



The Republic of China (Taiwan)

Inventory/New Chemical Notification Developments

Background

Taiwan has had quick industrialization and rapid growth during the latter half of the twentieth century. Today, Taiwan has a dynamic capitalist, export-driven economy with gradually decreasing state involvement in investment and foreign trade. Exports have provided the primary impetus for industrialization. The trade surplus is substantial, and foreign reserves are the world's third largest. Taiwan's current GDP per capita is equal to the average of EU Countries. Unlike its neighbors South Korea and Japan, the Taiwanese economy is chiefly dominated by small and medium sized businesses, rather than large business groups.

The Republic of China (Taiwan) is a multi-party democratic state. The head of state is the President, who is elected by popular vote for a four-year term, has authority over the five administrative branches (*Yuan*): the Control Yuan, Examination Yuan, Executive Yuan, Judicial Yuan and Legislative Yuan. The President appoints the members of the Executive Yuan as his cabinet, including a Premier, who is officially the President of the Executive Yuan; members are responsible for policy and administration. Because the Premier is appointed by the President, executive powers tend to be dominated by the party holding the Presidency.

Recent Election & Nominations

Ma Ying-jeou is the incumbent President of Taiwan. Winning the presidency in the ROC presidential election in March 2008, he became President on May 20, 2008. Ma won on a platform of economic revitalization and a promise to improve relations with mainland China. With Ma's election, both the Legislative and Executive Yuan are now under the same party (KMT) which will lead to the easing of what was previously legislative grid-lock between the two administrative branches.

In April 2008, President-elect Ma Ying-jeou asked Liu Chao-shiuan (who earned all of his academic degrees in the field of chemistry) to serve as the Premier (President of the Executive Yuan) of Taiwan. He accepted the position and his term as Premier took effect with Ma's incoming administration on May 20, 2008.

On May 6, 2008 (days before inauguration day), Premier Liu "called on all appointees to begin making substantive contributions from their very first day on the job so that the people would not have to see the government acting with incompetence." All members of his Cabinet were given the clear expectation to "hit the ground running."

Council of Labor Affairs (CLA)

Council of Labor Affairs (CLA) is a cabinet-level unit under the Executive Yuan. In April, 2008 Premier-elect Liu appointed lawyer and activist Wang Ju-hsuan as the Minister, Council of Labor Affairs. Upon becoming the Minister of CLA, Ms. Wang initiated what would be her “focus points” and mid-term plans.

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. “

And one of her mid-term Administration plans for 2009-2012 is;

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

- 1. Promote cross-agency chemicals management of workplace and develop regulations and system regarding chemicals management.***
- 2. Promote chemical hazard prevention plan and establish national registration and management system of chemical substances.***
- 3. Strengthen service information about management mechanism, precautions, promotion, and websites of chemicals; realize safety precautions of using chemicals. “***

Institute of Occupational Safety and Health (IOSH)

The Institute of Occupational Safety and Health (IOSH) is a research institute under the jurisdiction of the CLA. The responsibilities of the IOSH division of CLA include the analysis and application of “*scientific technology, surveys and analyses of various risk factors in the working environment.*”

New Chemical Substance Notification (NCSN) & National Chemical Substance Inventory (NCSI)

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.

IOSH/SAHTECH looked at and reviewed the chemical substance management mechanisms in Japan, EU, China, the US and Korea and out of this review, IOSH has proposed suggestions for a **New Chemical Substance Notification (NCSN) and National Chemical Substance Inventory** system in Taiwan. The new regulations will be drafted to be in a revision of the existing *Labor Safety and Health Act*.

The Safety and Health Technology Center (SAHTECH) is currently consolidating feedback and suggestions from multi-national companies, Industry associations and local industry for consideration by the CLA.

The SAHTECH members currently leading this effort are;

Jung-Pin Yu, PhD. (President of SAHTECH)

Jowitt Li, PhD. PEng. LEED AP (Mgr. Tainan Branch SAHTECH) – Dept. of Risk Control Technology

Anticipated Timing

- IOSH/SAHTECH plan to complete their work & have a final draft of the NCSN/NCSI regulation in 2009.

- Revised Labor Safety and Health Act is expected to be issued in 2010.

