





Overview of Chemical Regulations in THAILAND

- Hazardous Substance Act B.E. 2535 (1992);
[1st issued in B.E. 2535 (1992), revised twice in B.E. 2544 (2001) and B.E. 2551 (2008)]
- Under the responsibility of the **Ministry of Industry (MOI)**
- Diverse characteristics & usages of substances, enforcement is split over **6 authorities**:



Department of Agriculture (DOA), Ministry of Agriculture and Cooperatives (MOAC)



Department of Fisheries (DOF), MOAC



Department of Livestock Development (DLD), MOAC



Food and Drug Administration (FDA), Ministry of Public Health (MOPH)



Department of Industrial Works (DIW), MOI



Department of Energy Business (DOEB), Ministry of Energy (ENERGY)

MOI Notifications: List of Hazardous Substances

List	Responsible Authority	Sub-List
1	DOA	1.1 Controlled Substances 1.2 Group of Controlled Substance
2	DOF	2.1 Controlled Substances 2.2 Group of Controlled Substance 2.3 Group of Controlled Substance
3	DLD	3.1 Controlled Substances 3.2 Group of Controlled Substance
4	FDA	4.1 Controlled Substances 4.2 Group of Controlled Substance 4.3 Group of Controlled Product
5	DIW	5.1 Controlled Substances 5.2 Chemical Wastes 5.3 Used Electrical and Electronic Appliance 5.4 Others 5.5 Chemical Weapons 5.6 Groups of Substances Controlled by their Properties
6	DOEB	Natural Gas & Liquefied Petroleum Gas

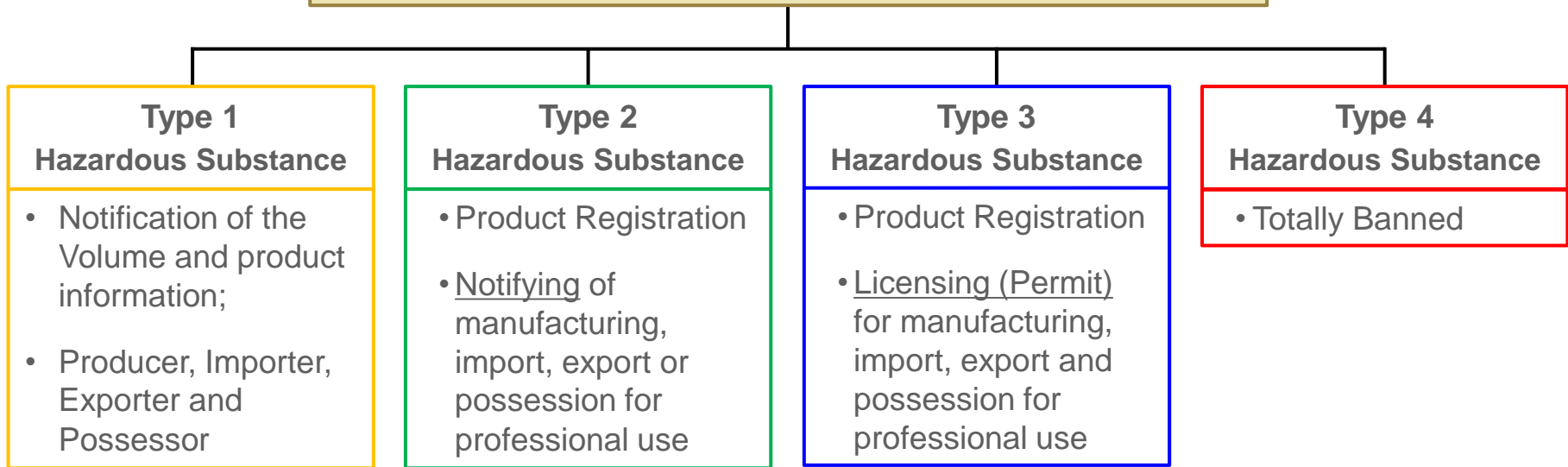
Time-to-time checking with the MOI Notification on the “List of Hazardous Substances B.E. 25XX (20XX)”

MOI Notification on “List of Hazardous Substances”

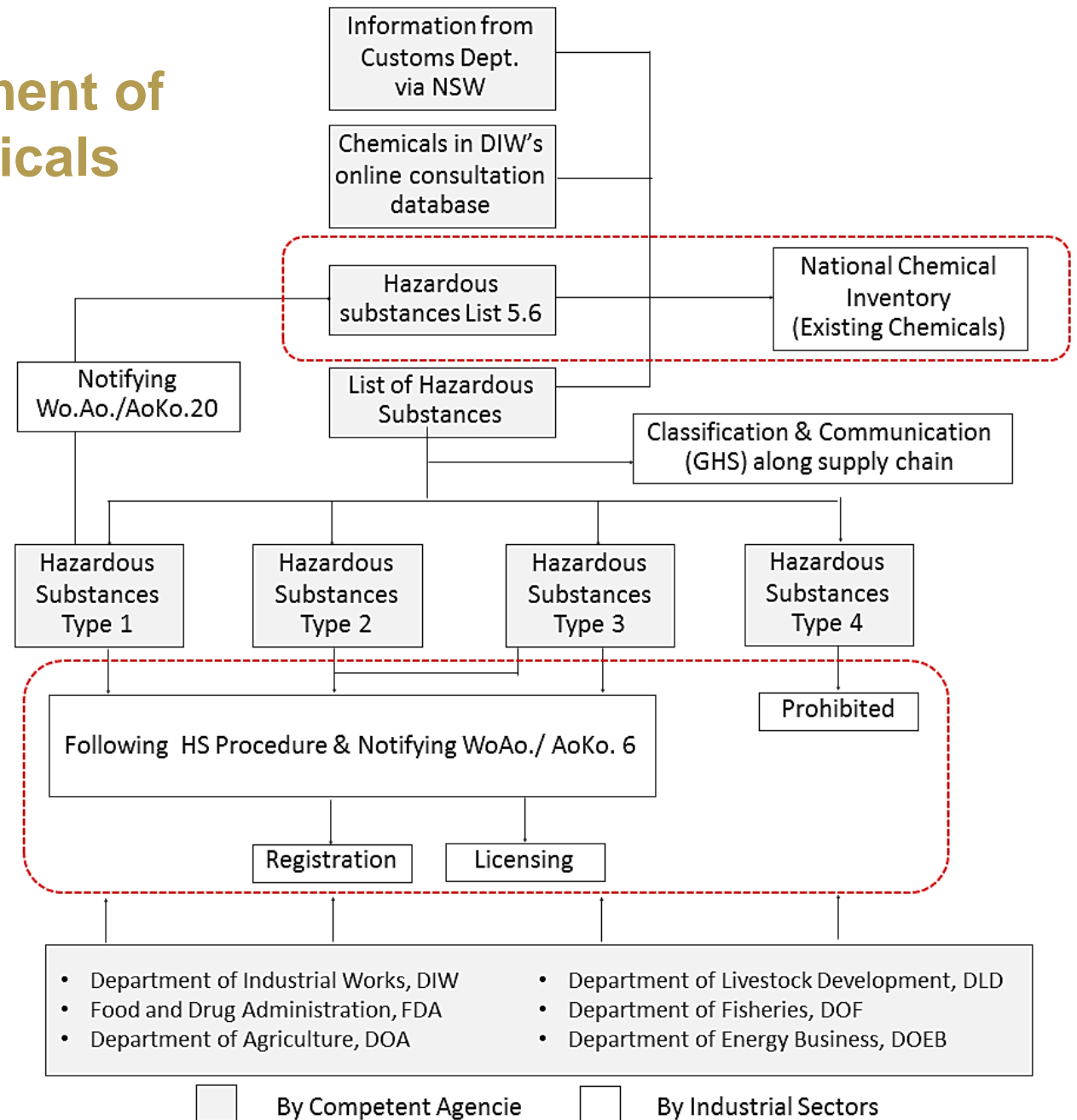
List of Hazardous Substances	Year	Link
List of Hazardous Substances No. 1	B.E. 2556 (2013)	http://php.diw.go.th/haz/wp-content/uploads/2016/12/announce56.pdf
List of Hazardous Substances No. 2	B.E. 2558 (2015)	http://php.diw.go.th/haz/wp-content/uploads/2016/12/announce58.pdf
List of Hazardous Substances No. 3	B.E. 2559 (2016)	http://www.diw.go.th/hawk/news/haz/4-60.pdf
List of Hazardous Substances No. 4	B.E. 2560 (2017)	http://www.diw.go.th/hawk/news/haz/4-61.pdf

