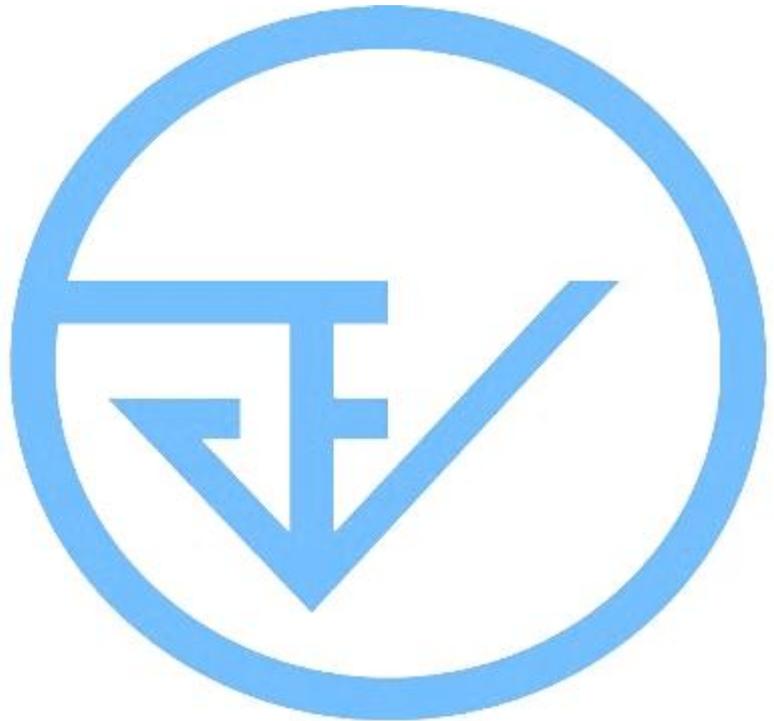


***Introduction
to the Regulations of
Hazardous Substances
Used in Household
and Public Health***

Introduction to the Regulations of Hazardous Substances used in Household and Public Health



Hazardous Substances Control Group

Bureau of Cosmetic and Hazardous Substances Control

Food and Drug Administration

Ministry of Public Health

March 2013

Made by Strategic planning and policy development unit
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Hazardous Substances Control Group

Vision

"To be the leading agency for consumer protection for hazardous substances used in household and public health products."

Mission

1. To regulate the hazardous substances used in household and public health products to ensure their quality and safety.
2. To strengthen and build up capacity of hazardous substance entrepreneurs.
3. To improve and enhance the effectiveness of operating system and human resource.
4. To promote and develop knowledge and research on hazardous substance products.

Background

Hazardous Substances Control Group, Bureau of Cosmetic and Hazardous Substances Control, Food and Drug Administration, is responsible for regulating the hazardous substance products for household and public health use to meet the quality and safety standards by the empowerment of the Hazardous Substance Act B.E. 2535 (1992).

The hazardous substances used in household and public health, include:

1. *Public health pesticides*

Any product containing pesticides or rodenticides, such as mosquito coils, insect repellents, ectoparasiticides, rat killers, ant killers, cockroach killers, and termiticides.

2. *Cleaning products*

Any product used for cleaning any surface or material, such as dishwashing products, liquid laundry detergents, toilet cleaners, glass cleaners, and car washing products (except powdered detergents).

3. Disinfectants

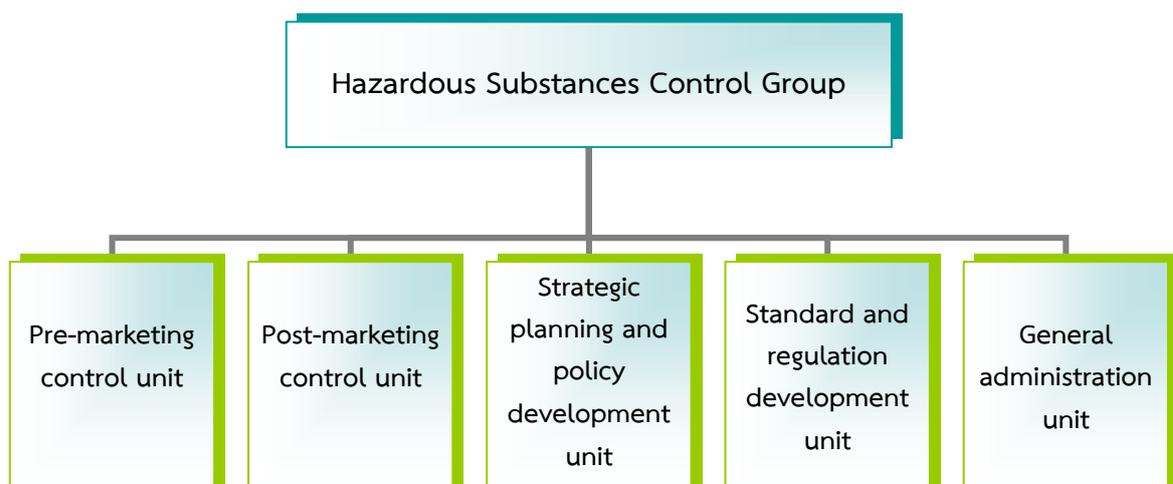
Any product used for killing germs on any surface or material or in the air, except those products used for pharmaceuticals and for medical devices.

4. Other consumer products

Other products, such as the drain opening products, paper correction products and alkyl cyanoacrylate adhesive.

In order to ensure that consumers shall receive the qualified and safe products, Hazardous Substance Control Group works on the developing laws and regulations to control and monitor hazardous substance products on the up-to-date situation, the approving for registration of hazardous substance products before placing on the market and the inspecting enterprises before licensing. For post-marketing controls, there are procedures of the monitoring product to meet the safety standard and the inspecting product after placing on the market. There are also the developing of the manufacturing standard of hazardous substance enterprises in accordance with the good manufacturing practices (GMP) and promoting the pest control operators (PCO). Additionally there are other projects including the developing of the study, the capability of staff and the consumer protection effectively.

Structure of the Hazardous Substances Control Group



Responsibility

Pre-marketing control unit

- Granting approval for registration of the hazardous substance products used in household and public health, e.g., public health pesticides, disinfectants, cleaning products, and other hazardous substance products.
- Granting permission of the manufacturing, import, export, and possession for professional use of type 3 hazardous substances.
- Granting notification receipt for manufacturing, import, export, and possession for professional use of type 2 hazardous substances.
- Granting product information receipt for manufacturing and import of type 1 hazardous substances.
- Granting related certificates such as certificate of free sale (CFS).
- Granting approval for the request for changing context and detail on licenses and product registration certificates.

Post-marketing control unit

- Inspecting enterprise premises for manufacturing, import, export and possession of hazardous substances, for licensing and surveillance purposes.
- Inspecting products after placing on the market.
- Law enforcement.
- Auditing manufacturing sites in accordance with the good manufacturing practices (GMP) guidelines.

Strategic planning and policy development unit

- Planning, budgeting, coordinating and project evaluation.
- Developing IT system of the hazardous substances control group.
- Improving organizational performance.
- Developing and training human resource.
- Building up capacity of business sector.

Standard and regulation development unit

- Reviewing and assessing chemical data and chemical product information in order to assess risks and hazards and place appropriate control measures.
- Considering whether or not substances or products are under regulations.
- Setting measures, criteria and legal procedures in order to regulate hazardous substances properly and safely.
- Serving as the secretariat of sub-committee on standards and registration of hazardous substances used in household and public health and coordinating with the hazardous substance committee and relating sub-committee (external agencies).
- Coordinating for international affair.

General administration unit

- Administration of documentation, finance, personnel, procurement and supply.
- Facilitating and assisting tasks such as coordinating, arranging meeting room, vehicle arrangement.

History of the Hazardous Substance Act

After World War II, a lot of DDT was used in wiping out malaria. The increasing use of pesticides in agriculture and chemicals in industries led up to the promulgation of the Toxic Substance Act of B.E. 2510 (1967). The toxic substances were classified into 2 classes; very toxic substances and toxic substances. Three responsible agencies, namely Ministry of Public Health, Ministry of Agriculture and Cooperatives, and Ministry of Industry, were involved. Later in 1973, some more measures on registration procedures and manufacturing, trade and import of toxic substances were added to the amendment of the Act, which was promulgated as the Toxic Substance Act, 2nd Amendment, B.E. 2516 (1973).

