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Latest Changes in Global Regulatory Requirements

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Agenda

- North America
 - United States
 - Export Notification - TSCA
 - Miscellaneous
 - Canada
 - Proposed DSL changes
 - Challenge to Industry Program
- REACH
- Globally Harmonized System (GHS)
 - Europe
 - North America
 - Japan
 - New Zealand
 - Asia
- Transportation
 - IATA/US DOT

Ariel/3E Company



- Nearly 20 years of industry leadership in the regulatory content area
- Products and services cover the entire regulatory lifecycle of a chemical
- First to introduce software to load regulatory data into SAP EHS (1999)
 - Product Safety
 - Dangerous Goods
 - Chemical property & hazard data
 - OCC certified content
- Serve customers world-wide
- Regulatory content and IT products supported by multinational staff with backgrounds in regulatory compliance, law, chemical engineering, systems and databases, international relations
- Global locations
 - United States
 - California
 - Metro Washington, DC
 - Tennessee
 - Europe
 - Japan (sales, only)

North America

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Export Notification – TSCA

Background

- TSCA 12(b) requires that any person who exports, or intends to export, a chemical substance or mixture subject to appropriate section 4, 5, 6, or 7 actions notify EPA of such export
- EPA then notifies the government of the importing country about the US regulatory action concerning the substance or mixture

North America – United States



Export Notification – TSCA

Background

- Original rule required annual notification for each country to which chemicals substances or mixtures subject to appropriate actions were exported
- Changes in 1993 allowed for one-time notification for chemicals subject to test rules or consent orders under section 4

Export Notification – TSCA

Changes – Effective January 16, 2007

(FR notice – November 14, 2006)

- Final rule changed annual notification requirements to **one-time notification** for exports of chemicals subject to the following TSCA actions:
 - Section 5(a)(2) Proposed or Final SNURs
 - Section 5(e) Consent Orders
 - Section 5(b) Data Submissions
- EPA stated in its November 14, 2006 final rule (see 71 FR 66241) that “any export notice for a chemical subject to a TSCA section 5(e), 5(a)(2), or 5(b) action submitted prior to the effective date of this final rule would satisfy the one-time reporting requirement established in the new rule.”

North America – United States



Export Notification – TSCA

Reporting Summary – Effective January 16, 2007

One-time Reporting Required

- Section 4(a) Final Test Rules
- Section 5(a)(2) Proposed or Final SNURs
- Section 5(e) Consent Orders
- Section 5(b) Data Submissions

Annual Reporting Required

- Section 5(f) Civil Actions
- Section 6 Proposed or Final Rules
- Section 7 Civil Actions

North America – United States



Export Notification – TSCA Additional Changes – Effective January 16, 2007

New – *de minimis* level

These exports **do not** require notification:

- Chemicals exported at a concentration of less than **1%** (by weight or volume)
- Known or potential human carcinogens exported at a concentration of less than **0.1%** (by weight or volume)
- PCBs exported at a concentration of less than or equal to 50 ppm (by weight or volume)

North America – United States



Export Notification – TSCA

Additional Changes – Effective January 16, 2007

Known or potential human carcinogen (definition)

- Listed in the latest edition of the Report on Carcinogens by the National Toxicology Program (NTP)
- IARC Group 1, Group 2A, or Group 2B classifications
- OSHA carcinogen or potential carcinogen (29 CFR part 1910, Subpart Z)

North America – United States



Export Notification – TSCA

No changes made to the following

- Exporters of chemicals subject to TSCA section 5(f), 6, or 7 actions will continue to be required to submit annual export notifications to EPA
- Notifications are to be sent to EPA within 7 days of forming the intent to export or on the day of export, whichever is sooner, and includes:
 - Name and address of exporter
 - Name of the chemical substance or mixture
 - The date of export or intended export
 - The country of import
 - The section of TSCA under which EPA has taken action