Classification of Hazardous Substances

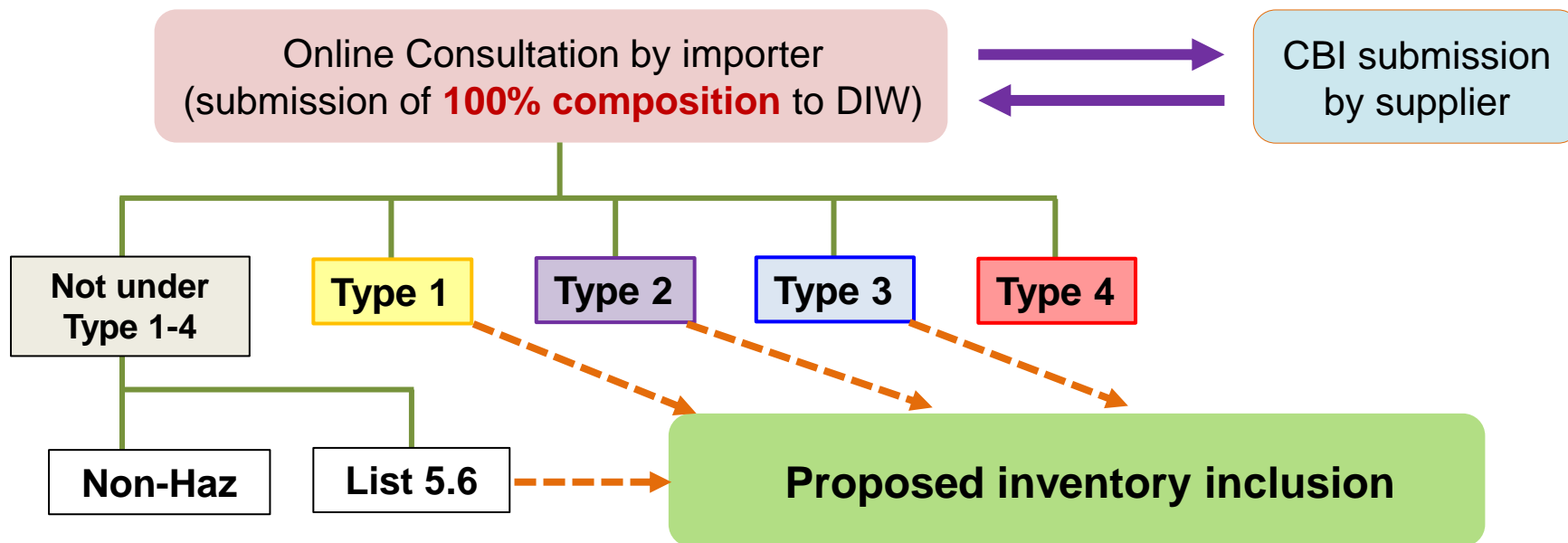
The Hazardous Substance Act B.E. 2535 (1992)



Current Management of Hazardous Chemicals



How to determine hazard type under DIW



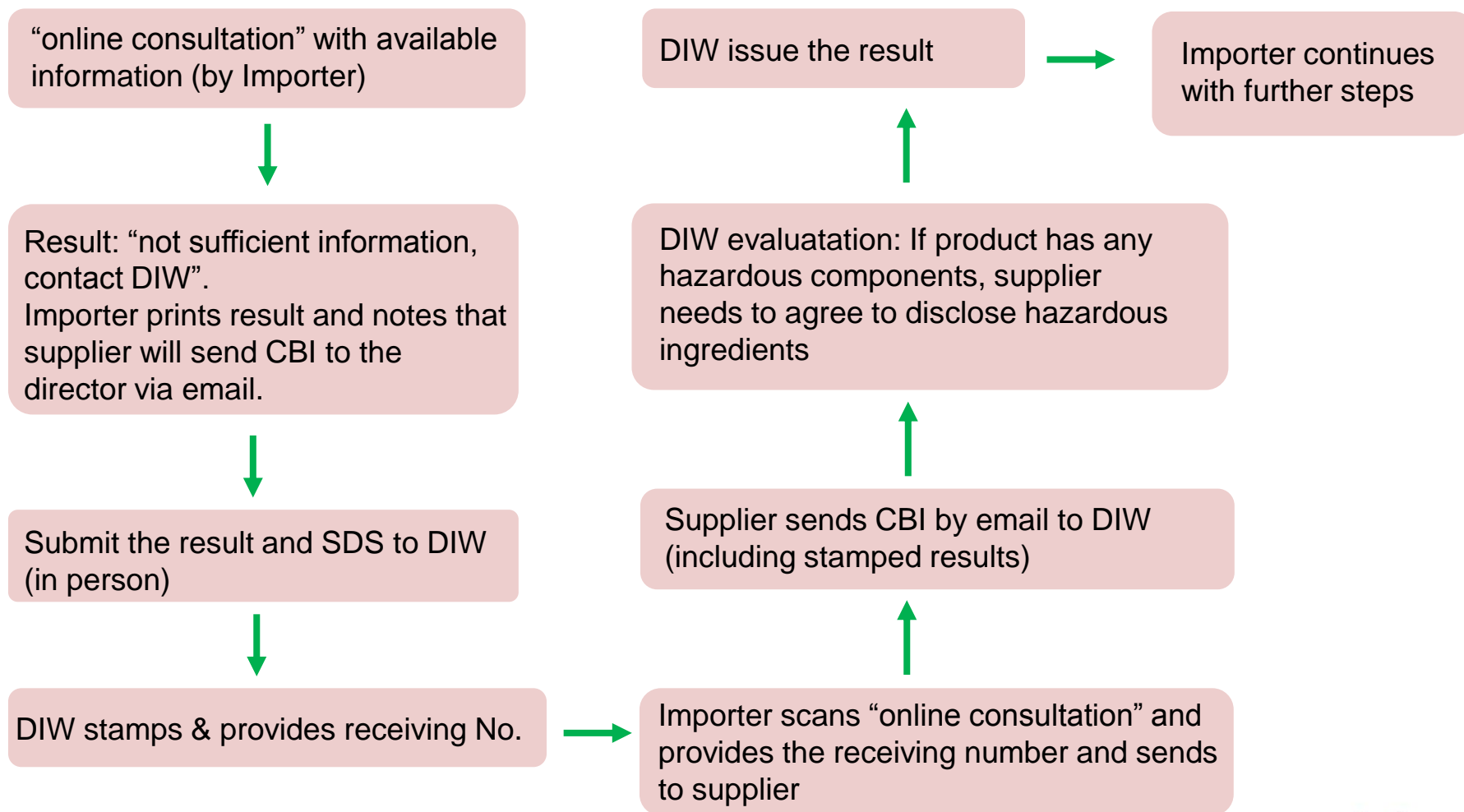
- ▶ Apply for 15 digits code for Type 1 (only in sub-list 5.1 and 5.4)
- ▶ Registration for hazardous substance Type 2 and 3
- ▶ Notify the DIW for Type 2 or Apply for license for Type 3
- ▶ Submit “Prior Informed Consent” before proceeding Customs clearance process
- ▶ Comply with safety measures in the ministerial notifications (*GHS-SDS and Labeling)