In 1992 the Hazardous Substance Act of B.E. 2535 (1992) was promulgated instead of the Toxic Substance Act B.E. 2510 (1967). The new Act included the classification of hazardous substances into 4 types according to degree of hazards and the needs for control and expanded its scope for thorough control. In addition, more responsible agencies were involved. The Hazardous Substances Act B.E. 2535 (1992) came into force in 1995 after the announcement of the hazardous substance list.

The hazardous substance list is periodically reviewed and up dated to cover more hazardous chemicals by taking into account chemical data, registrations in other countries, related conventions and international agreements.

In 2001, the Hazardous Substance Act, 2nd Amendment, B.E. 2544 (2001) were enacted by adding provisions on the Chemical Weapons Convention and its penalty. In 2008, the Hazardous Substance Act, 3rd Amendment, B.E. 2551 (2008) was promulgated. The Act was amended for more appropriated control of hazardous substances in the present situation, such as the stipulation of validity of type 2 hazardous substances notification receipt (not exceeding 3 years from the date of issuance), the stipulation of validity of registration certificate (not exceeding 6 years from the date of issuance) and the revision of the rates of fees.

Classification of Hazardous Substances and Its Relating Requirement
--

The Hazardous Substance Act of B.E. 2535 (1992) classifies hazardous substance into 4 types according to degrees of hazards, risks and needs of control.

The type 1 hazardous substance is the hazardous substance that has less impact on human health and environment than the other types. Manufacturers and importers are not required to register their products but product information must be notified to the authority. Furthermore, business operators must comply with the specified criteria and procedures, such as labelling, rules and conditions for manufacturing and storage. The notifying number must be declared on product label.

Examples of the type 1 hazardous substances under the responsibility of Thai Food and Drug Administration (Thai FDA) are as follows:

- Cleaning products, such as dish washing products, liquid laundry detergents containing anionic or nonionic surfactants as active ingredients (except nonylphenol ethoxylate).
- Adhesives containing alkyl cyanoacrylate as active ingredients.
- Swimming pool disinfectants containing calcium hypochlorite, sodium hypochlorite, dichloroisocyaauric acid and its salts, or trichloroisocyaauric acid and its salts as active ingredients.

The type 2 hazardous substance is the hazardous substance that has the degrees of hazards or risks **higher** than type 1. Manufacturers and importers must obtain product registration certificates. Manufacturers, importers, exporters or professional use possessors of the type 2 hazardous substances must notify the authority before the operations of type 2 hazardous substances. The hazardous substance registry number must be declared on the product label.

Examples of the type 2 hazardous substances under the responsibility of Thai FDA are as follows:

- Household and public health pesticides containing insect growth regulators (IGRs) as active ingredients.

- Cleaning products/disinfectants (except any products containing the type 1 or type 3 hazardous substances as active ingredients).

The type 3 hazardous substance is the hazardous substance that has the degrees of hazards or risks **higher** than the above mentioned types. Manufacturers and importers must obtain product registration certificates. Manufacturers, importers, exporters or professional use possessors of type 3 hazardous substances must receive the permission from the authority before the operations of type 3 hazardous substances. The hazardous substance registry number must be declared on the product label.

Examples of the type 3 hazardous substances under the responsibility of Thai FDA are as follows:

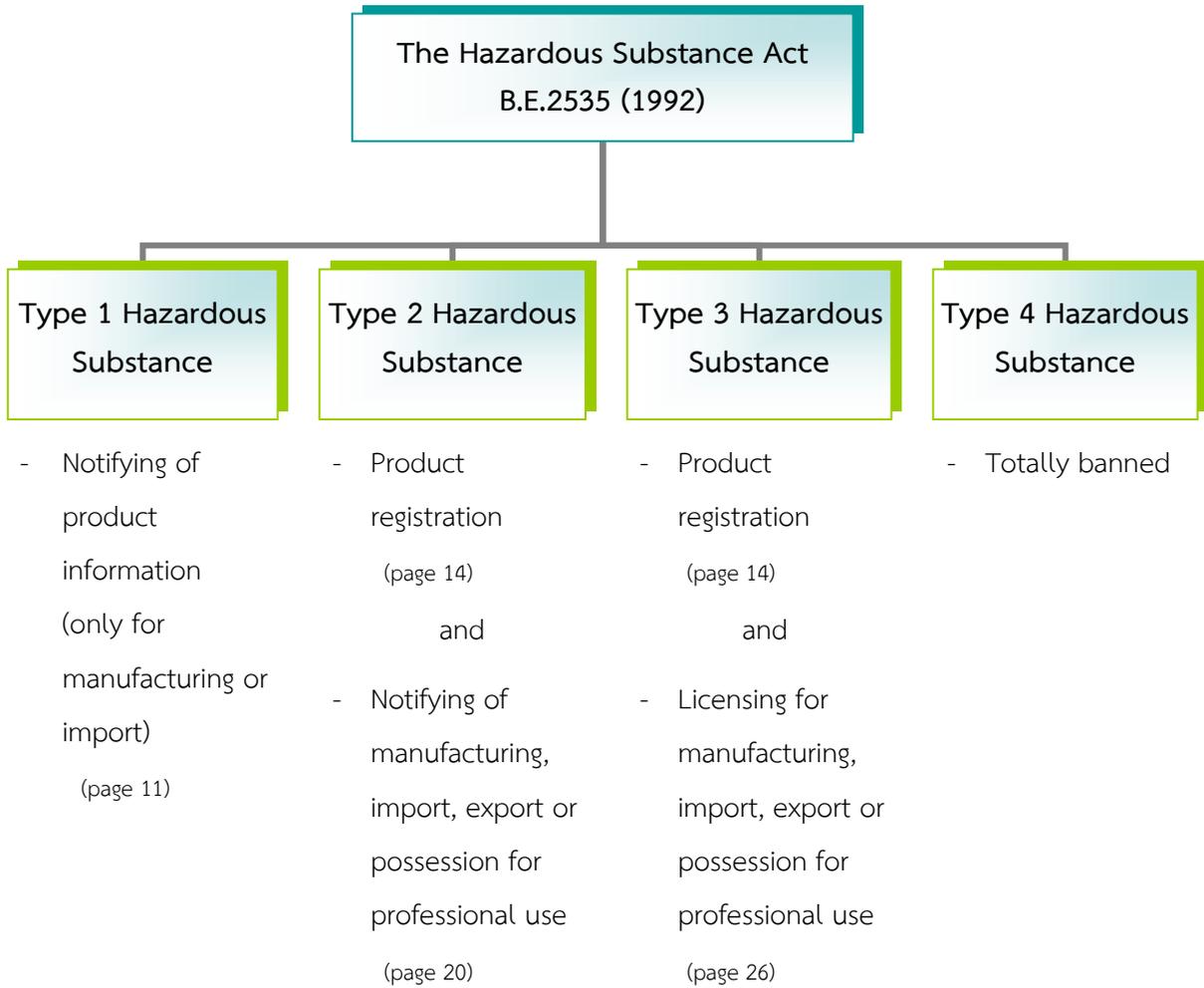
- Household and public health pesticides containing chlorpyrifos or pyrethroids as active ingredients.
- Cleaning products/disinfectants containing acids, alkalines, or aldehydes as active ingredients.

The type 4 hazardous substance is the hazardous substance that has high degrees of hazards or high risks either from its applications or its intrinsic properties, e.g., carcinogens, mutagens, reproductive toxicants or prohibited substances by the related conventions. Thus, manufacturing, import, export or possession of such substances is prohibited.

Examples of the type 4 hazardous substances under the responsibility of Thai FDA are as follows:

- DDT
- Chlordane
- Dieldrin

Classification of Hazardous Substances and Its Related Requirements



Hazardous Substance List

The Hazardous Substance Act B.E. 2535 (1992) classifies hazardous substances into 4 types (see details in “Classification of Hazardous Substances and Its Related Requirement” page 6). The names of hazardous substances, types of hazardous substances, responsible agencies and conditions of control are publicized in the annexed table of the Notification of Ministry of Industry on List of Hazardous Substances.