North America – United States



Miscellaneous

- EPA releases white paper on nanotechnology (Feb. 2007)
- States implement electronic recycling
- States regulate heavy metals
- VOC limits set for consumer products (Ohio)
- Various revisions to air/water/waste regs (i.e. TRI, CAA, RCRA, EPCRA)

North America – Canada

Proposed DSL changes

- On November 11, 2006, Canada's Minister of the Environment published a notice of intent to delete 1105 substances from the Domestic Substances List (DSL)
- 180 day comment period
- Substances slated for deletion are listed in WebInsight

North America – Canada



Challenge to Industry Program

- Launched on February 3, 2007
- Health Canada and Environment Canada published call for information on 15 of the 200 high priority substances
 - Manufactured or imported
 - How used by manufacturers/importers
 - In what quantities
 - By what companies or industrial sectors
 - In what quantities are they used, released and sold
 - Information on buyers
- Above information or request for an extension due by June 5th
- Applies to substances manufactured or imported at more than 100 kg in 2006
- Following review of information, Health Canada and Environment Canada will provide a 60-day comment period on their screening assessment and proposed risk measures
- Recommendations will be published by July 5, 2008 or earlier if industry does not provide new information during comment period
- 15 to 30 substances will be published at three-month intervals

North America – Canada



Challenge to Industry Program (cont.)

persistent, bioaccumulative, and inherently toxic to non-human organisms

- 78-63-7 Peroxide(1,1,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl)
- 1068-27-5 Peroxide, (1,1,4,4-tetramethyl-2-butyne-1,4-diyl)bis[(1,1-dimethylethyl)
- 6731-36-8 Peroxide, (3,3,5-trimethylcyclohexylidene)bis[(1,1-dimethylethyl)
- 12236-64-5 2-Naphthalenecarboxamide, N-[4-(acetylamino)phenyl]-4-[[5-(aminocarbonyl)-2-chlorophenyl]azo]-3-hydroxy-
- 43035-18-3 Benzenesulfonic acid, 4-[[3-[[2-hydroxy-3-[(4-methoxyphenyl)amino]carbonyl]-1-naphthalenyl]azo]-4-methylbenzoyl]amino]-, calcium salt (2:1)
- 54079-53-7 Propanedinitrile, [[4-[[2-(4-cyclohexylphenoxy)ethyl]ethylamino]-2-methylphenyl]methylene]-
- 59487-23-9 2-Naphthalenecarboxamide, 4-[[5-[[[4-(aminocarbonyl)phenyl]amino]carbonyl]-2-methoxyphenyl]azo]-N-(5-chloro-2,4-dimethoxyphenyl)-3-hydroxy-

high hazard to humans and a high likelihood of exposure to individuals in Canada

- 75-56-9 Oxirane, methyl-
- 91-08-7 Benzene, 1,3-diisocyanato-2-methyl-
- 91-20-3 Naphthalene
- 106-88-7 Oxirane, ethyl-
- 120-80-9 1,2-Benzenediol
- 123-31-9 1,4-Benzenediol
- 584-84-9 Benzene, 2,4-diisocyanato-1-methyl-
- 26471-62-5 Benzene, 1,3-diisocyanatomethyl-[5-1-o]

more information in **Canada Gazette February 3, 2007**

REACH

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REACH



- REACH = Registration, Evaluation, Authorization of Chemicals
- REACH impacts
 - Manufacturers
 - Importers
 - Distributors
 - Chemical Downstream Users
- Objectives of REACH
 - Protection of human health and the environment
 - Increased substitution and use of safer chemicals
 - Increased transparency
 - Promotion of non-animal testing
 - Maintenance and enhancement of the competitiveness of the EU chemical industry



REACH



Why a new regulatory framework

Existing regulation

- Concerns marketing of chemicals (including new chemical notification)*
- Different provisions for existing vs new substances
- *Responsibilities:*
 - Industry: classification, labeling and provisions of SDS; notification of new substances; provision of information
 - Authorities: risk assessment for existing substances, harmonization of classifications, marketing and use restrictions