Current Scheme Proposed by IOSH/SAHTECH (subject to change)

Establish a National Existing Chemical Substance List (ECSL).

There will be no fee for nomination to the original inventory.

Nomination/Registration Requirements

- Company Information (company name, address, telephone number)
- 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

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

Exemptions

- Articles (?) – “Chemical substance in a closed system confirmed not to release the solid chemical substance during normal use”
- Closed System Intermediates of a progressing reaction
- Chemicals used for National Defense
- By-products/impurities with no commercial application
- Export Only or Trans-shipment (?) – “Chemical substance stored in the dock warehouse for shipping.”
- Mixtures (all substances must be existing chemical substances)
- Naturally occurring unprocessed substances
- Chemical substances regulated by other laws.

Exemptions via submission a “Notification Exclusion Form”

- Low Volume chemicals ≤ 100 kg/yr (national amount)
- Research & Development chemicals < 10 kg/yr (national amount)
- Polymers with $M_n > 10,000$ Daltons
- Polymers containing < 5 wt% of “monomer” material of $\leq 1,000$ Daltons.

Substances for which a “Simplified Notification Form” is required;

Already listed on 4 or more existing national inventories (“proof” required)

Requirements;

- Chemical Identification Information
- Application/Use
- Quantity to be produced or imported, etc . . .

Full Notification Form (Major Content Requirements)

- Chemical substance identification information
- Technical information
- Hazard categories
- Exposure risk evaluation
- Recommended hazard prevention measures
- Commercial confidentiality declarations (including CBI substantiation information).

Nominal Review Period (for all forms of notification): 60 days (excluding the days required for “formal review”).

Technical Requirements for Full Notification

- Chemical and Physical Properties:
 - Danger of explosion, fire, oxidization, or corrosion.
- Toxicity:
 - Acute toxicity
 - Carcinogenicity
 - High cumulative effects
 - Genetic mutation.
- Ecological Toxicity:
 - Aquatic Toxicity
 - Material exposure half-life information

All tests must be performed in accordance with the methods described in CNS15030 or OECD announcements or the national standards set by the Bureau of Standards of the Ministry of Economic Affairs.

Testing requirements can be waived if the company can provide scientific evidence or complete information of the contents in a way similar to QSAR.

Inventory Listing: Taiwan is considering “immediate” listing or “delayed listing” and may make a separate “New Chemical Substances List” to differentiate from the original Existing Chemical Substances List.

Notifying party is the one responsible for production or import into Taiwan.

Notification Fees not established but will vary depending on the type of Notification.

Overview of Industry Proposals for the Development of a New Chemical Notification Scheme

The following is a summary of information that the European Chemical Industry Association (CEFIC) provided to SAHTECH for their consideration.

Compilation of the Chemical Inventory Recommendations

Eligible Substances: All chemical substances and polymers that are manufactured and imported (except those which are exempted or excluded) regardless of their volume prior to the "closing date" established by the Authorities for nomination to the inventory.

Polymers together with the monomers and other reactants used should be nominated.

Mixtures should not be nominated (but the individual constituents should be nominated).

Persons eligible to nominate: All local manufacturers and importers. For CBI reasons, foreign suppliers must be allowed to submit confidential information directly to the proper authorities.

Stage 1 - Initial Preparation: Establish and circulate an initial core inventory. Consider adopting an inventory or inventories in part or in whole of chemicals that are already on those existing inventories.

Stage 2- Nominations to the Inventory: Once the core inventory is established, invite all manufacturers and importers to nominate chemical substances they import or manufacture.

Make provisions for confidential inventory nominations via appropriate generic name listings. Taiwan must have appropriate CBI protection in place.

Timing: Provide a minimum of 6 months for the Stage 2 nomination process. However, there should be provisions to allow for the nomination of any qualifying substance for inclusion in the inventory even after the inventory is formally published.

Chemical Nomenclature: CAS nomenclature should be adopted. Definitions of chemical categories and guidance on nomination procedures should be published.

Information Requirements: CAS Name and Number only (if available).

Inventory Review: After initial publication a minimum of 3 months should be allowed for inclusion of omissions (need for nomenclature corrections not mentioned but implied).