The current list is the Notification of Ministry of Industry on List of Hazardous Substances B.E. 2556 (2013). The hazardous substances under the responsibility of Thai FDA are on the “**List 4**” that is divided into “**List 4.1, List 4.2 and List 4.3**” (see details in Appendix page 50).

The List 4.1 is designated as the list of chemical names. CAS No., types of hazardous substances and conditions of control are also designated.

The List 4.2 is designated as the list of chemical groups with the same functional group or mechanism of action. CAS No., types of hazardous substances and conditions of control are also designated.

The List 4.3 is designated as the list of product groups or purpose of use. CAS No., types of hazardous substances and conditions of control are also designated.

The primary steps for checking your chemicals or products

The primary steps to check any chemical or any product is a hazardous substance under the responsibility of Thai FDA, are listed as follows:

1. Checking whether the product’s active ingredients match to any of chemicals listed in “List 4.1” and its use corresponds to the conditions specified in “List 4.1”.
2. Checking whether the product’s active ingredients are a substance in any of chemical groups listed in “List 4.2” and its use corresponds to the conditions specified in “List 4.2”.
3. Checking whether the use of product or product claims match to any of those in “List 4.3”.

Chemicals or products that fall in any mentioned conditions are classified as hazardous substances used in household or public health under the responsibility of Thai FDA. Consequently, compliance to the specified criteria and procedures for each type of hazardous substances is required.

Any product that falls into type 1 hazardous substance must be notified the authority of the product information. If any product falls into type 2 or type 3 hazardous substances, it must be registered and manufacturing, import, export, or possession for professional use must be notified (for type 2 hazardous substances) or must be licensed (for type 3 hazardous substances).

Notifying the Product Information of Type 1 Hazardous Substance

Manufacturers or importers of type 1 hazardous substances must notify the information of hazardous substance products to the authority by submitting an application form, namely **Notification of Product Information of Type 1 Hazardous Substance Wor Ohr./Sor Tor 5 (วอ./สอ ๕) (page 13)**, and the required documents stated in the form. In case of production, the information must be notified to the authority within 15 days since the first production date. Only the first import, the information must be notified to the authority before clearing shipment at the customs. If the manufacturing or storage sites of type 1 hazardous substance are located in Bangkok, the manufacturers or the importers must notify at the FDA office or by registered mail. If the manufacturing or storage sites of type 1 hazardous substance are located in other provinces, the manufacturers and the importers must notify at the provincial public health office where the sites are located. Export and possession for professional use of type 1 hazardous substances are not required to notify the authority.

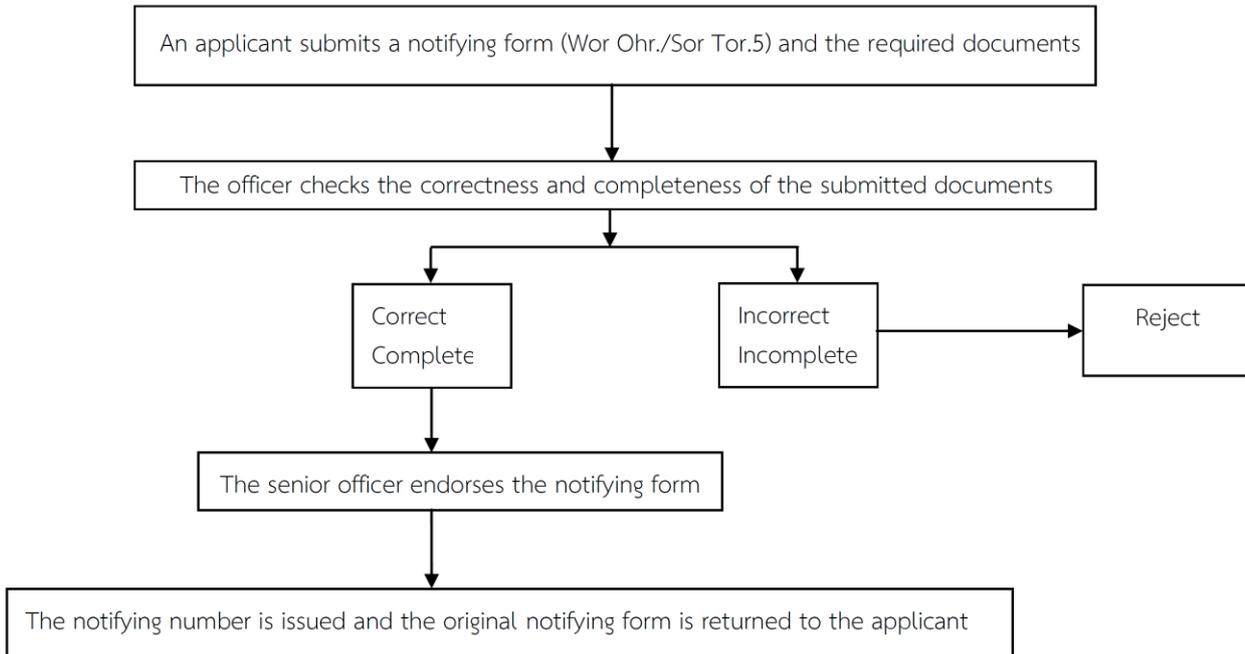
Fee

None

Validity of a product information receipt
of type 1 hazardous substance

No specified validity

Flow Chart for Notifying the Product Information of Type 1 Hazardous Substance



Notification of Product Information of Type 1 Hazardous Substance
(only for the items under the FDA's responsibility)

Type of Operation Manufacturing Import
Applicant's Name _____
Contact Address No. _____ Moo _____ Soi/Street _____
Road _____ Tambon/Sub-District _____ Amper/ District _____
Province _____ Postal code _____ Telephone _____
Fax _____
Taxpayer ID No. _____

Would like to notify the Type 1 Hazardous Substance as follows:

Trade Name _____
Physical Appearance _____ Type of Usage _____
Amount of Manufacturing/Import _____ Litre/ Kilogram/ Ton per year
Active Ingredients Contents and Other Constituents

Name of Manufacturing Plants or Storage Location _____ Contact Address No. _____ Moo _____
Soi/Street _____ Road _____ Tambon/Sub-District _____
Amper/ District _____ Province _____ Postal code _____ Telephone _____ Fax _____
In case of Import, Name of Foreign Manufacturer _____ Country _____
(Signature) _____ Authorized Person
(_____)

I hereby attach the documents as details below

- (1) A copy of identification card in case of natural person
- (2) A copy of certificate of juristic entity registration and a copy of power of attorney

For FDA officers

Receive the notification of type 1 hazardous substance. Notifying number _____

Signature _____ Officer
(_____)

Hazardous Substance Registration

According to The Hazardous Substances Act B.E. 2535 (1992), the manufacturers or the importers of type 2 or type 3 hazardous substances need to obtain the registration certificates prior to the further actions such as notifying their manufacturing or import of the type 2 hazardous substance or obtaining the license of manufacturing or import of the type 3 hazardous substance. Nevertheless, there are some exemptions for some hazardous substance products that are not required for registration such as deodorizers or insect repellents containing naphthalene or *p*-dichlorobenzene as an active ingredient, paper correction products in the forms of water-based solution or tape without organic solvents, and hazardous substance products belonging to the government agencies. The registration certificate shall be valid for a period not exceeding six years from the date of issuance.