REACH regulation

- Concerns manufacture, onsite use, and marketing of chemicals
- Different requirements for phase-in substances (based on existing and new substance status)
- *Responsibilities:*
 - Industry: registration, provision of data, evaluation, proposal of risk management measures, co-operation, classification, labeling, provisions of SDS and CSR
 - Authorities: evaluation and decision on restrictions, authorizations, animal testing

* Dangerous Substance Directive (67/548/EEC), Preparations Directive (1999/45/EC), Marketing and Use Restrictions Directive (76/769/EEC), Risk Assessment Regulation (793/93)

REACH



How does REACH affect industry

- Requires all substances produced or imported in quantities over 1 ton/yr to be registered
- Consolidates current EU inventories (EINECS and ELINCS) and creates new industry list with product registration number
- Requires separate registration for each producer
- Requires participation of both producers/importers and down-stream users
- Advocates “substitution” and “minimal animal testing” resulting in the need for data sharing

REACH



How does REACH work

Registration

(responsibility of chemical producers/importers)

- All substances (substances >1 ton) must be registered **by producer and by use**
- Includes information on chemical properties, manufacturing, uses, classification, labeling, exposure information
- Data obtained through computer modeling, epidemiological studies or animal testing
- Animal testing requires pre-approval
- Data sharing between producers required
- Substances produced in quantities > 10 tons/yr require a Chemical Safety Report (CSR)
- CSRs require data from down-stream users

REACH



How does REACH work

- Evaluation
 - Substances presenting a risk to human health or the environment
 - Two types of evaluation
 - Dossier evaluation prior to animal testing
 - Substance evaluation with regards to risk and risk management
- Authorization
 - Restricts the application and/or use of the substance
 - Substances likely to be subject to authorization/restriction
 - Category 1 and 2 carcinogens, mutagens or reproductive toxins
 - Persistent, bio-accumulative & toxic substances (PBT and vBvPs)
 - Endocrine disrupters (i.e. flame retardants)
 - Substances already covered by Directive 76/769/EEC

REACH



Manufacturer/Importer Responsibilities under REACH

- Registration
 - Data submitted based on thresholds
 - Identification of risk management measures
 - Maintenance of registration information (i.e. currency)
 - Testing scheme proposals
- Evaluation
 - Provision of additional information
- Authorization
 - Application dossier
 - Provision of information for socio-economic assessments

IMPORTANT

In order to produce and manufacture substances must be registered according to the established timeframe

REACH



Information in the Supply Chain

- Safety Data Sheets (SDS)
 - Primary information carrier in the supply chain
- Chemical Safety Reports (CSR)
 - Substance > 10 tons/yr
 - Includes information on
 - Chemical safety assessment
 - All identified uses
 - Proposed classification/packaging/labeling
 - Guidance on safe use
 - Input to the SDS

REACH



Downstream User Responsibilities

- Registration
 - Exposure scenarios information
 - Information on uses not reported by manufacturers/importers
 - Alternative risk management measures
- Evaluation
 - Provision of further information if required
- Authorization
 - Provision of information about authorized uses
 - Compliance with authorization (noted on SDS)

REACH



Data Sharing under REACH

- Purpose
 - avoidance of unnecessary animal testing (vertebrates)
- Benefits
 - Transparency
 - Substance Information Exchange Forum (SIEF)
 - One submitter for hazardous properties and classification data; some other data may be submitted jointly (i.e. chemical safety report); other data submitted individually
 - Cost sharing
 - voluntary or forced
 - Penalties
 - determined at national level

REACH



Special Provisions in REACH

- Special provisions have been determined for
 - Substances on ELINCS
 - Polymers – no registration or evaluation necessary
 - Intermediates – varies from non-isolated and isolated
 - Articles
 - Substances imported in preparations – below classification limits
- Re-evaluation rights
- Confidentiality issues

REACH



Deadlines for Pre-Registration/Registration

- New & existing substances are subject to registration requirements; different deadlines
- New substances
 - not on EINECS or ELINCS and not pre-registered
 - Registration requirements start June 1, 2008
- Existing substances
 - Pre-register
 - June – November, 2008
 - 11 year phase-in schedule
 - If pre-registration is missed
 - Substance must be registered by June 1, 2008
 - No phase-in