Inventory after Publication: The inventory should be a dynamic one, not closed, so that inadvertent omissions and necessary corrections can be made as well as have newly notified substances added to the inventory. There should be both Public and Confidential sections to the Inventory.

Language and Form: English and the National language of Taiwan. Available in both hard copy and electronic. Internet accessible.

New Chemical Substance Listings: The nominating company should be given the option of an immediate inventory listing or a delayed (5 year) listing. If an immediate inventory listing is not specifically requested, then the default should be a delayed listing.

Substances on the Inventory should be exempt from any type of notification or application.

Definitions

Chemical Substance: A chemical element or a compound formed by combinations of chemical elements, occurring either in nature or as a result of a chemical reaction, or an uncombined radical.

Preparation: Intentional combination of two or more chemical substances (i.e., all mixtures that do not occur naturally or that are not the result of a chemical reaction).

Chemical Product: A chemical substance or mixture of chemical substances as distributed in commerce; may contain impurities and/or by-products; often marketed under trade names.

Polymer (OECD definition): A substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least 3 monomer units which are covalently bound to at least 1 other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein the differences in the molecular weight are primarily attributable to differences in the number of monomer units.

Article: Any manufactured item formed into a specific physical shape or design during manufacture and has, for its final use, a function or functions dependent in whole or in part on its shape or design.

Non-isolated intermediate: Substances produced within a sequence of chemical reactions between starting materials and the end product which are: contained in the reaction vessel, fully consumed in the course of the chemical reaction, part of an uninterrupted manufacturing process and not likely to be released into the environment.

Naturally-occurring substance: Substances occurring in nature which are unprocessed; processed only by manual, gravitational, or mechanical means, by dissolution in water, by floatation, or by heating solely to remove water; or extracted from air by any means.

Impurity/By-product: Contaminant or partially unreacted materials formed in the preparation of a substance, found in minimal concentration in the starting materials or formed during the manufacturing process. These are not necessary to the end use of the product, have not been intentionally added to the substance, and do not enhance the commercial value of the substance.

UVCB: (Unknown or Variable composition Complex reaction products and Biological material) Mixtures derived from natural sources or complex reactions that cannot be characterized due to the complex or variable nature of the composition.

Exclusions and Exemptions from notification requirements

- Substances subject to other regulations (e.g., pharmaceuticals/medicinal products, pesticides, etc.)
- Existing substances (i.e. those already listed on the inventory)
- Cosmetics
- R&D and test market substances
- Naturally occurring substances
- Hydrates (if the anhydrous form is listed)
- Alloys
- Impurities & By-products

- Non-isolated chemical intermediates (formed in-situ)
- Site-limited intermediates
- Substances formed inadvertently upon exposure to environmental factors or upon storage
- Substances formed during the intended end use of a substance or mixture
- Substances formed unintentionally during the blending of a mixture or formulation
- Radioactive materials
- Wastes
- Substances used solely for national defence
- Substances in Articles
- Substances functioning as intended
- Mixtures
- Substances in transit under customs control
- Substances in articles where the shape or design is more important than chemical nature.
- Products regulated by other laws with equivalent requirements

Research and Development Exemption

Definition: “Research and Development substance” (R&D) means a substance that is undergoing systematic investigation or research, by means of experimentation or analysis, other than test marketing, the primary objective of which is:

- (a) Create or improve a product or process, or
- (b) Determine the technical viability or performance characteristics of a product or process, or
- (c) Evaluate a substance prior to its commercialization, which includes pilot plant trials, production trials or panelist tests under supervision, other than test marketing, in order to modify the technical specifications in response to the performance requirements of potential customers.”

It is not necessary to make a distinction between “scientific research and development” and “process orientated research and development.”

There should be no fixed volume amount or time limit on R&D activities. The amount and time should be restricted only by that which is needed to conduct the R&D work which will vary on a case-by-case basis.

No form should be required for implementing the R&D exemption. Rather, require conduction under the supervision of a technically qualified individual, risk evaluation by the manufacturer, communication of risks to those handling the substance, maintenance of appropriate records that would be available for inspection if needed. Appropriate commercial restrictions (but no prohibitions) may be imposed.

