

**Institute of Occupational Safety and Health, Council of Labor Affairs, Executive Yuan
Symposium with the Industry on “Evaluation of a New Chemical Substances
Notification Mechanism at the Work Site”, a Research Project for 2008**

All business enterprises are encouraged to attend and present relevant opinions.

Nowadays, the major advanced countries and business institutions are developing a registration system for chemical substances and the subsequent implications such as hazard classification, risk evaluation, and safety measures for chemical substances based on the considerations that chemical substances may, directly or indirectly, have immediate destructive and irreversible impact on human health or the surrounding environment due to their production, use, storage, or application in different fields. The announcement of new chemical substances plays an important role in the management and registration mechanism for chemical substances. As mentioned in the New Chemicals Notification Strategy (NCNS) of OECD, the authorities will collect exposure, or risk information of every new emerging chemical substance for the evaluation of its hazards and the stipulation of subsequent preventive and cautionary measures.

In response to the needs of chemical substance management at the work site, and of the amendments of the regulations, the Institute conducted the “Evaluation of New Chemical Substances Notification Mechanism at Work Site” research project to accumulate and analyze information about the new chemical substance notification mechanisms of major countries (Japan, the European Union, Canada and the United States). The current conditions of the industries in Taiwan are also taken into consideration to propose suggestions for the new notification mechanism at the work site suitable for our country (Figures 1 and 2) and to perfect the chemical substance management system of our country in coordination with the international chemical substances management trend of Globally Harmonized System and Strategic Approach to International Chemicals Management.