* March 2013 for substance, March 2017 for Mixtures

Confidential Business Information (CBI)

- DIW requires **full disclosure** of ingredients
- CBI will be used internally within DIW for classification & evaluation only (but hazardous compounds will be public)
- CAS No. must be provided (if no CAS No., the chemical structure must be provided)
- DIW established its own mechanism (e.g. providing confirmation letter without CBI disclosure for non-hazardous substance/product) for CBI protection
- To dates, submission of CBI possible directly from oversea supplier to DIW
- No guarantee of confidential data to registration holder (importer & distributor)
- DIW will not include CBI information in inventory
- CBI request may takes around 8-12 months (minimum).

Confidential Business Information (CBI)



What we should know?

- Supplier name must be mentioned clearly in the CBI letter.
- Online consultation report of the product with the same tradename (from same supplier) can be referred for import clearance with different importers.
- CAS No. must be provided (if no CAS No., the chemical structure must be provided).
- DIW published the „rules to reject CBI submission“ ([available in Thai language](#)) e.g.
 - *Consultation result mismatched with SDS; different tradename; wrong product status/ identification*
 - *Not provide 100% ingredients data from manufacturing **within 3 months***
- For non-hazardous substance, range of percentage $\leq 10\%$ is acceptable.
- For hazardous substance Type 1 – 4, only exact percent is acceptable.
- The chemical reaction chart or procedure must be provided for the residues without CAS No.
- Only certified 100% material certification will be accepted (with authorized signature and seal with company stamp).

What we should know?

- Chemical information data from Consultation result **with actual production/ import data** will include in the chemical inventory but the officer will verify the data before input in the inventory (criteria is under consideration).
- From October 2017, DIW allows the daughter company in Thailand to do the consultation on behalf of importer. The daughter company or authorized person must have POA from the manufacturer.
- The new Hazardous substance Act will be announced.
- The Hazardous Substance Single Submission ([HSSS](#)) is launch online for the registration of hazardous substance Type 2,3 and licensing of Type 3.



ระบบการอนุญาตวัตถุอันตราย ณ จุดเดียว

Hazardous Substance Single Submission: HSSS

กรมโรงงานอุตสาหกรรม DEPARTMENT OF INDUSTRIAL WORKS

(Example for Confidential Business Information)

Company Logo

CONFIDENTIAL

Date:

To
Hazardous Substances Control Bureau,
Department of Industrial Works,
Ministry of Industry,
The Kingdom of Thailand

This letter is in response to the request for chemical composition for... (product name)... which imported in to Thailand by ... (name of importer).... This information is being requested for hazardous classification purpose. The information disclosed in this letter can only be shared on a need-to-know basis with the Hazardous Substance Control Bureau (HSCB) for the purpose of importation. This closure corresponds to HSCB document number XXXX.... and applies date... (day/month/year).....

The composition of... (product name) ...as follows :

Product name: XXXX
Manufactured by: XXX.
Country of origin: XXX

Component	CAS No.	Wt%
1.....		
2.....		
3.....		
Total		100

Sincerely,

Signature

Name of authorized person

Title:XXX

Division or group or section etc.

Name of company.....

Phone: XXX

E-mail: XXXX

(Example for disclosure letter)

Company Logo

Date:

To
Hazardous Substances Control Bureau,
Department of Industrial Works,
Ministry of Industry,
The Kingdom of Thailand

This is approval letter to Hazardous Substance Control Bureau to disclose following composition(s) in ... (product name)..... that classified as Hazardous Substance according to Hazardous Substance Act B.E. 2535 for registration and/or license purpose.

Product name: XXXX

Reference : HSCB document number...XXXX..... and apply date ... (day/month/year)...

Name of Importer : ...XXXXXX.....

Component of Hazardous Substance	CAS No.	wt%
1.....		
2.....		

Manufactured by: XXX

Country of origin: XXX

Sincerely,

Signature

Name of authorized person

Title:XXX

Division or group or section etc.....

Name of company...xxxxxx.....

Phone: XXX

E-mail: XXXX

HS List 5.6: Controlled Substances based on Hazard Properties

No.	Hazard Properties
1	Explosive
2	Flammable substance
3	Oxidizing agent or Peroxide
4	Toxic Substance
5	Mutagen
6	Corrosive
7.	Irritant
8.	Carcinogen
9.	Toxic substance to reproductive organ
10.	Environmentally hazardous substance

Hazardous Substance Type 1 under the condition “...*only substances or mixtures not having responsible agency for production or import. They shall be complied with criteria and method prescribed by MOI...*”

Notification of Ministry of Industry
Subject: Declaration of the production or import of hazardous substances of list 5.6
under the responsibility of Department of Industrial Works
B.E. 2558 (2015)