New Chemical Notification

Simplified Notification Scheme Proposal

Criteria: A simplified notification should apply to new chemical substances that are new in Taiwan but which are listed on two or more inventories of other countries.

Data Set Proposal

- A GHS compliant MSDS and label.

- Acute toxicity summary - oral or dermal (inhalation for volatile liquids or gases). Genotoxicity summary - bacterial reverse mutation result, and in the case of a positive response an in-vitro chromosome aberration study.
- Confirmation of listing on two existing inventories.

Toxicity tests by GLP certified labs in accordance with OECD, ISO, EU, US EPA or other equivalent guidelines; however, GLP may not be possible or needed for certain testing (e.g. physical properties testing).

Other scientifically sound, relevant data should also be accepted.

Use of read-across data from chemicals of similar structure as well as modeling (QSAR should be accepted).

Use of mutual recognition of new substance approvals by other countries such as the US (TSCA), Canada (DSL), Australia (NICNAS) and the EU.

New low volume chemicals imported or manufactured at <1000 kg/year

Recommendation: Adopt an exemption from notification for those substances manufactured or imported at <1000 kg/yr.

No submission should be required and substance is not added to the inventory; however manufacturers and importers should;

- Have available a good quality MSDS in compliance with GHS in Chinese as adopted in Taiwan
- Assure use of substance meets all applicable Taiwan health and safety regulations. An abbreviated risk assessment addressing the known hazards of the substance, potential exposure, and environmental release and disposal.

Companies may be audited to demonstrate compliance with manufacture/import volumes.

New chemicals imported or manufactured at ≥ 1000 kg/year

Manufacturers and suppliers should provide the following information set. These elements may be addressed by submission of actual test data, information from the literature, or scientific mechanisms such as analog or surrogate information. Applicant should assure that the use of the substance meets all applicable Taiwan health and safety regulations.

Upon completion, substance will be added to the Chemical Substance Inventory.

Chemical identity

- Chemical name
- CAS number
- Molecular formula and structure
- Purity
- Appearance

Physical-chemical

- Melting or boiling point
- Water solubility; partition co-efficient
- Assessment of flash point, flammability and explosive properties

Toxicity

- Acute toxicity to reflect most likely route of human exposure
- Skin and eye irritation; skin sensitization
- Mutagenicity test

Ecotoxicity

- Biodegradation
- Acute fish toxicity test

From a self-declaration form or letter:

- Quantity to be manufactured and/or imported annually
- Possible human exposure to workers or public
- Anticipated release to environment

MSDS will provide: Use(s), emergency, first-aid measures and storage requirements.

A pre-submission dialogue with IOSH, review committee and notifier should be conducted to reach agreement on which parameters need to be evaluated and provide only relevant data.

Assessments from other regulatory authorities should be considered in an evaluation of a substance.

Review time: 90 calendar days

Result:

- Permit issued by the Taiwanese Authorities and required for import or manufacture
- Chemical substance will be added to the Taiwan inventory of existing chemicals
- Unlimited volume allowed for import or manufacture.

New Chemical Substances having similar structures

Two potential situations for the notification of new non-Inventory listed chemical substances having similar structures:

- (1) New chemical substances that are new in Taiwan but which are of similar structure to others already listed on the Taiwanese Inventory,
- (2) A group of new chemical substances, not listed on the Taiwanese Inventory, that have similar structures and/or usage, similar test(s) data and/or other information,

Notification of these types of substances should allow for the adoption of the “read -across” of data from one substance to a similar substance.

The grouping of substances whose physicochemical, toxicological or ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity would be considered as a group or “category” of substances.

Application of the group concept requires that physicochemical properties, human health effects and environmental effects/fate may be predicted from data for a reference substance within the group by interpolation and/or extrapolation to other substances in the group (read -across approach) avoiding the need to test every substance for every endpoint.

In line with other jurisdictions (for example the US and EU) it is proposed that hazard assessments for toxic endpoints be performed by using a tiered approach, i.e. starting with an evaluation of all of the data already available. These would include animal in vivo and in vitro data, and human evidence and case reports, as well as data from (Quantitative)-Structure Activity Relationships ([Q]SARs) or read-across.