The required documents for registration

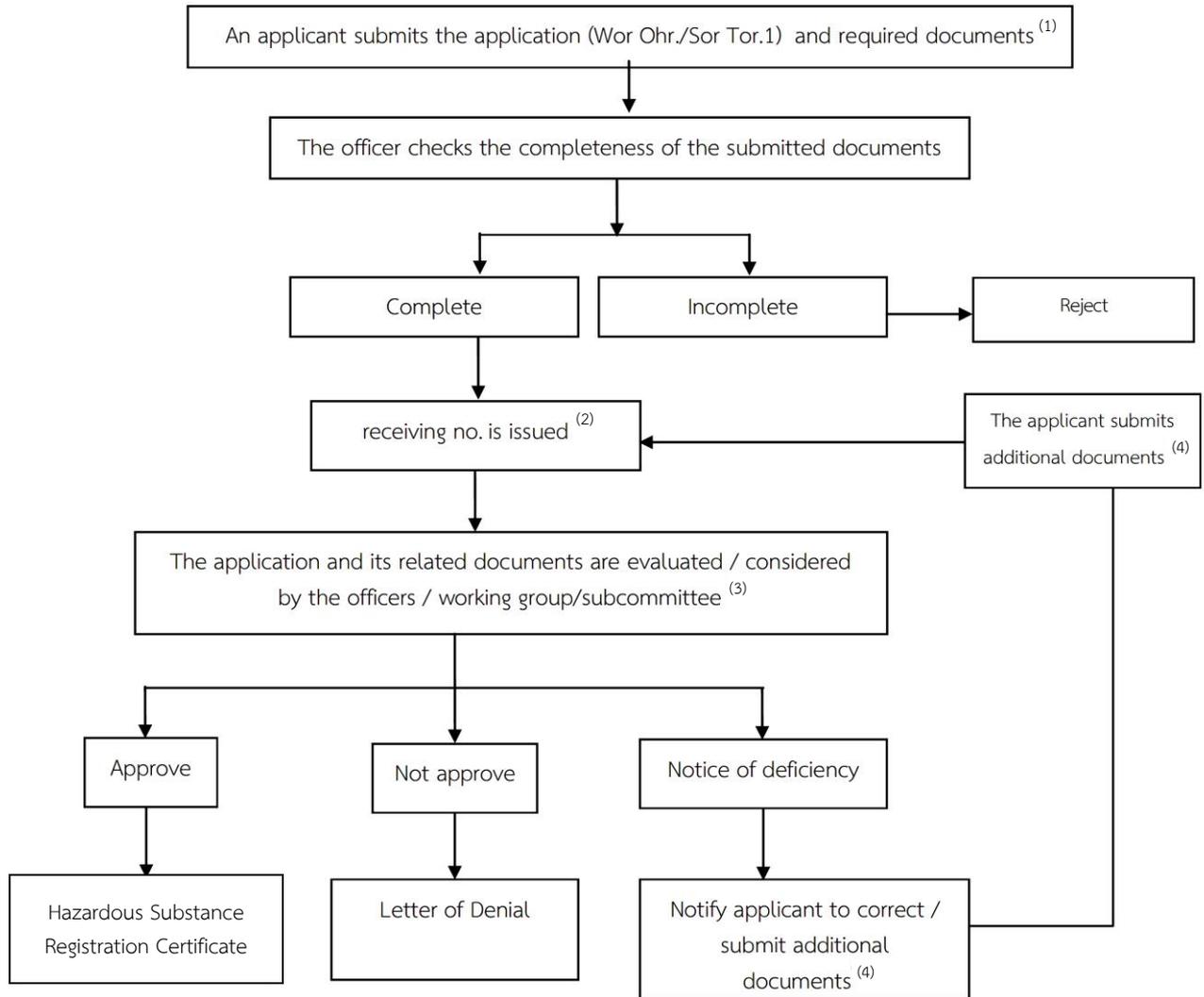
1. **Hazardous Substance Registration Application Form Wor Ohr./Sor Tor 1 (วอ./สอ ๑) (page 17)**
2. Product labels
3. Product formula
4. Manufacturing, packaging and labelling processes
5. Physical and chemical properties of hazardous substance product
6. Safety data sheet (SDS) of product or of all ingredients declared in the product formula
7. Efficacy test result (in case of pesticides, disinfectants and bleaches)
8. Certificate of analysis of active ingredient content (in case of the product contains any hazardous substance on the list of 61 hazardous substances that require the quantitative analysis of active ingredients)
9. Certificate of free sale (only the imported products of pesticides)

There are some differences of data requirements for registration of existing hazardous substances, new hazardous substances, technical grade pesticides, pre-mixed pesticides, and finished products. Therefore, the Hazardous Substances Control Group has provided **the Checklist of Required Documents for Hazardous**

Substance Registration (page 18) in order to ease the manufacturers and the importers for preparing the documents.

Fee	2,000 Baht
Renewal Fee	2,000 Baht
Validity of a registration certificate	Valid until December 31 st of the sixth year of issuance

Flow Chart for Registration of Hazardous Substance



- (1) An applicant must prepare original documents with their copies in every submission
- (2) Return a copy of documents and give an appointment to follow up
- (3) Application of product registration will be proposed to the product registration working group or the subcommittee on standards and registration of hazardous substances used in household and public health products in the case of;
- new active ingredients
 - new uses
 - products concerning efficacy tests
 - other cases (if necessary)
- (4) Dead line for resubmission of additional documents
- 30 days for the 1st resubmission
 - 20 days for the 2nd resubmission
 - if failure to meet the 2nd deadlines or the documents are still deficient, the application will be rejected

Hazardous Substance Registration Application Form

Date.....Month.....Year (B.E).....

I/We.....(Applicant's Name) Ageyears Nationality.....
(Natural person/juristic person)

Taxpayer ID No.....

Contact Address No..... Moo..... Soi/Street.....

Road..... Tambon/Sub-District..... Amper/District..... Province.....

Postal Code..... Telephone..... Fax..... E-mail address.....

Would like to Manufacture Import Type 2 Type 3 Hazardous Substance

The details are as follows

1. Trade Name.....
2. Name and Amount of Hazardous Substances (Active Ingredients).....
.....
.....
3. Type of Usage.....
4. Characteristics of Hazardous Substances.....
5. Name and Address of Manufacturer.....
.....
6. In case of Import, Name and Address of Distributor (if available).....
.....
7. Type and Appearance of Packaging or Containers and Packaging Size.....
.....

I hereby attach 2 copies of documents and other evidences for registration as details below

- Documents and other evidences for hazardous substance registration according to the requirement of Thai FDA (4 copies, if to be registered substances have yet to be registered)
- Product's labels and leaflets (if available)
- Copy of certificate of juristic entity registration or identification card with copy of Commercial registration (if available) in case of natural person
- Power of attorney (if needed)

Signature.....Applicant

(.....)

Checklist of Required Documents for Hazardous Substances Registration

Company name..... Trade Name.....

List of Documents	Type of Hazardous Substances						Remarks
	1.1	1.2	2.1	2.2	3.1	3.2	
	4 copies		2 copies				
1) Hazardous Substance Registration Application Form							
2) Labels: format and text							
3) Hazardous substance information							
3.1 General information							
3.2 Physical and chemical properties							
3.3 Analytical methods							
3.4 Toxicological data							
3.5 Environmental impact (soil, water, living species, waste/unused chemicals management)							
3.6 Indication/use rate/usage							
3.7 Safety data sheet (SDS)							
3.8 Summary of hazardous substances data list							
4) Product information							
4.1 General information: formula and their function in preparation							
4.2 Physical and chemical properties							
4.3 Manufacturing process							
4.4 Oral-rat LD ₅₀ data							
4.5 Safety data sheet (SDS) of product or of all ingredients (except water)							
4.6 Indication/use rate/usage							
4.7 Efficacy test results or other references							Except pre-mixed pesticides
4.8 Report of analysis of active ingredient content							If AI is listed on the list of 61 hazardous substances that require the quantitative analysis of AI, except pre-mixed products.
4.9 Copy of permitting to manufacture or import product samples for efficacy test or analysis of AI content							
4.10 Certificate of free sale (if imported) or Copy of Hazardous Substance registration certificate of AI (if manufactured)							For pesticide products only
5) Certified letter (confirming that the product has been registered by Thai FDA)							
6) Power of attorney (or copy of identification card in case of natural person)							
7) Letter of Agreement to Rules and Conditions or copy							

As you have submitted the applications with all documents to Hazardous Substance Control Group, all documents and applications are:

1st submission Date..... complete incomplete and the following documents are missing

Signature
(Authorized Person/Applicant)

Signature
(Officer)

2nd submission Date..... complete incomplete and the following documents are missing

Signature
(Authorized Person/Applicant)

Signature
(Officer)

3rd submission Date..... complete incomplete and the following documents are missing

Signature
(Authorized Person/Applicant)

Signature
(Officer)

Remarks

- not required
- Types of hazardous substances used in this checklist**

Registration	Technical grade raw materials		Finished or semi-finished or pre-mixed products	Processed duration ¹
	Pesticides	Disinfectants/ Cleaning products	Pesticides/Disinfectants/ Cleaning products	
AI was registered and nothing changes from the previous registration.	3.1	-	3.2	30 working days
AI was registered but there are changes; formulation, type of usage, and etc.	2.1	-	2.2	45 or 75 working days
New AI (Never been registered)	1.1	-	1.2	120 working days

¹excludes waiting time for requested documents from company

- You can check the Thai FDA-registered AI at the Hazardous Substance Control Group.