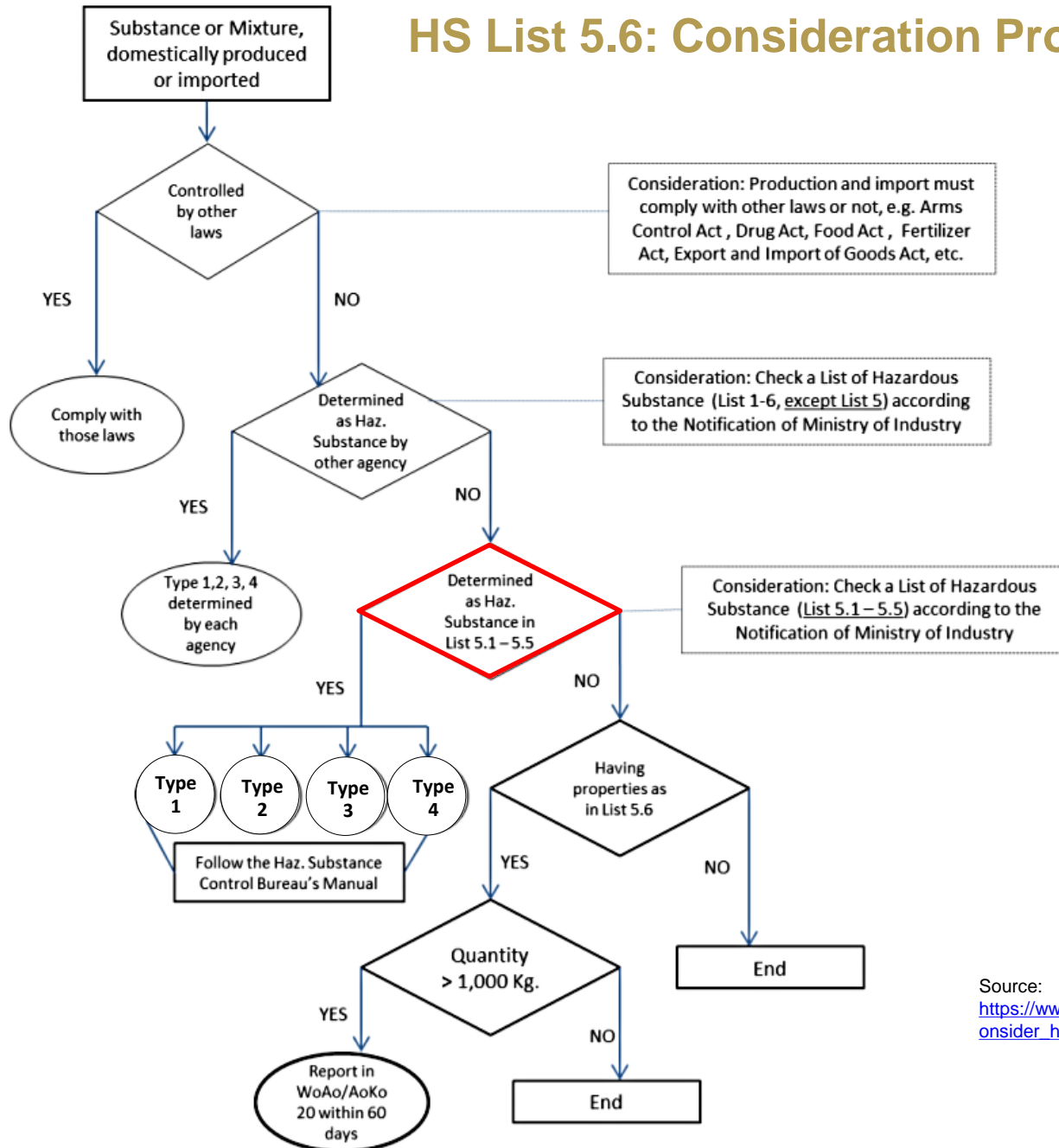
By the virtue of section 5 paragraph three of the Hazardous Substance Act B.E. 2535 (1992) and section 20(1) of the Hazardous Substance Act B.E. 2535 which has been amended by the Hazardous Substance Act (No.3) B.E. 2551, the Minister of Industry, with the opinions of the Committee on Hazardous substance, hereby issues the ministerial notification as follows:

Article 1 In this Notification:

“Hazardous substance” means hazardous substance under the responsibility of Department of Industrial Works listed in List 5.6 Groups of Hazardous Substances by their Properties prescribed in List 5 which is annexed to the Notification of Ministry of Industry on List of Hazardous Substances in pursuant to the provision in section 18 paragraph two of the Hazardous Substance Act B.E. 2535.

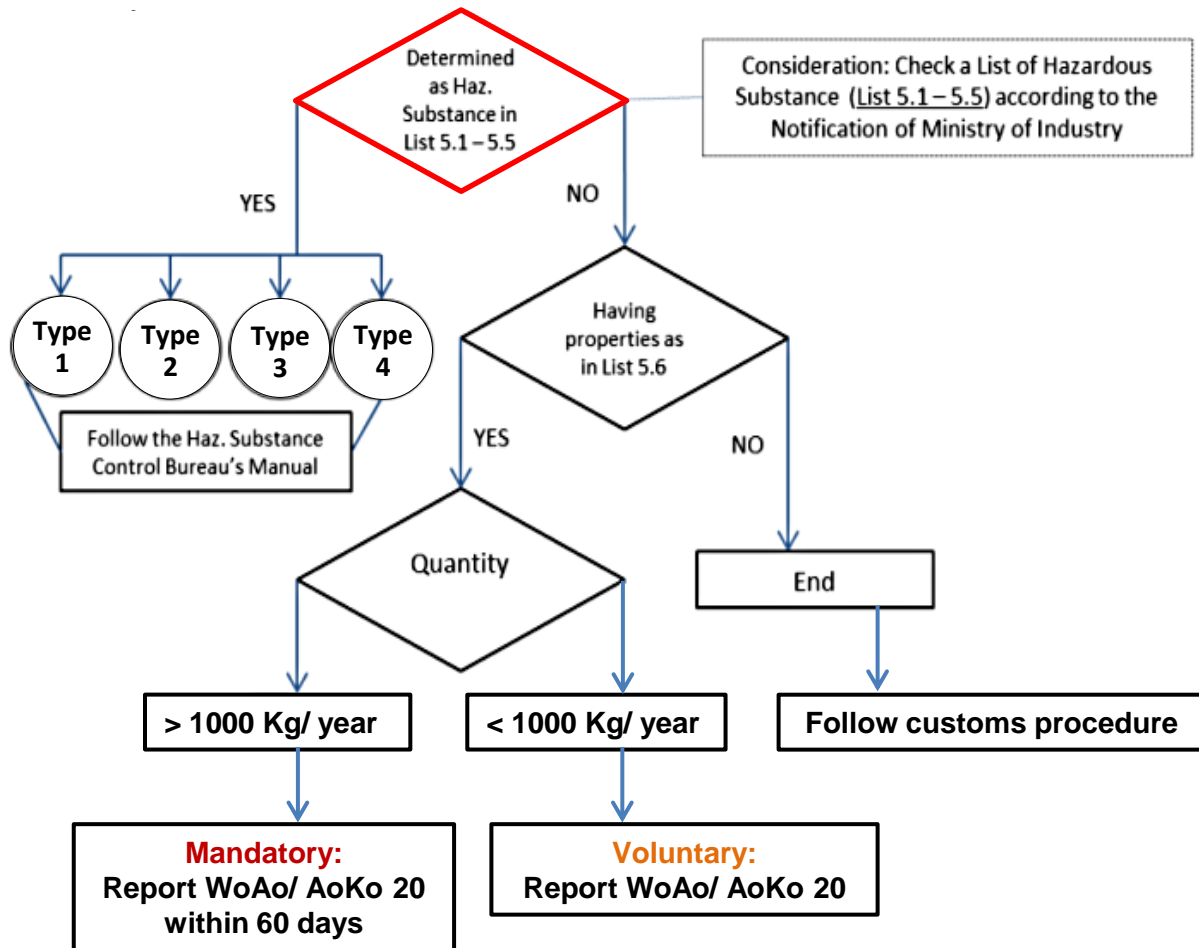
<http://www.diw.go.th/hawk/news/haz/%E0%B8%9A%E0%B8%8A%205.6.pdf>

HS List 5.6: Consideration Procedure



Source:

https://www.jetro.go.jp/ext_images/thailand/pdf/28Add_explanac_onsider_hazard_substance_List_5_6.pdf



- Thai Producer or importer of hazardous substance in the amount >1,000 kg/ year shall declare the information according to the WoAo/AoKo 20 Form (List 5.6 notification)
- Products which are not Type 1-4, but show hazard sign on SDS
- Imported > 1t/year



กรมโรงงานอุตสาหกรรม
DEPARTMENT OF INDUSTRIAL WORKS

ระบบการแจ้งข้อเท็จจริงของวัตถุอันตรายตามบัญชี ๕.๖

- การตอบหารือกรณีกักกัน
- การแจ้งข้อเท็จจริงการพลัด-พาเข้า (วอ./อก.20)

Username and password



Username (member code)



.....