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

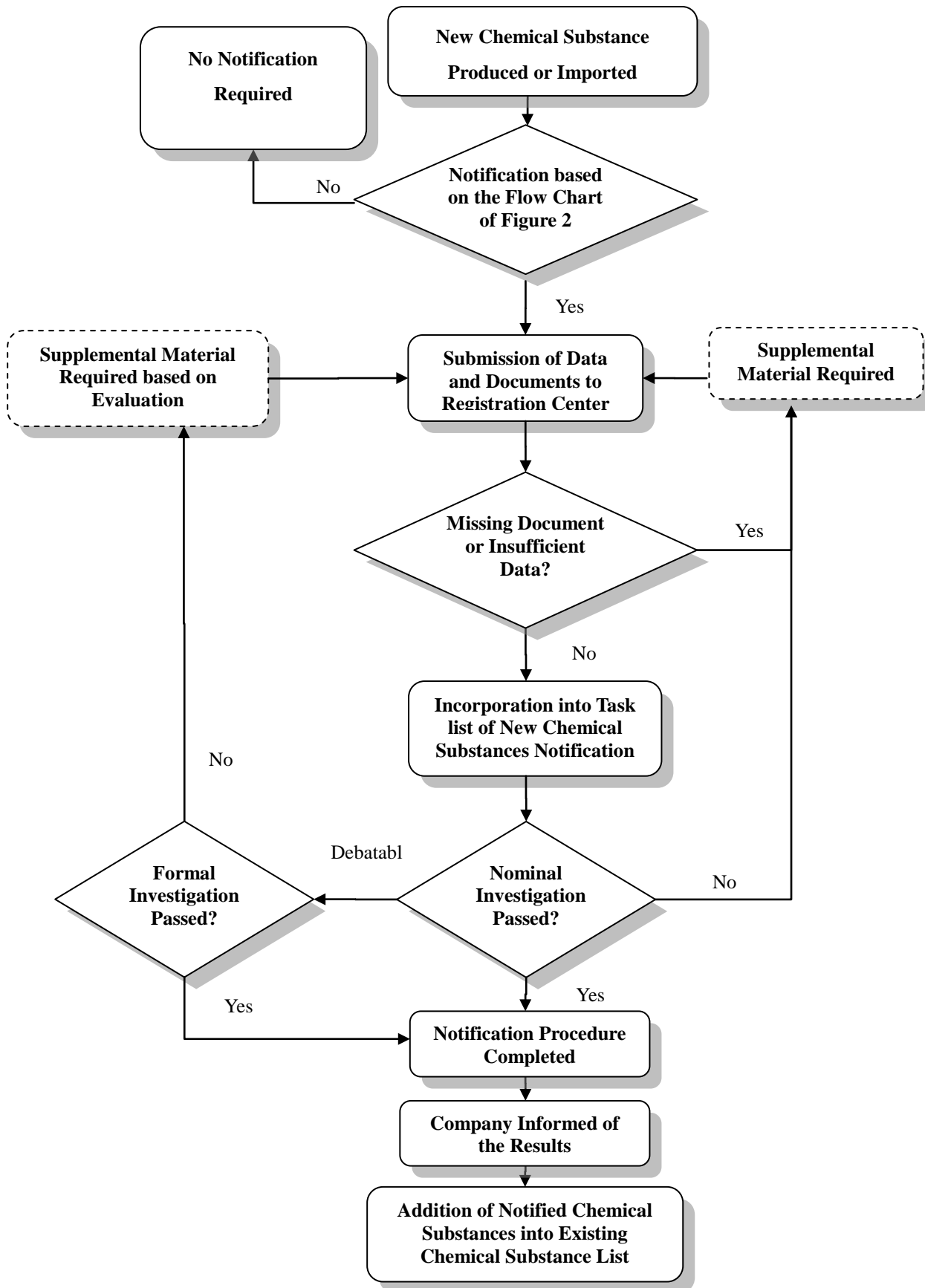
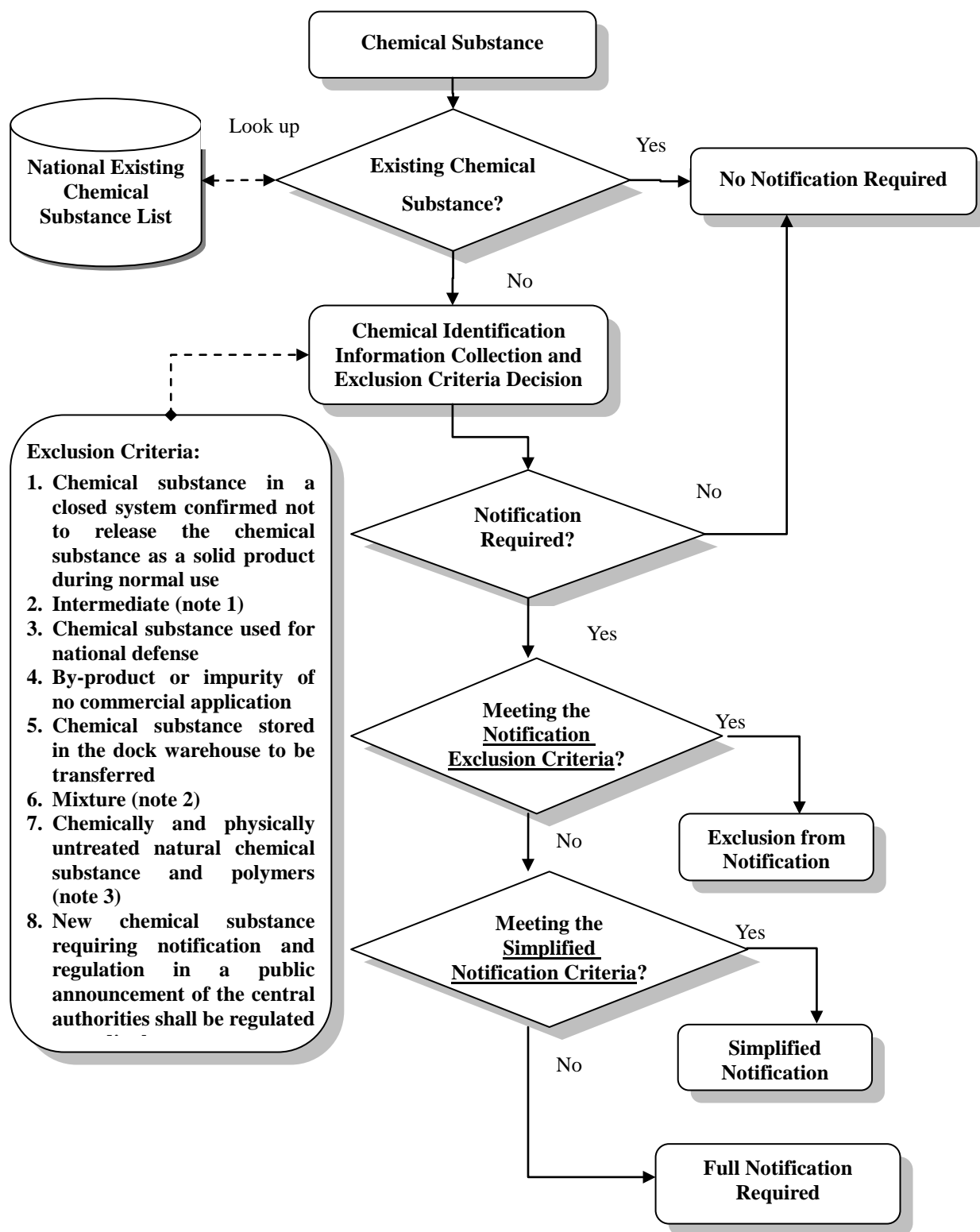