In case of the incomplete documents, please prepare and resubmit to the Hazardous Substance Control Group with this form.

Notifying of Type 2 Hazardous Substance

Manufacturers or importers of type 2 hazardous substances must obtain the product registration certificates and notify the production or import of the type 2 hazardous substances to the authority. Exporters or possessors for professional use must notify their export or possession of Thai FDA-registered products to the authority.

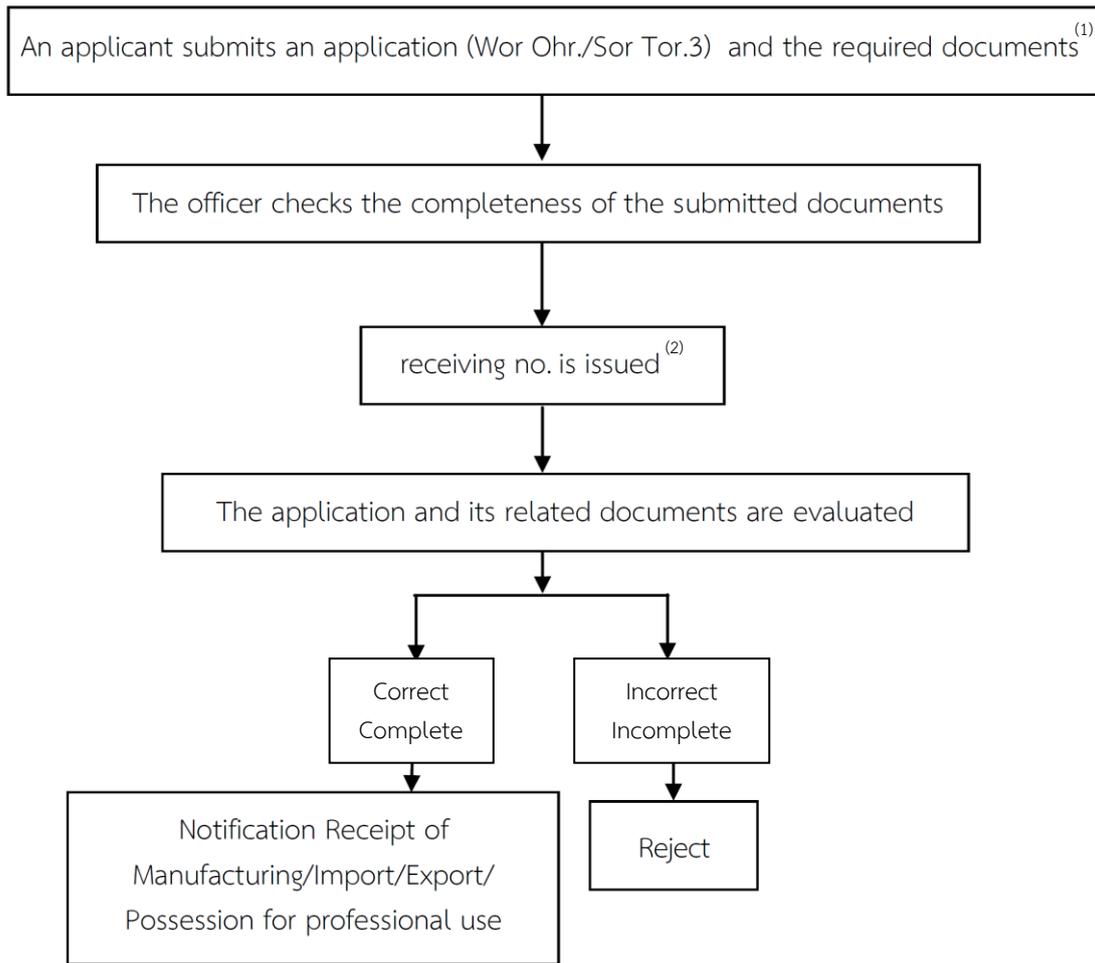
In case of possession for professional use of the type 2 hazardous substances, possessors can notify to the authority at the FDA office or the provincial public health office, depending on where the storages sites are located.

All types of notification must submit an application form, namely **Type 2 Hazardous Substance Operation Notification Report Wor Ohr./Sor Tor 3 (วอ./สธ ๓) (page 22)** and the required documents according to the checklists provided by the Hazardous Substances Control Group.

- For permitted places **(page 23)**
- For new operating places/production line **(page 24)**

Fee	None
Renewal Fee	None
Validity of all types of notification receipt	Valid until December 31 th of the third year of issuance

Flow Chart for Notifying of Type 2 Hazardous Substance



(1) An applicant must prepare original documents with their copies in every submission.

(2) Return a copy of documents and give an appointment to receive the notification receipt.

Type 2 Hazardous Substance Operation Notification Report

Date..... Month..... Year (B.E).....

I/We.....
(Natural person/juristic person)

Age.....years Nationality..... Taxpayer ID No.....

Contact Address No..... Moo..... Soi/Street..... Road.....

Tambon/Sub-District..... Amper/District..... Province.....

Postal code..... Telephone..... Fax..... e-mail address.....

Would like to notify our operation related to Type 2 Hazardous Substance according to the Hazardous Substances Act B.E.2535 (1992) as follows:

1. Type of Operation Manufacturing Import Export Possession for Professional Use

2. Trade Name.....

..... Hazardous Substance Registry No.....

(If possess more than 1 item of hazardous substance for professional use, please specify as enclosing documents)

3. Name of Manufacturer or Importer or Possessor.....

Address..... Moo..... Soi/Street.....

Road..... Tambon/Sub-District..... Amper/District.....

Province..... Postal code..... Telephone..... Fax.....

4. Name of Storage Location.....

Address..... Moo..... Soi/Street.....

Road..... Tambon/Sub-District..... Amper/District.....

Province..... Postal code..... Telephone..... Fax.....

5. In case of Import, Name of Foreign Manufacturer..... Country.....

6. In case of Export, the Destination Country.....

7. Amount of Manufacturing or Import or Export per year..... (Litre or Kilogram or Ton)

Amount of Possession for Professional Use

Maximum Amount of Possession..... (Litre or Kilogram or Ton)

Specific Area for Maximum Amount of Possession..... Square Meter

8. Name of the Experts or Personnel Responsible for this Operation (regarding to announcements on Section 20 (2) as stated in the Hazardous Substance Act B.E.2535) (1992).....

I hereby attach 2 copies of documents and other evidences as details below

- Copy of certificate of juristic entity registration or identification card with copy of Commercial registration (if available) in case of natural person
- Power of attorney (if needed)
- Copy of Hazardous substance Registration Certificate
- Sketch map of the enterprise location and neighboring area (in case of new applicants)
- Layout of the enterprise building (in case of new applicants)
- Document showing expertise of experts or personnel responsible for this operation (regarding to announcements on Section 20 (2))

Signature..... Applicant or Authorized Person

(.....)

Checklist of Required Documents for Notification of Type 2 Hazardous Substance for Permitted Places

Applicant's Name..... Trade Name.....

Type of Usage Pesticide Cleaning Products & Others Disinfectants

Physical Appearance Powder Liquid Aerosol Others.....