เข้าสู่ระบบ

*** กรณีที่ท่านเป็นสมาชิกระบบตอบข้อหารือเคมีภัณฑ์เดิมอยู่แล้วไม่ต้องสมัครใหม่ ให้ใช้ หมายเลขสมาชิก และรหัสผ่านเดิม ***สมัครขอใช้บริการ แยกใช้สมาชิก/พิมพ์สว.๒/ลิ้มรหัสผ่าน

รณวัตถุอันตรายไปใช้ดังนี้



กรมวิชาการเกษตร



กรมประมง



กรมปศุสัตว์



สำนักงานคณะกรรมการอาหารและยา



กรมโรงงาน

***** ผู้ประกอบการที่ยื่นหารือไว้ใน วันที่ 23-24 กันยายน 2558 และ 2 ตุลาคม 2558 เนื่องจากทางกรมโรงงานอุตสาหกรรมตรวจพบข้อผิดพลาดของระบบ ที่ไม่ถูกต้องจนต้องให้ท่านเข้ามาหารือใหม่อีกครั้ง *****

Related Laws

กฎหมายที่เกี่ยวข้อง

Explanation on List 5.6

คำแนะนำสำหรับการพิจารณา
วัตถุอันตราย ตามบัญชี ๕.๖

การสมัครขอใช้บริการ

Manual of Service Registration

คู่มือการใช้งานระบบ

Manual of Notification System

หมายเหตุ - การแจ้งข้อมูลองค์ประกอบของสาร ไม่ครบ 100% ระบบอาจจะประมวลผลไม่ถูกต้อง ทางกรมโรงงานอุตสาหกรรมจะไม่รับผิดชอบใดๆ ทั้งสิ้น

- กรณีเป็นสารกัมมันตรังสี หรือ วัตถุติดเชื้อ ไม่ต้องแจ้งผ่านระบบนี้ ให้ไปดำเนินการติดต่อหน่วยงานที่รับผิดชอบ

- การแจ้งข้อเท็จจริงตามแบบ วอ./อก.20 เป็นการแจ้งในกรณีที่สารเคมีที่นำเข้าหรือผลิต ไม่เป็นวัตถุอันตรายชนิดที่ 1, 2, 3 ซึ่งต้องแจ้งข้อเท็จจริงตามแบบ วอ./อก. 6

คำแนะนำ : Browser :แนะนำให้ใช้ Chrome, IE9 หรือสูงกว่า

HS List 5.6: Controlled Substances based on Hazard Properties

Notifying of Hazardous Substance Type 1 as in List 5.6 “[Form WoAo./AoKo. 20](#)”

Required information in “Form WoAo./AoKo. 20”:

- Legal entity information (e.g. name of the applicant, age, nationality, TAX ID, address, contact info, etc.)
- Type of notification ○ production ○ import
- Type of chemical / product ○ substance ○ mixture
- Chemical name / trade name
- HS code
- UN number (if any)
- Chemical / product information (chemical name, chemical formula, CAS No., content (% w/w), etc.)
- Volume per year (in kilogram)
- Physical state (solid / liquid / gas / others)
- Container / packaging details
- Manufacturer and country of origin
- Supplier / distributor
- GHS classification (if any)
- Physical and chemical properties
- Toxicological information
- Ecological information
- Disposal consideration
- Application (usage)

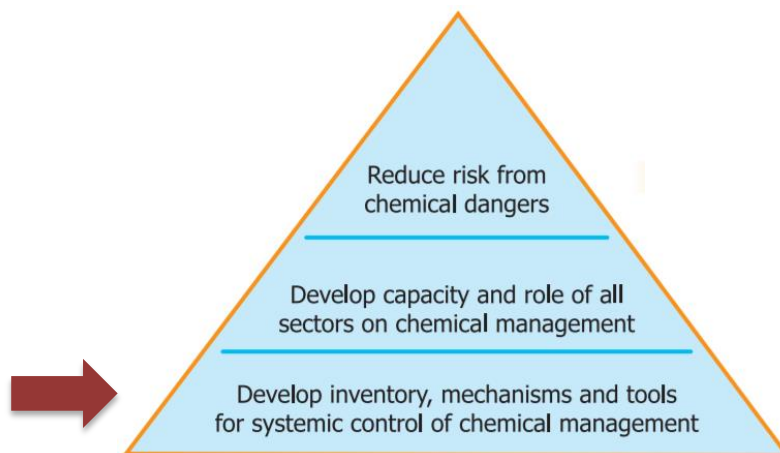
Thailand Existing Chemicals Inventory (TECI)

Thailand Existing Chemicals Inventory (TECI) is the national inventory that contains chemical substances imported and produced in Thailand. The development of TECI is part of a project listed under the **First Phase Action Plan (2012-2015) of the 4th National Strategic Plan on Chemical Management (2012-2021)**.