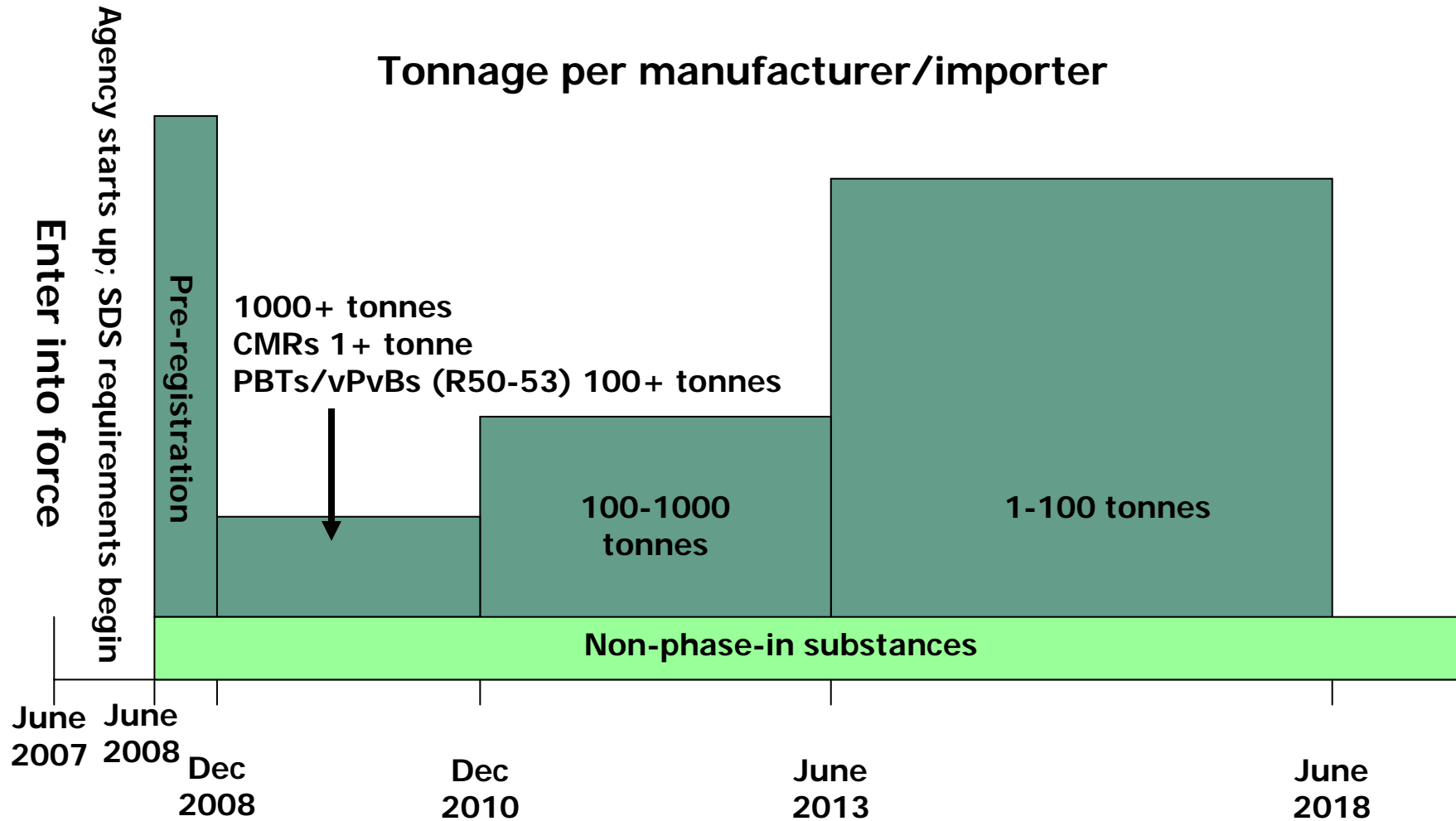
REACH



Deadlines for Pre-Registration/Registration

- New & existing substances are subject to registration requirements; different deadlines
- New substances
 - not on EINECS or ELINCS and not pre-registered
 - Registration requirements start June 1, 2008
- Substances registered between June 1 – November, 2008
 - November 30,2010
 - All substances > 1000 ton/year
 - Carcinogens, Mutagens, Reproductive Toxins > 1 ton/year
 - Very toxic to aquatic environment > 100 ton/year
 - May 31,2013
 - Substances < 1000 ton/year, but > 100 ton/year
 - May 31,2018
 - Substances < 100 ton/year, but > 1 ton/year

REACH Registration schedule



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Pre-registration is simple

- Content
 - Substance identity (CAS and EINECS numbers)
 - Name and address of registrant
 - Expected dead-line for registration (tonnage dependant)
 - List of similar substances, if any
- Each substance needs to be registered individually
- Existing or new substances not pre-registered will not benefit from the 11-year phase-in
- Agency will publish list of pre-registered substances by January 1, 2009

REACH

Registration is more complex

- Technical dossier
 - Identify of the manufacturer/importer
 - Identity of the substance
 - Information on manufacture and use
 - Classification and labelling
 - Exposure information
 - Guidance on safe use
 - Study summaries – substance properties
- Chemical Safety Report, if 10 ton/year

REACH



Articles

- Finished products ranging from pens to printer cartridges to textiles to plastic bottles to computers
- Substances intended to be released from articles under normal and reasonably foreseeable conditions of use
 - must follow the requirements for substance registration (i.e. pre-registration and volume deadlines)
- Very High Concern articles - substance not intended to be released from articles under normal and reasonably foreseeable conditions of use must notify if the following conditions are met
 - Substance > 1 ton/year
 - Concentration > 0.1% weight by weight
 - Producer or importer cannot exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal
- If substance already registered for use, no need to follow article requirements