Proposal for Regulation of Polymers

Adopt the OECD definition of a polymer. Adoption of this common polymer definition by Taiwan would serve to differentiate between polymers and non-polymers and help ensure that polymeric substances are treated the same in all regulatory controlled regions.

Adopt the "2 Percent Rule" for Polymers. This would harmonize the reporting and inventory searching and listing rules with the other international systems that use a 2 percent standard.

Keep the proposed polymer exemptions of Mn > than 10,000 Daltons and those where the total molecular weight of constituents < 1,000 Daltons is < 5 wt%, but also include a third exemption for polymers with a Mn > 1,000 and containing < 25% of polymer with molecular weight below 1,000 Dalton and less than 10% of polymer with molecular weight below 500 Dalton.

For further international harmonization, it is suggested that Taiwan adopt an additional exemption which is part of the regulatory schemes in EU, Philippines and Korea: "Polymers consisting of monomers (present at equal or greater than 2%) listed in the existing chemicals inventory."

Allow these (and other) exemptions to be self-actuated by industry in order to make efficient use of authority and industry resources. No applications or submissions are recommended.

Other New Polymer Notifications

For polymers not meeting the exemption criteria, it is suggested that data set requirements consist of general physical-chemical properties (usually available from Material Safety Data Sheets) and one acute toxicity test or one aquatic toxicity test and one Genotoxicity test (Ames test). This data set is required by the Korean regulatory scheme for simplified polymer notifications.

Confidential Business Information

Any Chemical Management System must have the means to properly and securely handle Confidential Business Information.

Confidential Business Information is any information developed or acquired by a business about a substance, product or process, and its production, sale, or use, which allows the business to obtain or retain business advantage from its right to such information. This is a broad definition, but appropriately so. Confidential Business Information may encompass a broad range of information, which will be different for different companies in different situations.

What should be considered Confidential

- Chemical Identity,
- identity of the manufacturer/importer,
- manufacturing process,
- manufacturing site, and

- “links to any of this information” (i.e. product composition, description of impurities, raw material information, production, import and sales volume, manufacturing costs, customer lists, profits, uses of product, test data, or names of company personnel involved with the material).

Duration: The confidentiality allowed for the identity of a product should be permanent as long as it meets the definition of such information.

Necessary Elements to maintain CBI

- Appropriate facilities for maintaining CBI (secure storage facilities, locks, security systems, ability to prevent access from outside the system)
- Appropriate procedures (collect only CBI,
- Authorization for Access (should be limited to those with a *need to know*, have a well defined process for requesting the information and granting authorization),
- Procedures for tracking CBI within the Agency, and
- Sanctions for Disclosure – penalties for those who do not comply.

What should not be considered Confidential

information such as safe handling information and recommended actions to take in emergency situations (e.g., fire fighting, spill clean-up and other emergency response information). Much of this information can be found on the Material Safety Data Sheet (MSDS) associated with the material. Emphasis should be placed on the development of high quality MSDS which describe the potential hazards rather than on full disclosure of compositional information.

Industry Obligations

A company should be prepared to substantiate requests for protection on Confidential Business Information. This means that the company has themselves taken measures to protect their own information and implemented internal procedures similar to those described above.

ATTACHMENTS

Institute of Occupational Safety and Health, Council of Labor Affairs, Executive Yuan Letter to Industry (for September 10, 2008 meeting)

Draft of Taiwan NSN Registration Form

Draft of Existing Chemical Nomination Form

Links

GHS Implementation Status Presentation (CLA/SAHTECH – Feb. 2008)

http://ghs.myweb.hinet.net/EN_GHS/Taiwan_2008_GHS_Implementation%20Update.pdf

Taiwan Council of Labor Affairs (CLA) website

http://www.cla.gov.tw/cgi-bin/SM_theme?page=431d3444

Council of Labor Affairs (CLA) Organization Chart

http://www.cla.gov.tw/cgi-bin/SM_theme?page=43322668

Attachment I

Institute of Occupational Safety and Health, Council of
Labor Affairs, Executive Yuan

Letter to Industry

Invitation to September 10, 2008 Meeting

Attachment II

Draft of Taiwan NSN Registration Form

Attachment III

Draft of Existing Chemical Nomination Form