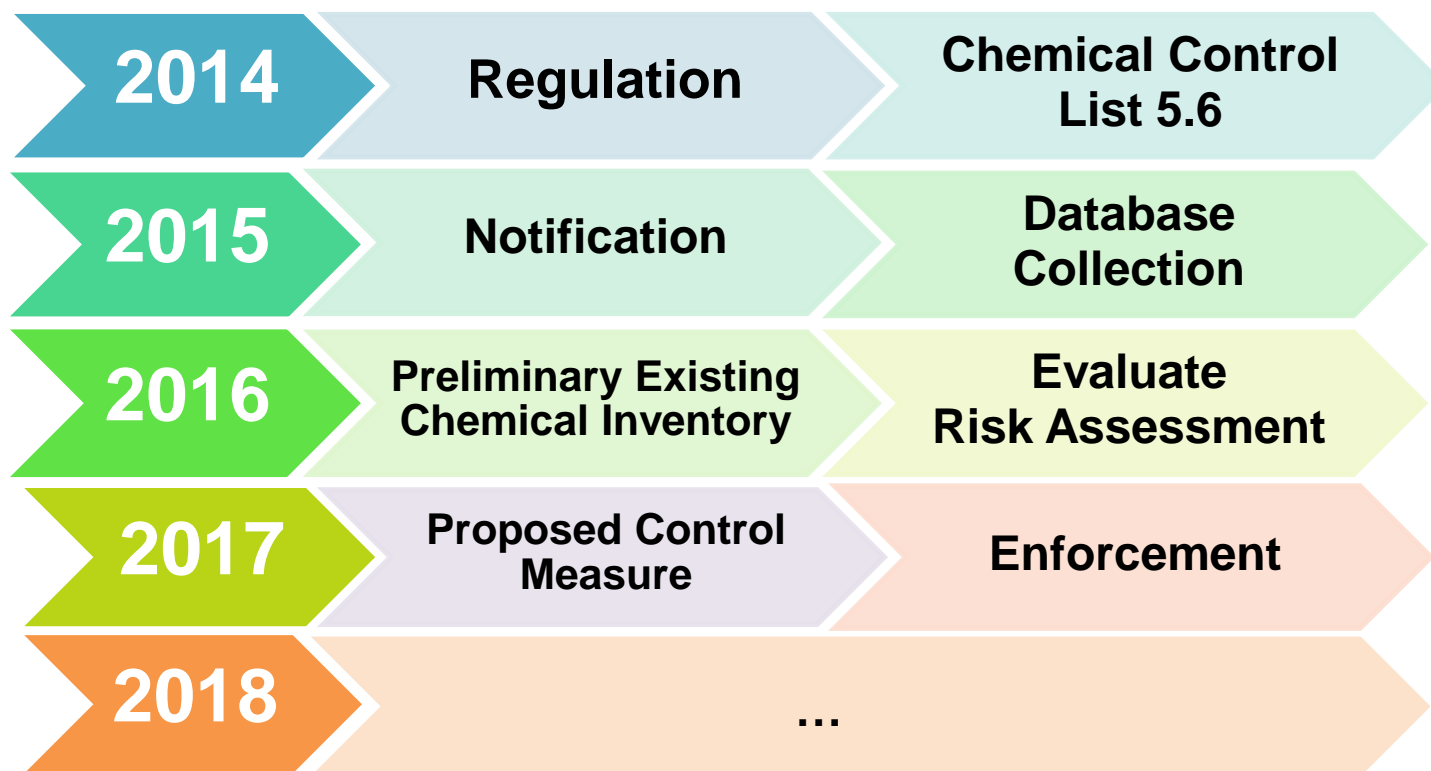
The project was implemented to serve **Strategy 1 of the 4th Plan** which covers the development of chemical database, mechanisms and tools for fully integrated system of chemical management.

Strategy 1

“Develop chemical inventory, mechanisms and tools for system control of chemical management”



Road Map of Thailand Existing Chemical Inventory



Future Plans for Thailand Existing Chemical Inventory

- ▶ Preliminary of Thailand Existing Chemicals Inventory: <http://haz3.diw.go.th/invhaz/>
- ▶ Search only for CAS number (later on for company name & trade name)



- ▶ No date for official 1st version of inventory yet
- ▶ Update of Hazardous Substance Act is in process
- ▶ Public Hearing ended in June 2017, no date for enforcement available yet

Formaldehyde (CAS No. 50-00-0)

กรมโรงงานอุตสาหกรรม
DEPARTMENT OF INDUSTRIAL WORKS

สำนักควบคุมวัตถุอันตราย
HAZARDOUS SUBSTANCES CONTROL BUREAU

ทำเนียบสารเคมีที่มีอยู่แล้วของประเทศไทยฉบับเบื้องต้น
(Preliminary of Thailand Existing Chemicals Inventory)

หน้าหลัก | วัตถุอันตราย

Listed as hazardous substance: Type 2, No. 296

CAS-Number 50-00-0

เป็นบัญชีวัตถุอันตรายชนิดที่ : 2

ลำดับที่ : 296 ชนิดของวัตถุอันตราย : 2

Regulated as hazardous substance in List 5.1

เป็นบัญชีวัตถุอันตรายตามบัญชี : 5.1

ชื่อวัตถุอันตรายตามบัญชีวัตถุอันตราย :
 ฟอร์มาลดีไฮด์ (formaldehyde) หรือ เมทานัล (methanal)
 เจือปน :
 ยกเว้นที่เป็นสารตั้งต้นในการผลิตเรซิน และเว้นแต่ในส่วนที่อยู่ในความรับผิดชอบของกรมประมง


Name of hazardous substance as shown in the List 5.1 and Condition

ชื่อสารเคมีตามข้อมูลจากอินเทอร์เน็ต(CASLIST):
 Formaldehyde

Name of hazardous substance as shown in the internet (CASLIST)

Type 2 hazardous substance

Water (CAS No. 7732-18-5)



กรมโรงงานอุตสาหกรรม
DEPARTMENT OF INDUSTRIAL WORKS

สำนักควบคุมวัตถุอันตราย
HAZARDOUS SUBSTANCES CONTROL BUREAU

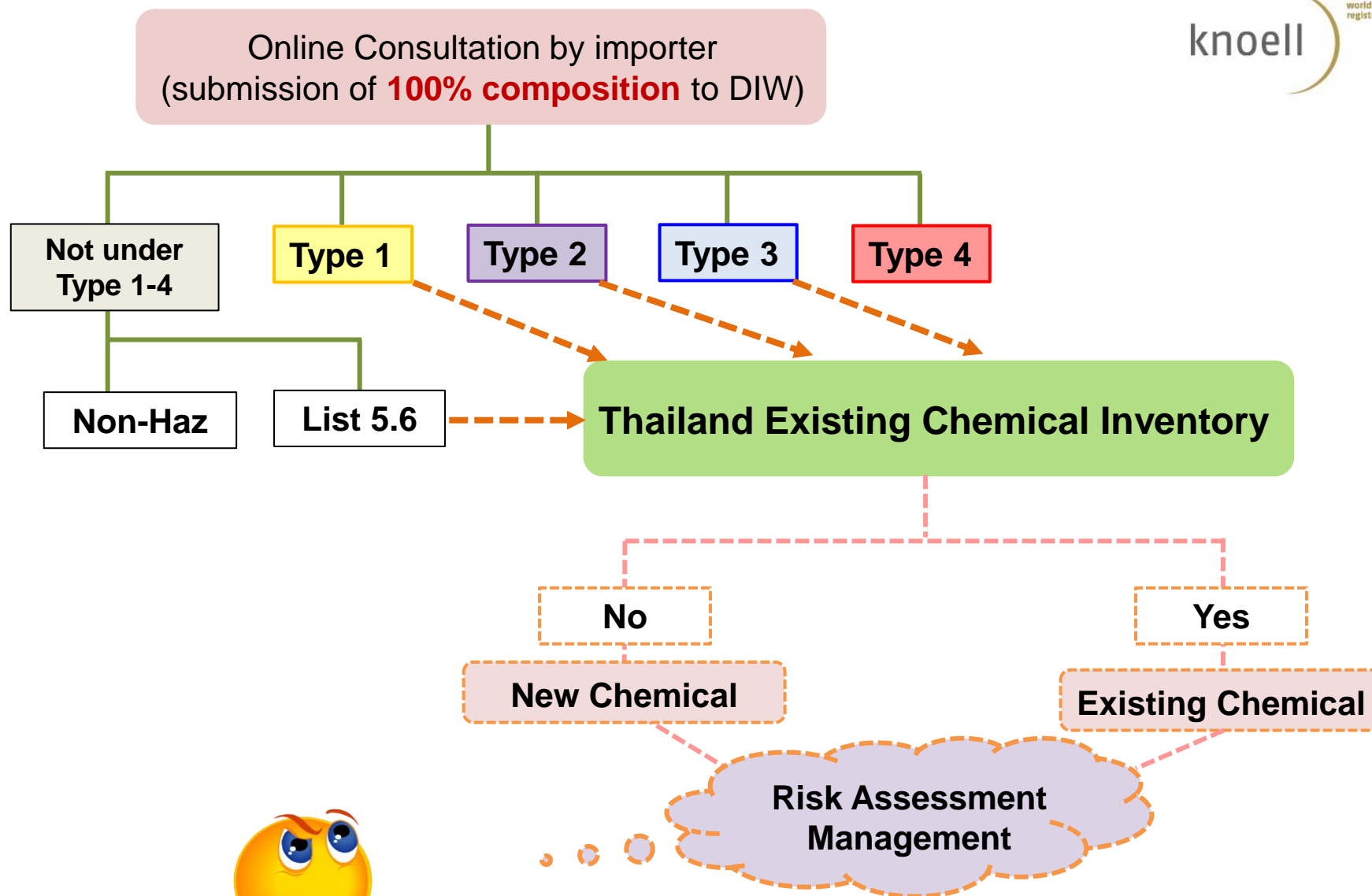
ทำเนียบสารเคมีที่มีอยู่แล้วของประเทศไทยฉบับเบื้องต้น
(Preliminary of Thailand Existing Chemicals Inventory)