REACH



What to do - in general

- Ensure imports are properly registered; work with European operations or importers
- Chemicals and products sold elsewhere for use in products ultimately imported into EU must be registered
- Don't forget - protect confidential business information

What to do - now

- Establish an inventory of substances used in Europe (manufactured and imported)
 - Identity (CAS number)
 - Tonnage
 - Known classification
- Decide what substances to register when
- Determine if any substance is likely to get on candidate list for authorization
- Downstream users to inform importer/manufacture of use
- Update Safety Data Sheets by June 1, 2007



Globally Harmonized System

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GHS Europe



General Comments

- **Draft regulation is available**
- **Public internet consultation has taken place (August 21 – October 21, 2006); comments are available**
- **Implementation goals**
 - **Stay close to GHS format and terminology (UN Purple Book)**
 - **Remain global**
 - **Keep scope as close as possible to existing EU system**
 - **Maintain current level of protection**
- **Not all GHS categories will be included in EU implementation**
- **Some of the current EU elements not covered under GHS will stay**
- **Implementation will be aligned with REACH**

GHS Europe



EU GHS Timeline (proposed)

- Phase 1
 - up to 3 years after entry into force of REACH
 - Current EU classification required for substances & mixtures; GHS optional
- Phase 2
 - 3 to 7 or 8 years after entry into force of REACH
 - Both EU and GHS classifications required for substances. Use only GHS for the label, but both for the SDS. Mixtures must use EU classification; GHS is optional
- Phase 3
 - 7 or 8+ years after entry into force of REACH
 - Both substances & mixtures must use the GHS classifications

GHS Europe



Changes as a result of EU GHS Regulation (proposed)

- Labels will be different
 - Some symbols are the same
 - Pictograms will be different
 - black on white with red frame instead of black on orange
- EU R & S phrases will be replaced by GHS hazard and precautionary statements
- The signal words 'Danger' and 'Caution' will be introduced

