force: June 1, 2007
 - Established a European Chemicals Agency
 - Amended Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
 - Available in most of the 23 official EU languages

- **Scope:**

Manufacture, import, placing on market and use of substances (on their own, in preparations or in articles (i.e. finished products))

- **Goals:**

- Improving health and safety of workers and the general public.
- Improving environmental protection – avoiding chemical contamination of air, water, soil and damage to biodiversity
- Maintaining a competitive/innovative chemicals

Key Elements:

- Introduces a Single Coherent System for new (non phase-in) and existing (phase-in) substances
- Registration of manufactured/imported chemical substances > 1 tonne/year (Various dead-lines over a 11 years period)
- Increased information and communication throughout the supply chain – changes to SDS requirements
- Evaluation of some registered substances
- Use of substances of very high concern will require Authorisation
- Restrictions: “Safety net”
- Classification and Labelling Inventory
- Chemicals Agency to manage the system.
 - REACH-IT including IUCLID 5

- Manufacturers: Required to register chemical substances exported to the EU (1 or more tons per year)
- Pre-registration (June 1, 2008 – Dec. 1, 2008)
 - Substances on their own, in preparation or articles which are not pre-registered during this period cannot be manufactured in the EU or imported into the EU
 - Companies exporting to the EU cannot pre-register (or register) themselves
 - EU Importer, or
 - Nominated EU-established “Only Representative” (OR)

Must pre-register or register

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“phase-in substances” staggered deadlines

- November 2010:
 - All substances: 1000 tons and above
 - Carcinogen, Mutagen, Toxic to Reproduction (CMR cat. 1 or 2): above 1 ton/year
 - Very aquatic toxic (R50/53): above 100 tons
- June 2013:
 - Substances: 100 tons or more (but less than 1000 tons)
- June 2018:
 - Substances: 1 ton or more (but less than 100 tons)

- Submission of a simple pre-registration dossier to the Agency latest by December 1, 2008
 - Content:
 - Substance identity
 - Name and address of registrant
 - Expected dead-line for registration (tonnage dependant)
 - Similar substances (for read-across purposes)
- Existing or new substances not pre-registered will not benefit from the 11 year phase-in period

• Therefore ->

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**Do not miss the pre-
registration dead-line!**

Latest Changes (May 2008):

- “Ors” on behalf of more than one non-EU manufacturer for a certain substance must submit a separate registration for each of these substances manufacturers
- Non-EU manufacturer of a substance exported into Community territory indirectly by a non-EU formulator (which uses that substance in its preparation) can appoint an “OR” to register the tonnage exported by the exporter

- A non-EU formulator can refer to a registration made by an “OR” appointed by its non-EU supplier (follows from earlier point)
- Non-EU manufacturers that decide to change their appointed “OR” for a particular substance can submit an update to the ECHA & do not need to submit entirely new registration dossier
 - Newly appointed “OR” has to submit a new registration dossier
 - In agreement with the old “OR,” the new “OR” can simply update the registration dossier

Latest Changes (August 2008):

- Substances of Very High Concern (SVHC)
- Definition: Article 57 of Regulation (EC) No 1907/2006
- Proposed list (1st Draft) - Aug. 12, 2008
 - “Candidate List”
 - Authorization List (Annex XIV) – June 2009
 - Prohibited unless authorized

- Most → least developed legal regimes (presents its own legal challenges)
- Comprehensive regulatory knowledge locally (country specific) needed

Compliance will be:

- Lengthy process
- Challenging to keep up with any key regulatory changes (dynamic)
- Transitional (occurring over period of months/years)

Non-compliance:

- Penalties
- Cannot market products

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Questions



Thank you

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