หน้าหลัก | บัญชีวัตถุอันตราย

CAS-Number ค้นหา

ไม่พบอยู่ในทำเนียบข้อมูล

Not found in the inventory

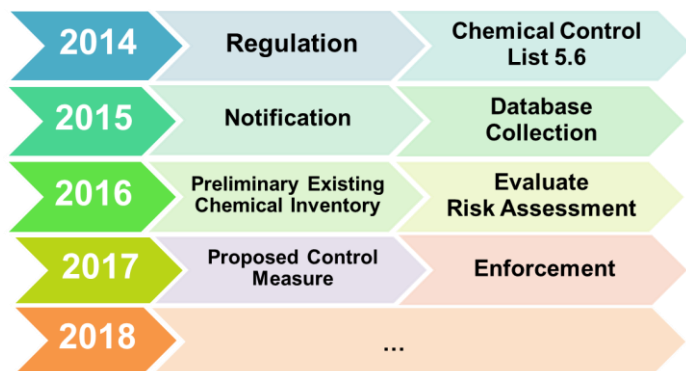


(Still under the exploring step)

Proposed Risk Assessment

Informative workshop took place on 13th November 2017:

- ▮ Detailed plans of Risk Assessment is not available
- ▮ Currently only gathering ideas and advise
- ▮ Most probably adapt approaches from other regions (EU/ US/ Japan)
- ▮ Focus on Human Health and Ecological Risk Assessment
- ▮ No timeline available until when Risk Assessment may become effective



Hazardous Substance Single Submission (HSSS)

- ▶ <http://203.151.85.238/singlesubmit/#/login>

ระบบการอนุญาตวัตถุอันตราย ณ จุดเดียว
Hazardous Substance Single Submission: HSSS
กรมโรงงานอุตสาหกรรม DEPARTMENT OF INDUSTRIAL WORKS

ชื่อผู้ใช้:

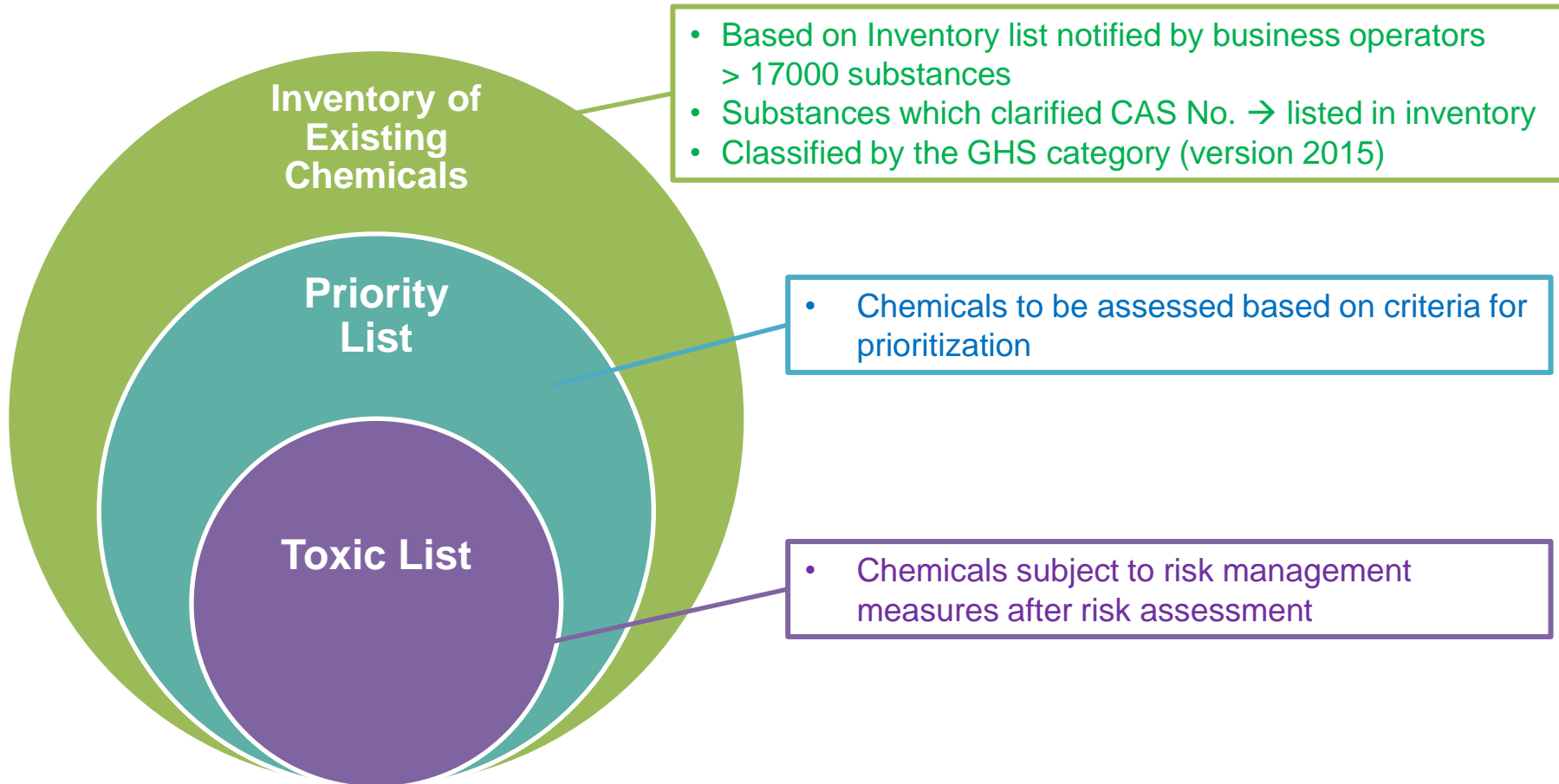
รหัสผ่าน:

