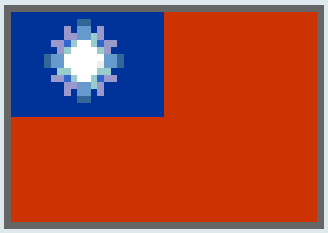
Inventory/New Chemical Notification Developments in Taiwan

GlobalChem 2009
Baltimore, Maryland



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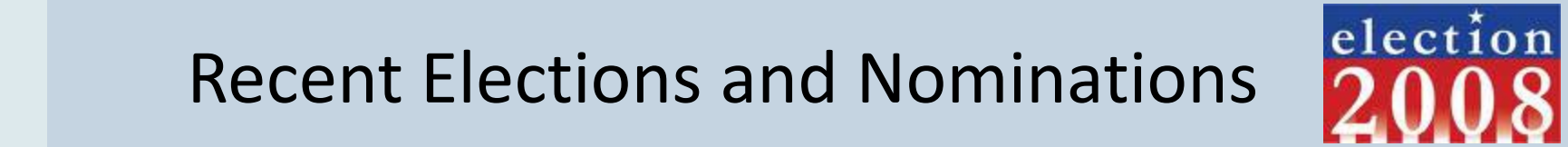
Inventory/New Chemical Notification Developments

- Recent Election & Nominations – 2008
- Council of Labor Affairs (CLA) – Administrative Plans (2009 – 2012)
- Institute of Occupational Safety and Health (IOSH) - Draft New Chemical/Inventory Proposal
- Industry Proposals for NCN/Inventory
- Taiwan's Motivation for implementation
- Anticipated Timing

Recent Elections and Nominations



- Ma Ying-jeou became President on May 20, 2008.

  - Both the Legislative and Executive Yuan are now under the same party (KMT)
  - This will lead to the easing of what was previously legislative grid-lock between the two administrative branches.

- Liu Chao-shiuan appointed by President Ma to serve as the Premier (President of the Executive Yuan)

  - Premier Liu's academic degrees are all in the field of chemistry
  - All members of his Cabinet were given the clear expectation to "hit the ground running."

Council of Labor Affairs (CLA)

- (Jennifer) Wang Ju-hsuan appointed Minister, Council of Labor Affairs
  - Lawyer and resolute to "*benefit workers through implementing laws or regulations*"

- One of Minister Wang's focus points for 2009 is;

  "Establish the promotion plans for national registration and management system of chemical substances to protect health of our citizens and facilitate sustainability of environment. "

Council of Labor Affairs (CLA)

CLA's mid-term Administration plans for 2009-2012

"Promote management and awareness of chemicals to eliminate chemical hazards.

- ***Promote cross-agency chemicals management of workplace and develop regulations and system regarding chemicals management.***
- ***Promote chemical hazard prevention plan and establish national registration and management system of chemical substances.***

New Chemical/Inventory - Taiwan

- Nov. 15, 2007: Interagency meeting (CLA, EPA, NFA) on GHS Implementation; *"the need for developing a national hazard chemical inventory for future GHS implementation was identified."*

- The Institute of Occupational Safety and Health (IOSH) - a research institute under the jurisdiction of the CLA was designated to take the lead.

New Chemical/Inventory - Taiwan

- In 2008, IOSH enlisted the assistance of the Safety and Health Technology Center (SAHTECH) to conduct the ***"Evaluation of New Chemical Substances Notification Mechanism at Work Site"*** research project.

- Review of chemical management practices in Japan, EU, China, the US and more recently, Korea.

Current Scheme Proposed by IOSH/SAHTECH

- Establish a National Existing Chemical Substance List
  - Software-based nomination system (electronic)

- Submission information
  - Company Information (name, address, telephone)
  - Chemical Substance Name (IUPAC Chinese and English names and Chinese common name)
  - Chemical Abstracts Service No. (CAS No.)
  - Chemical Formula of the Chemical Substance
  - Molecular Weight of the Chemical Substance
  - Annual Quantity of the Chemical Substance (ranges)

Current Scheme Proposed by IOSH/SAHTECH

- Establish a New Chemical Notification System that will add the notified substance to the ECSL.

- Exclusions (impurities, by-products, naturally occurring, articles, regulated by other laws, etc.)