GHS Europe



GHS categories not implemented by EU Regulation (draft)

- Flammable gases, category 2
- Flammable liquids, category 2
- Skin corrosion/irritation, category 3
- Acute toxicity, category 5
- Aspiration hazards, category 2
- Acute aquatic toxicity, categories 2 and 3

Article 14 and Annex II include additional label elements from the current EU system

GHS North America



- United States
 - Impacts
 - OSHA
 - Published advance notice of proposed rulemaking in Sept. 2006
 - Issued guide comparing GHS MSDS requirements with ANSI, ISO and HCS – Oct. 2006
 - No proposal yet
 - EPA – FIFRA
 - Whitepaper outlining OPP concepts - 2004
 - Public meeting with stakeholders to review issues – Oct. 2006
 - No proposed rule
 - DOT
 - Aligning all related regulations with GHS; expected to be completed in 2007 with changes effective in 2008
 - CPSC
 - Conducting an assessment of GHS implementation issues
 - No implementation schedule

GHS North America



- Canada
 - Implementation process well laid out
 - Summary of results of deliberations by the sectors affected by GHS was developed
- Mexico
 - GHS will be implemented as soon as other key economies implement the system

GHS Japan



Chemical Classification Program

- Based on GHS
- Purpose: assist companies in developing
 - Safety Data Sheets
 - Labels
- METI, MHLW and MOE implemented GHS as a joint project
 - Industrial Safety and Health Law was amended in 2005
 - Industries voluntarily apply GHS labeling framework of the Poisonous and Deleterious Substances Control Law recommended – Dec. 2005
 - Japanese Industrial Standards (dictates SDS format) was revised according to GHS – Dec. 2005
 - Chemical labeling standards were introduced for the first time – Mar. 2006
- In the process of classifying 1500 target chemicals
 - 1400 chemicals have been processed as of March 2006
 - Was to be completed by 2006 year-end but delayed
- GHS classification manual available
 - http://www.meti.go.jp/policy/chemical_management/kokusai/GHS/GHS_Classification_Manual.htm

GHS New Zealand



Introduced through the Hazardous Substances and New Organisms (HSNO) Act

- Classification
 - Almost entirely consistent with GHS
 - Deviations published in 2003; plan to introduce as amendments in 2006/2007
 - “User Guide to the HSNO Thresholds and Classifications” developed for classification of mixtures
 - During 2007, include the following in a searchable database together with classification cut-off concentrations and assigned label elements
 - ~ 2500 chemicals classified directly from HSNO/GHS endpoints
 - 4000 chemicals have been partially classified indirectly
- Hazard Communication
 - Code of practice for work place signage and placarding approved
 - Code of practice for Safety Data Sheets to be approved shortly
 - Preparation of labeling codes is underway
 - Primary labeling guidance is available on the ERMA New Zealand website
- Safety Data Sheets
 - Adopted 16 header Safety Data Sheet format
 - As of July 1, 2006 all hazardous substances have been transferred under new HSNO legislation

GHS Asia



Asian Countries very active; most intend to initiate a program by 2008

- Australia
 - First draft documents in the workplace sector introduced; comment period ran from February 1 – March 15, 2007
 - Progress in other sectors is on-going
 - Implications for labeling of consumer products, including pesticides
- Korea
 - Published draft standards in 2006
- Cambodia, Malaysia, Singapore, Philippines, Thailand, all very active

Transportation

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Transportation



IATA and DOT – Hazardous Material Shipping Rules

- IATA - Dangerous Goods Regulation, 48th edition
 - Published December, 2006
 - Effective January 1, 2007
- DOT revised the hazardous material shipping rules to harmonize with international standards
 - Final Rule December 29, 2006 (71 FR 78596)
 - Effective January 1, 2007

Changes bring DOT into alignment with International Maritime Dangerous Goods Code, UN recommendations, and various other groups

Transportation



Changes include

- Proper shipping names
- Hazard classes
- Packing groups
- Packaging authorizations
- Air transport quantity limitations
- Vessel stowage requirements

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