[ลืมรหัสผ่าน](#)

[สมัครสมาชิก](#)

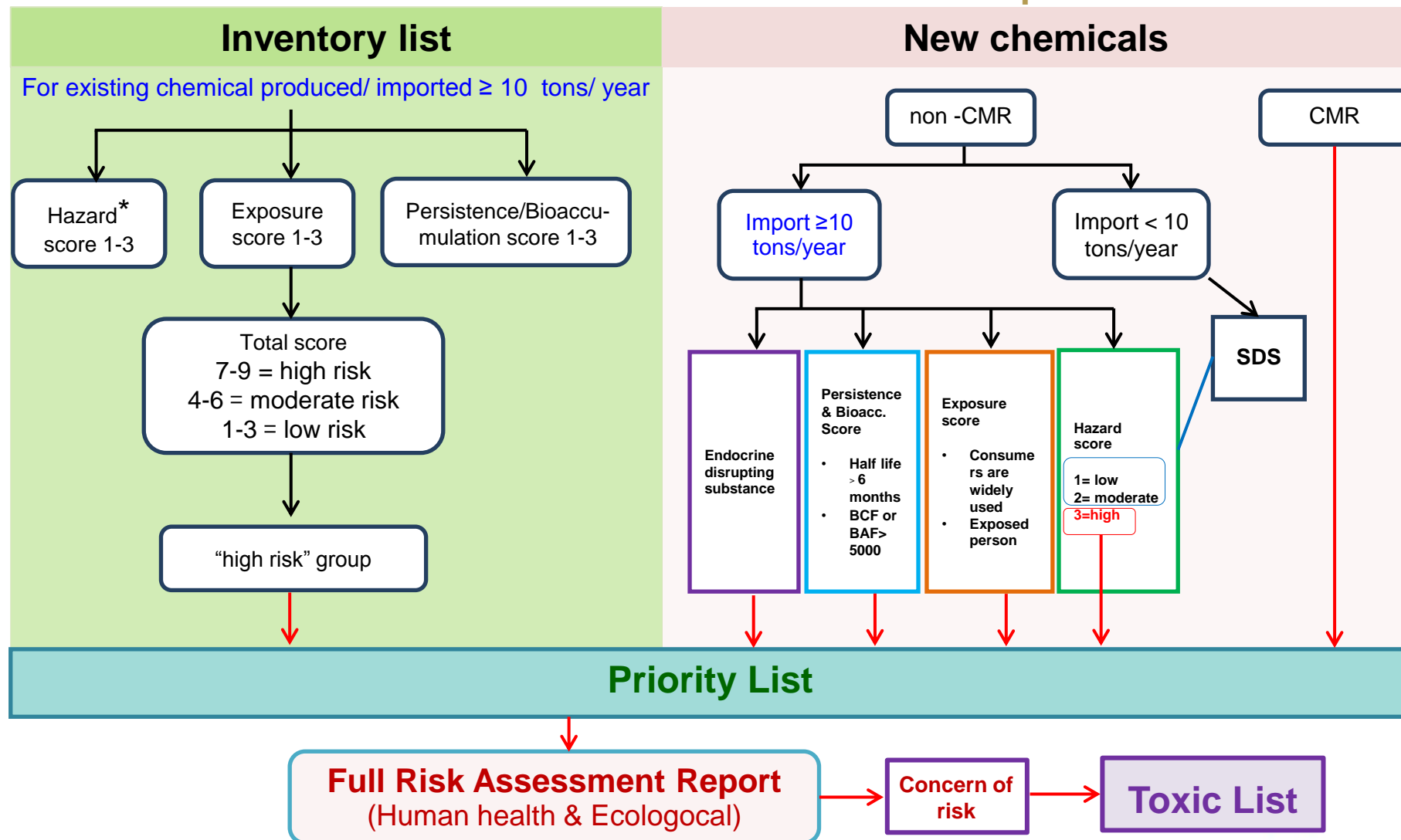
- ▶ HSSS is a web based hazardous substance registration system in collaboration with relating six agencies who were also responsible for hazardous substances.
- ▶ It is enable importers and manufactures to submit substances information which were classified as hazardous substance Type 2 and Type 3.
- ▶ For HSSS, this year, all documents can be submitted online, but a physical copy of the licence must be collected from the DIW office.

Proposed Risk Assessment



Only proposed idea* and not official information

Selection of Hazardous Substances for Risk Assessment process



Necessary information for the Priority List of Existing Chemicals:

Hazard:

1. Toxicity profile of substance: acute toxicity (any route of exposure), carcinogenicity, mutagenicity; genotoxicity, reproductive toxicity; causes damage to nervous system ; aspiration toxicity, acute & long-term hazards to the environment
2. Hazard classification: according to the GHS 2015

Exposure:

1. Use type
2. General population & environmental exposure
3. Toxic Release Inventory (TRI)/ non-TRI

Persistence/Bioaccu-mulation:

1. Half-life of substance
2. Bioconcentration factor (BCF) and bioaccumulation factor (BAF)

If total score is in a range of 7 – 9 → High Risk → Full Risk Assessment Report → “concern of risk substance” shall be included in “Toxic list”

For the new chemicals:

Chemicals might fall under the priority list if;

1. Carcinogenic, mutagenic, reprotoxic (CMR) substances
2. Chemicals with volume of production/ import ≥ 10 tons/ year and has at least one of the following conditions;
 - a) Hazard score = 3 (high); or
 - b) Consumers are widely used;
 - c) Exposed person*;
 - d) Half-life > 6 months;
 - e) Bioconcentration factor (BCF) and bioaccumulation factor (BAF) > 5000
 - f) Endocrine disrupting substance;

*1000 exposed person in the factory or 100 inhalation exposure occurs or 250 skin contact occurs

Proposed Changes on Hazardous Substance Act – the 3rd revision

Most important proposed changes:

- ▶ No registration required if only transported through the country (transboundary movement)
- ▶ Not allowing Hazard Substance Type 4 transboundary movement
- ▶ Having definition for Re- Import and Re-Export (no registration, only notification required)
- ▶ To allow government office to regulate activities related to product advertising and sale promotion
- ▶ Production or Importation of Hazard Substance Type 2 and 3 must be registered before. The registration license would be valid for 10 years
- ▶ There is the announcement for exemption on importation of Hazard Substance for studying, testing analytical and RD as issued before
- ▶ Definition of liability regarding any damages occurring from chemical products
- ▶ Adjustment of Hazard Substance committee and the procedures aims to enhance and streamline requirements in the processing of license and permit

Thank you very much for your attention

Dr. Piyatida (Tung) Pukclai

Asia-Pacific Business Development & Regulatory Policy Director

Dr. Knoell Consult Thai Co. Ltd.

4th Floor Unit 407 Airport Business Park (B-Building)

92/1 Mahidol Road T. Haiya A. Muang Chiang Mai Thailand 50100

Phone: +66 (0)52 080454

Mobile: +66 (0)8 82510303

Fax: +66 (0)52 080452

E-mail: PPukclai@knoell.com

Internet: <http://www.thailand.knoell.com/en>