Type of Operation 1. Manufacturing 2. Import 3. Export 4. Possession for Professional Use

Part 1 Checking Documents						
List of Documents	For Officer Used				For Evaluation Officer Used	
	1	2	3	4		
1. Application Form (Wor Ohr./Sor Tor 3)					<input checked="" type="checkbox"/> complete <input type="checkbox"/> incomplete	
2. Copy of Hazardous Substance Registration Certificate					<input checked="" type="checkbox"/> complete <input type="checkbox"/> incomplete	
3. Copy of Related License or Notification Receipt					<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
4. Original and a copy of Certificate of Pest Control Operator Training (the original will be returned)					<input checked="" type="checkbox"/> complete <input type="checkbox"/> incomplete	
5. Copy of Power of Attorney					<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
6. Letter of Agreement to Rules and Conditions or copy					<input type="checkbox"/> complete <input type="checkbox"/> incomplete	
Part 2 Documents Submission Results						
As you have submitted the applications with all documents to Hazardous Substance Control Group, all documents and applications are:						
1st submission Date..... <input checked="" type="checkbox"/> complete <input type="checkbox"/> incomplete and the following documents are missing						
Signature			Signature			
(Authorized Person/Applicant)			(Officer)			
2nd submission Date..... <input type="checkbox"/> complete <input type="checkbox"/> incomplete and the following documents are missing						
Signature			Signature			
(Authorized Person/Applicant)			(Officer)			
In case of the incomplete documents, please prepare and resubmit to the Hazardous Substance Control Group.						
Part 3 Documents Evaluation Results						
<input type="checkbox"/> complete/correct						
<input type="checkbox"/> incomplete/incorrect and inform the applicant to return all documents						
Signature						
Date.....						

Remark not required

Part 3 Documents Evaluation Results

- complete/correct
- incomplete/incorrect and inform the applicant to return all documents

SignatureEvaluation Officer

Date.....

Remark not required

unofficial form

Hazardous Substance Licensing

Manufacturers or Importers of type 3 hazardous substances shall register and apply for manufacturing license or import license for such substances. Exporters of registered type 3 hazardous substance also need to apply for export license.

For those who possess for professional use of type 3 hazardous substances and have the storage locations in Bangkok, they must submit the application (Form Wor Ohr. 8) to Thai FDA. If the storage locations are in other provinces, the application form must be submitted to the Provincial Public Health Office in that area.

An entrepreneur must submit an application form, namely **Hazardous Substance Manufacturing Licensing Application Form, Form Wor Ohr. 1 (แบบ รอ. ๑) (page 29)** (in case of production), **Hazardous Substance Import Licensing Application Form, Form Wor Ohr. 3 (แบบ รอ. ๓) (page 31)** (in case of import), or **Hazardous Substance Export Licensing Application Form, Form Wor Ohr. 5 (แบบ รอ. ๕) (page 33)** (in case of export) and the required documents according to the checklists provided by the Hazardous Substances Control Group.

- For permitted places **(page 35)**
- For new operating places/production lines **(page 36)**

Fee	Depending on the yearly amount of manufacturing/import/export
	Depending on the yearly amount of possession and the storage area (only the possession for professional use purpose)
Renewal Fee	As equal to the license fee paid for each type of licenses
Validity of all types of license	Valid until December 31 th of the third year of issuance

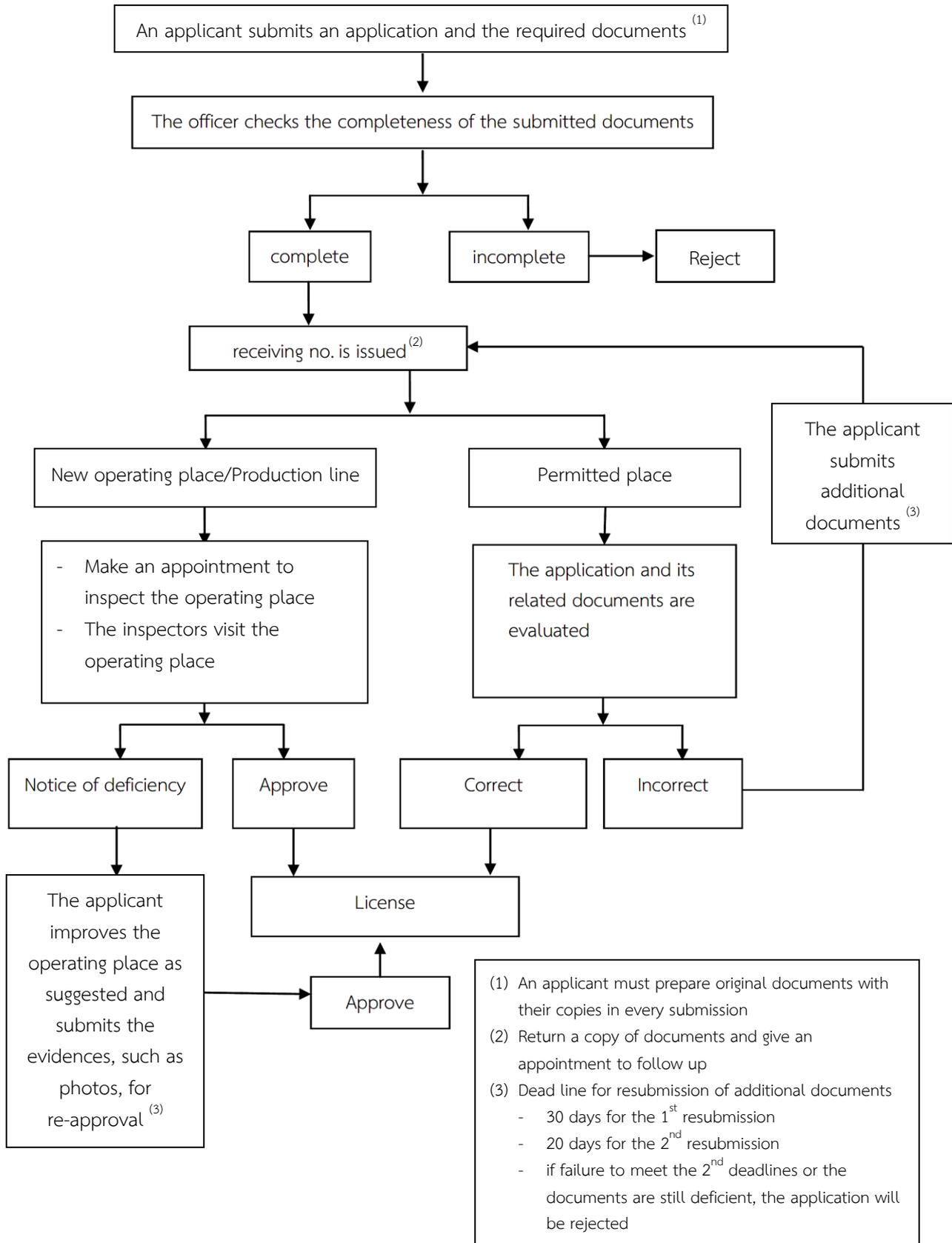
Fee for Hazardous Substance Manufacturing/Import/Export License

- (a) 500 Baht for less than 10 metric tons
- (b) 1,000 Baht for 10 to less than 50 metric tons
- (c) 1,500 Baht for 50 to less than 100 metric tons
- (d) 3,000 Baht for 100 metric tons and up

Fee for Hazardous Substance Possession License

500 Baht for less than 10 metric tons a year and less than 500 square meters of the specified storage area

Flow Chart for Applying the Hazardous Substance License



(1) An applicant must prepare original documents with their copies in every submission

(2) Return a copy of documents and give an appointment to follow up

(3) Dead line for resubmission of additional documents

- 30 days for the 1st resubmission
- 20 days for the 2nd resubmission
- if failure to meet the 2nd deadlines or the documents are still deficient, the application will be rejected

Hazardous Substance Manufacturing License Application Form

Date.....Month.....Year (B.E.).....

I/We.....
(Natural person/juristic person) Age.....years Nationality.....

Taxpayer ID No.....

Contact Address No..... Moo..... Soi/Street.....

Road..... Tambon/Sub-District..... Amper/District.....

Province..... Postal Code..... Telephone..... Fax.....

Name of the Hazardous Substance Manufacturer.....

Address No..... Moo..... Soi/Street..... Road.....

Tambon/Sub-District..... Amper/District..... Province.....

Postal Code..... Telephone..... Fax.....