Figure 1. Flow Chart of New Chemical Substances Notification for the Industry



Note 1: Intermediate of the progressing chemical reaction in a reaction tank or production process

Note 2: Notification is required for a new chemical substance composed of a mixture.

Note 3: The polymer indicated here refers to a natural polymer, a chemically or physically treated polymer with an average molecular weight greater than 10,000 daltons, or a polymer whose monomer has an average molecular weight greater than 1,000 daltons and a weight percentage less than 5%.

Note 4: such as radioactive substances, raw materials of pesticides, food, food additives, drugs, and controlled drugs.

Figure 2. New Chemical Substance Notification Decision Flow Chart

**“Evaluation of New Chemical Substances Notification Mechanism at Work Site”
Questionnaire**

Company: _____ Contact Person: _____

Mailing Address: _____

Date: _____ Telephone Number: _____

E-mail Address: _____

Attending the symposium: yes no (limited to one person per company)

Major Items of New Chemical Substances Notification Mechanism	Contents of Scheduled Items	Suggestions:
I. Exclusion Criteria for New Chemical Substances	<p>The chemical substance described above refers to that meeting the exclusion criteria which requires no notification:</p> <ol style="list-style-type: none"> 1. Chemical substance in a closed system confirmed not to release the solid chemical substance during normal use 2. Intermediate of the progressing chemical reaction in the reaction tank or production process 3. Chemical substance used for national defense 4. By-product or impurity of no commercial application 5. Chemical substance stored in the dock warehouse for shipping 6. Mixture; a mixture whose components are new chemical substances should not be excluded 7. A chemically and physically untreated natural chemical substance and polymer, a chemically or physically treated polymer with an average molecular weight greater than 10,000 daltons, or a polymer whose monomer has an average molecular weight greater than 1,000 daltons and a weight percentage less than 5% 8. A new chemical substance (radioactive substance, raw material for agricultural uses, food additive, drug, controlled drug) requiring 	

Major Items of New Chemical Substances Notification Mechanism	Contents of Scheduled Items	Suggestions:
	notification and regulation by public announcement of the central authorities shall be regulated accordingly	
II. New Chemical Substance Notification Forms	<p>The styles and types of the forms required for the notification of new chemical substance are described below:</p> <ol style="list-style-type: none"> 1. "Notification Exclusion Form" for New Chemical Substances <p>The Notification Exclusion Form for New Chemical Substances is designed mainly for the following:</p> <ol style="list-style-type: none"> (1) A new chemical substance whose production or imported quantity per year throughout the country is less than or equal to 100 kg, or (2) A new chemical substance that is used exclusively for experiments, research, and development and whose production or imported quantity per year throughout the country is less than or equal to 10 kg. (3) A polymer with an average molecular weight $\leq 10,000$ Daltons, or a polymer whose monomer has an average molecular weight $\leq 1,000$ Daltons and a weight percentage $\geq 5\%$. <ol style="list-style-type: none"> 2. "Simplified Notification Form" for New Chemical Substances <p>The Simplified Notification Form for New Chemical Substances is mainly for the notification of new chemical substances confirmed not to meet the exclusion criteria. If the following conditions are met, the Simplified Notification Form may be used for the notification of a new chemical substance:</p> <p>The chemical satisfies the definition of a new chemical substance and has been included in the existing chemical substances list by four (4) or more other countries or regional economic entities or included in the chemical substances list of countries such as the United States, the European Union, Japan, Korea, Canada, or Australia. The company shall submit the related proof, to be verified, prior to the notification process using the Simplified Notification Form.</p> <ol style="list-style-type: none"> 3. "Full Notification Form" for New Chemical 	