- Exemptions (via notification form)
  - Low Volume chemicals ≤ 100 kg/yr (national amount)
  - R&D chemicals < 10 kg/yr (national amount)
  - Polymers with Mn > 10,000 Daltons
  - Polymers containing < 5 wt% of “monomer” material of ≤ 1,000 Daltons.

Current Scheme Proposed by IOSH/SAHTECH

- Simplified Notification
  - Substances listed on 4 or more existing inventories
  - Requirements;
    - Chemical Identification Information
    - Application/Use
    - Quantity to be produced or imported, etc . . .
- “Proof” will be required

Current Scheme Proposed by IOSH/SAHTECH

- Full Notification Requirements
  - Chemical substance identification information
  - Technical information
    - Physical/Chemical Properties
    - Mammalian Toxicity
    - Ecological Fate/Aquatic Toxicity
  - Hazard categories (GHS classification)
  - Exposure risk evaluation
  - Recommended hazard prevention measures
  - Commercial confidentiality declarations (including CBI substantiation information)

Current Scheme Proposed by IOSH/SAHTECH

- Testing via OECD or National Standards
- Waivers based on scientific justification
- QSAR accepted
- 60 Day Review
- Immediate and/or Delayed Listing (undecided)
- Notification Fees will vary (not yet established)

Industry Proposals to IOSH/SAHTECH

- Compilation of Inventory
  - ✓ Eligible substances: In commerce before a specified closing date regardless of their volume
  - ✓ Eligible substances should always remain eligible (no time restriction)
  - ✗ Adopt an existing inventory(ies) as a “core inventory” and invite industry to make further nominations
  - ✓ CBI must be allowed and protected

Industry Proposals to IOSH/SAHTECH

- Exclusions & Exemptions (25 proposed)
- R&D Exemption
  - No distinction needed between Laboratory and Process Oriented R&D
  - No preset volume limit
  - Appropriate records and documentation
  - No submission

Industry Proposals to IOSH/SAHTECH

- Simplified Notification
  - Eligibility = listing on 2 or more existing inventories
- Data Requirements
  - GHS compliant MSDS and label
  - Acute toxicity summary
    - Oral or dermal or inhalation
    - Genotoxicity summary
    - Confirmation of listing on inventories
- Read-across and QSAR data accepted

Industry Proposals to IOSH/SAHTECH

- LVE <1000 kg/yr (no submission required)
- New chemicals at ≥1000 kg/year
  - Chemical identity (name, purity, CAS, mol formula)
  - P/C data (MP/BP, Kow, water solubility, FP)
  - Toxicity (1 acute route, eye/skin irr., mutagenicity)
  - Ecotoxicity (acute fish, biodeg)
  - MSDS
  - 90 day review

Industry Proposals to IOSH/SAHTECH

- Polymers
  - Adopt OECD definition
  - 2% monomer rule
  - Keep proposed polymer exemptions
  - For those not meeting exemption requirements
    - General P/C properties
    - One acute toxicity test
    - One aquatic toxicity test
    - One genotoxicity test
- Security of CBI is essential

Taiwan's Motivation for Creating an Inventory

- Know what chemicals are used in Taiwan and the volumes manufactured and imported
- Public pressure, to avoid incidents, help identify next steps in chemical management.
- Give them the ability to implement GHS for all substances and ensure accurate GHS classification is undertaken by importers.
- (GHS) Classify all substances on the inventory (2nd phase governmental activity)
- Request data on new chemicals via a new chemical notification scheme

Timing and Future Plans

- Anticipated Timing (a best guess)
  - Complete review and draft of final regulation recommendation by SAHTECH: mid-2009
  - Announcement of regulation: late-2009/early-2010
  - Initiate Inventory Nominations: early-2010
- Industry hopes to continue communication with IOSH/SAHTECH

Taiwan Web-Sites

- Council of Labor Affairs (CLA)

  http://www.cla.gov.tw/cgi-bin/SM_theme?page=431d3444
- Institute of Occupational Safety and Health

  http://www.iosh.gov.tw/English/Default.aspx
- Safety and Health Technology Center

  http://www.sahtech.org/AboutSahtech/Introduction2.aspx

Thank you
Questions??