Name of the Hazardous Substance Storage Location.....

Address No..... Moo..... Soi/Street..... Road.....

Tambon/Sub-District..... Amper/District..... Province.....

Postal Code..... Telephone..... Fax.....

Name of the Experts or Personnel Responsible for Storage (regarding to announcements on Section 20 (2) as stated in the Hazardous Substance Act B.E. 2535 (1992))

(If there is more than 1 storage site, fill the details in the back page of this form)

Would like to apply for manufacturing license of the hazardous substance as follows:

Name, Chemical Formula ⁽¹⁾ and Concentration of Hazardous Substance.....

Physical Appearance and Formulation ⁽²⁾.....

Trade Name (if any).....

Amount.....

Remark.....

-2-

Name of the Experts or Personnel Responsible for Production (regarding to announcements on Section 20 (2) as stated in the Hazardous Substance Act B.E. 2535 (1992))

.....

I hereby attach the following documents for manufacturing license consideration as details below ⁽³⁾

- Copy of identification card/ or foreign identification card
- Copy of certificate of juristic entity registration
- Copy of VAT registration certificate (ภ.พ. ๒๐)
- Copy of hazardous substance registration certificate (if registered)
- Sketch map of production location for hazardous substance and neighboring area
- Sketch map of storage location for hazardous substance and neighboring area
- Layout of production building and storage building for raw materials and finished products
- Document showing manufacturing process
- Document showing expertise of experts or personnel responsible for production and storage such substance
- Document showing packaging or containers of hazardous substances
- Safety Data Sheet
- Other (Please specify)

For your consideration ⁽⁴⁾

(Signature)Authorized person

- Remark
- (1) No need to specify the chemical formula for hazardous substance under the responsibility of Thai FDA, Department of Agriculture, Department of Fisheries and Department of Livestock Development
 - (2) No need to specify the formulation for hazardous substance under the responsibility of Department of Industrial Works
 - (3) The above mentioned documents are for the first application or only for the amendment of any documents submitted from the prior export license
 - (4) Please mark ✓ in the in front of the required statements

Name of the 2nd Storage Location

Address No..... Moo..... Soi/Street..... Road.....

Tambon/Sub-District..... Amper/District..... Province.....

Postal Code..... Telephone..... Fax.....

Name of the Experts or Personnel Responsible for Storage (regarding to announcements on Section 20 (2) as stated in the Hazardous Substance Act B.E. 2535 (1992))

.....

(If there are more than 2 storage sites, please specify as enclosing documents)

Hazardous Substance Import License Application Form

Date.....Month.....Year (B.E.).....

I/We.....Age.....years Nationality.....
(Natural person/juristic person)

Taxpayer ID No.....

Contact Address No.....Moo.....Soi/Street.....

Road.....Tambon/Sub-District.....Amper/District.....

Province.....Postal Code.....Telephone.....Fax.....

Name of the Hazardous Substance Storage Location.....

Address No.....Moo.....Soi/Street.....Road.....

Tambon/Sub-District.....Amper/District.....Province.....

Postal Code.....Telephone.....Fax.....

Name of the Experts or Personnel Responsible for Storage (regarding to announcements on Section 20 (2) as stated in the Hazardous Substance Act B.E. 2535 (1992))

(If there is more than 1 storage site, fill the details in the back page of this form)

Would like to apply for import license of the hazardous substance as follows:

Name, Chemical Formula⁽¹⁾ and Concentration of Hazardous Substance.....

Physical Appearance and Formulation⁽²⁾.....

Trade Name (if any).....

Manufacturer.....

Country of Production.....

Amount.....

Remark.....

I hereby attach the following documents for import license consideration as details below ⁽³⁾

- Copy of identification card/ or foreign identification card
- Copy of certificate of juristic entity registration
- Copy of VAT registration certificate (ภ.พ. ๒๐)
- Copy of hazardous substance registration certificate (if registered)
- Copy of report of analysis of active ingredient content
- Sketch map of storage location for hazardous substance and neighboring area
- Layout of storage building for hazardous substance (regarding to announcement on Section 20 (1) as stated in Hazardous Substance Act B.E. 2535 (1992) to clarify the criteria of the storage location)
- Document showing expertise of experts or personnel responsible for storage such substance
- Document showing packaging or containers of hazardous substances
- Safety Data Sheet
- Other (Please specify)

For your consideration ⁽⁴⁾

(Signature)Authorized person

Remark

- (1) No need to specify the chemical formula for hazardous substance under the responsibility of Thai FDA, Department of Agriculture, Department of Fisheries and Department of Livestock Development
- (2) No need to specify the formulation for hazardous substance under the responsibility of Department of Industrial Works
- (3) The above mentioned documents are for the first application or only for the amendment of any documents submitted from the prior import license
- (4) Please mark ✓ in the in front of the required statements

Name of the 2nd Storage Location

Address No..... Moo..... Soi/Street..... Road.....

Tambon/Sub-District..... Amper/District..... Province.....

Postal Code..... Telephone..... Fax.....

Name of the Experts or Personnel Responsible for Storage (regarding to announcements on Section 20 (2) as stated in the Hazardous Substance Act B.E. 2535 (1992))

.....

Name of the 3rd Storage Location

Address No..... Moo..... Soi/Street..... Road.....

Tambon/Sub-District..... Amper/District..... Province.....

Postal Code..... Telephone..... Fax.....

Name of the Experts or Personnel Responsible for Storage (regarding to announcements on Section 20 (2) as stated in the Hazardous Substance Act B.E. 2535 (1992))

.....

Hazardous Substance Export License Application Form

Date.....Month.....Year (B.E.).....

I/We.....
(Natural person/juristic person) Ageyears Nationality.....

Taxpayer ID No.....

Contact Address No.....Moo.....Soi/Street.....

Road.....Tambon/Sub-District.....Amper/District.....

Province.....Postal Code.....Telephone.....Fax.....

Name of the Hazardous Substance Storage Location.....

Address No.....Moo.....Soi/Street.....Road.....

Tambon/Sub-District.....Amper/District.....Province.....

Postal Code.....Telephone.....Fax.....

Name of the Experts or Personnel Responsible for Storage (regarding to announcements on Section 20 (2) as stated in the Hazardous Substance Act B.E. 2535 (1992))

.....
.....

(If there is more than 1 storage site, fill the details in the back page of this form)

Would like to apply for export license of the hazardous substance as follows:

Name, Chemical Formula ⁽¹⁾ and Concentration of Hazardous Substance.....

.....
.....

Physical Appearance and Formulation ⁽²⁾.....

Trade Name (if any).....

Destination Country.....

Amount.....

Remark.....

.....

I hereby attach the following documents for import license consideration as details below ⁽³⁾

- Copy of identification card/ or foreign identification card
- Copy of certificate of juristic entity registration
- Copy of VAT registration certificate (ร.พ. ๒๐)
- Copy of hazardous substance registration certificate
- Copy of report of analysis of active ingredient content
- Sketch map of storage location for hazardous substance and neighboring area
- Layout of storage building for hazardous substance (regarding to announcement on Section 20 (1) as stated in Hazardous Substance Act B.E. 2535 (1992) to clarify the criteria of the storage location)
- Document showing expertise of experts or personnel responsible for storage such substance
- Document showing packaging or containers of hazardous substances
- Safety Data Sheet
- Other (Please specify)

For your consideration ⁽⁴⁾

(Signature)Authorized person

- Remark**
- (1) No need to specify the chemical formula for hazardous substance under the responsibility of Thai FDA, Department of Agriculture, Department of Fisheries and Department of Livestock Development
 - (2) No need to specify the formulation for hazardous substance under the responsibility of Department of Industrial Works
 - (3) The above mentioned documents are for the first application or only for the amendment of any documents submitted from the prior export license
 - (4) Please mark ✓ in the in front of the required statements

Name of the 2nd Storage Location

Address No. Moo Soi/Street Road

Tambon/Sub-District Amper/District Province

Postal Code Telephone Fax

Name of the Experts or Personnel Responsible for Storage (regarding to announcements on Section 20 (2) as stated in the Hazardous Substance Act B.E. 2535 (1992))

Name of the 3rd Storage Location

Address No. Moo Soi/Street Road

Tambon/Sub-District Amper/District Province

Postal Code Telephone Fax

Name of the Experts or Personnel Responsible for Storage (regarding to announcements on Section 20 (2) as stated in the Hazardous Substance Act B.E. 2535 (1992))

Checklist of Required Documents for Applying the Hazardous Substance License for Permitted Places

Applicant's Name..... Trade Name.....