Major Items of New Chemical Substances Notification Mechanism	Contents of Scheduled Items	Suggestions:
	<p style="text-align: center;">Substances</p> <p>The Full Notification Form for New Chemical Substances is mainly for the notification of new chemical substances for which the Simplified Notification Form cannot be used. The Form is used for the full notification of new chemical substances.</p>	
III. Contents (including items) in Notification of New Chemical Substance		
IV. Notification Review Procedure		
V. Test Items		
VI. Mechanism for Announcing New Chemical Substances to Be Included in the Existing Chemical Substances List		
VII. Definition of Notification Party		
VIII. Notification Review Fee		
IX. Commercial Confidentiality Declaration	<p>The notification party applying for a commercial confidentiality declaration shall submit proof in accordance with each of the following:</p> <p>The information is deemed commercially confidential</p>	

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	<p>by the notification party.</p> <p>The notification party has taken appropriate measures to secure the confidentiality of commercial information under the current situation.</p> <p>The information has been acquired by the third party via legal and reasonable channels and with the consent of the company.</p> <p>The information has not been disclosed in this country or any other country.</p> <p>The disclosure of this information is reasonably anticipated to cause actual damage to the competitiveness of the company.</p> <p>The disclosure of the information is reasonably anticipated to cause actual loss to the company or allow a competitor to gain actual benefit.</p> <p>In addition to the proof in accordance with the above conditions, the notification party shall also provide the following information:</p> <p>The potential damage to the company of the notification party if the identification information of the substance appears in the material list or is made public.</p> <p>The potential use of the identification information of the substance by the competitor</p> <p>The competitor is unaware of the fact that the substance is being produced, imported, or used due to the protection and care taken by the company with the commercial identification information.</p> <p>The substance has been awarded a patent and its identification information has been disclosed due to the patent application</p> <p>Information about the substance has been made public (for example, in a technical journals or business publication) and is already being produced, imported, or used.</p> <p>The protective measures to avoid identification information of the substance from being disclosed and the disclosure of information up to date</p> <p>Release or loss of the waste material into the</p>	

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	<p>environment</p> <p>Reverse expulsion</p> <p>Purposes of the manufacturing, importation, and use of the substance</p> <p>Disclosure of the following hazards from the substance known from international organizations or other countries; as far as the notification party is aware:</p> <p>Immediate or long-term effects on the environment</p> <p>The formation, or potential formation, of substances harmful to the environment</p> <p>Formation, or potential formation, of substances harmful to human life and health (if confirmed, detailed information is required)</p>	
<p>X. Existing Chemical Substances List</p>	<p>The implementation of the New Chemical Substances Notification Mechanism must be based on the Existing Chemical Substances List of the country. Considering that there is no Existing Chemical Substances List in the country and the implementation of new chemical substance notification regulations is required in the future, the registration process for the existing chemical substances will be provided free of charge for the chemical importation or production companies in the country in order to establish an Existing Chemical Substances List.</p> <p>The items for the nomination and registration of the existing chemical substances required for the company to cooperate include:</p> <ol style="list-style-type: none"> 1. Company Information (company name, address, telephone number) 2. Chemical Substance Name (IUPAC Chinese and English names and Chinese common name) 3. Chemical Abstracts Service No. (CAS No.) 4. Chemical Formula of the Chemical Substance 5. Molecular Weight of the Chemical Substance 6. Annual Quantity of the Chemical Substance: <ul style="list-style-type: none"> <input type="checkbox"/> <10 kg <input type="checkbox"/> 10 kg ~ 1 ton <input type="checkbox"/> 1 ton ~ 100 tons <input type="checkbox"/> 100 tons ~ 1,000 tons <input type="checkbox"/> 1,000 tons 	

Major Items of New Chemical Substances Notification Mechanism	Contents of Scheduled Items	Suggestions:
<p>Note: The contents of the items for the New Chemical Substance Notification Mechanism detailed in this document are still in the policy recommendation stage. Discussions among the government agencies and the opinions of the companies involved will be required as references for further amendments.</p>		
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