Type of Usage Pesticide Cleaning Products & Others Disinfectants

Physical Appearance Powder Liquid Aerosol Others.....

Type of Operation 1. Manufacturing 2. Import 3. Export

Part 1 Checking Documents	For Officer Used		
	(1)	(2)	(3)
List of Documents			
1. Application Form			
2. Product information			
2.1 General Information: formula, compositions and their function in preparation			
2.2 Physical and chemical properties			
3. Document showing manufacturing and containing process			
4. Document showing packaging or containers of hazardous substances			
5. Safety Data Sheet (SDS)			
6. Copy of Hazardous Substance Registration Certificate (if any)			
7. Copy of Related License			
8. Copy of Power of Attorney			
9. Letter of Agreement to Rules and Conditions or copy			
Part 2 Documents Submission Results			
As you have submitted the applications with all documents to Hazardous Substance Control Group, all documents and applications are:			
1st submission Date..... <input type="checkbox"/> complete <input type="checkbox"/> incomplete and the following documents are missing			
Signature		Signature	
(Authorized Person/Applicant)		(Officer)	
2nd submission Date..... <input type="checkbox"/> complete <input type="checkbox"/> incomplete and the following documents are missing			
Signature		Signature	
(Authorized Person/Applicant)		(Officer)	
In case of the incomplete documents, please prepare and resubmit to the Hazardous Substance Control Group.			

Remark not required

Part 1 Checking Documents						
List of Documents	For Officer Used					
	1			2	3	4
	1.1	1.2	1.3			
13.6 Notice of "Hazardous Substance" "No smoking, drinking, eating and food storage"						
13.7 Warning signs regarding to the related announcements						
13.8 Notice of "No entry" or "Hazardous substances are used in this area"						
13.9 Accident hazard prevention system or equipments e.g. fire protection and firefighting equipment, medical boxes, wash basins, or emergency bathing facilities						
13.10 Equipment to deal with leaked hazardous substances e.g. sand, sawdust etc.						
13.11 Wastewater treatment						
13.12 Storage area/room of working equipment, work suits and personal protection gear						
13.13 Preparing containers						
14. Original and a copy of Certificate of Pest Control Operator Training (the original will be returned)						
15. Copy of ID card of the Certified Pest Control Operator						
16. Working Operation Confirmation Letter of the Certified Pest Control Operator						
17. Customers Contract						
18. Leasing/rental contract or location consensual agreement						
19. Copy of Power of Attorney						
20. Letter of Agreement to Rules and Conditions or Copy						
Part 2 Documents Submission Results						
As you have submitted the applications with all documents to Hazardous Substance Control Group, all documents and applications are:						
1st submission Date..... <input type="checkbox"/> complete <input type="checkbox"/> incomplete and the following documents are missing Signature Signature (Authorized Person/Applicant) (Officer)						
2nd submission Date..... <input type="checkbox"/> complete <input type="checkbox"/> incomplete and the following documents are missing Signature Signature (Authorized Person/Applicant) (Officer)						
In case of the incomplete documents, please prepare and resubmit to the Hazardous Substance Control Group.						

Remark not required

<p style="text-align: center;">Control of Hazardous Substance Possession for Professional Use (Pest Control Operator; PCO)</p>

According to the Hazardous Substance Act B.E. 2535 (1992), any entrepreneur who possesses the hazardous substances for professional use as pest control operator, to control termites, ants, insects, rats, or other pests in household or building, is requested to have Type 3 Hazardous Substance Possession License or Type 2 Hazardous Substance Possession Notification Receipt.

Later on, in B.E 2547 (2004), Thai FDA has determined that the person who possesses the hazardous substance for professional use as pest control operator must have the expert or specialized person to control such substances. That person must be trained and qualified for related area such as pests management, hazardous substances, equipment, biological and ecological of related pests e.g. termites, cockroaches, mosquitoes, ants, rats. Besides, Thai FDA also set that the expert must attend the training to renew the certificates every 3 years.

Those who possess such substances for professional use must comply with rules and regulation in the Ministry of Public Health announcement regarding criteria of processing procedure, possession for professional use, and hazardous substance storage that Thai FDA is responsible for B.E. 2555 (2012). Thai FDA has designed the criteria for storage location, the personnel, hazardous substance operation, security standard for using the substance to ensure that all process are operated theoretically correctly and safe for any lives, animals, plants, assets and environment. Apart from this, the authorized person to possess the hazardous substances for professional use must purposely select according to its term of use as indicated on the labels and the products must have already been registered with Thai FDA.

Certificate of Free Sale (CFS)

Thai FDA requires a certificate of free sale (CFS), when companies import pesticide products. The CFS provides the evidence that the product is legally sold or distributed in the open market, freely without restriction, and approved by the regulatory authorities in the country of origin.

According to the Order of Thai FDA No. 398/2544 and No. 122/2548 regarding the CFS for import of health products and the Bureau of Cosmetic and Hazardous Substances Control announcement regarding the CFS for import of household or public health products intended to inhibit, prevent, control, repel, and get rid of insects, rodents or other pests (given on April 12th, 2011), the CFS must be the original and have details as follows:

1. Country of CFS issuance

The CFS must be issued by the country of production. If the country of production cannot issue the CFS, importers can use the CFS issued by the countries of distribution in condition that:

- 1.1 The distributor possesses the household or public health products and hires the manufacturer in other countries to produce such products.
- 1.2 The household or public health products do not sell in the country of production because there is no case to use this product in the country of production.
- 1.3 Other cases depend on Thai FDA consideration.

However, the certificate of origin must be required from the country of production. Also, the notification letter from the manufacturer must state the reasons why the country of production cannot issue the CFS.

2. Agencies responsible for issuance of the CFS and certificate of origin

The CFS and certificate of origin must be issued or certified wording by the governmental regulatory agency or by a private institute recognised by the government of such country.

3. The certifying of CFS

3.1 The CFS must be certified by an agency of the Ministry of Foreign Affairs or an office of commercial affairs of Thailand in such country.

3.2 If the CFS is sent from the governmental regulatory agency to Thai FDA directly such as ICAMA (China), the certification by an agency of the Ministry of Foreign Affairs or an office of commercial affairs of Thailand in such country is not necessary.

4. The details in CFS

The CFS must state:

4.1 Name of the product: If other name occurs different from the CFS, importers must have the notification letter from the manufacturer guarantees that it is the same product.

4.2 Name and address of manufacturer

4.3 List of active ingredients and their concentrations

4.4 Indicate that the product is freely sold in its home market. If the CFS does not present this sentence or others phrases/sentences that have the same meaning as mentioned above, the importer must send any supporting documents, such as a copy of registration certificate, to guarantee its sale in the country of production. However, the supporting documents must be certified by an agency of the Ministry of Foreign Affairs or an office of commercial affairs of Thailand in such country.

5. The validity of CFS

5.1 Depending on the time prescribed in the certificate.

5.2 For 2 years from the date of issuance (in case of not present the validity period).

GHS Implementation in Hazardous Substances Products for Household and Public Health Use

Thailand has adopted the Globally Harmonized System of Classification and Labelling (GHS), developed by the United Nations, into the classification and communication of the hazards of chemicals and chemical products under the Hazardous Substances Act B.E. 2535 (1992). Implementation of GHS covers hazardous substances in industry, agriculture, and household and public health sectors. In 2012, GHS is firstly implemented to hazardous substances in industrial sector with 1-year transition period for single substances and 5-year transition period for mixtures. The other sectors will soon implement GHS at the varying time depending on readiness and circumstances.

Thai FDA, which is responsible for regulating hazardous substances for household and public health use empowered by the Hazardous Substance Act B.E. 2535 (1992), has conducted continuous activities to promote and support GHS implementation. Capacity building activities as well as legislation revision in relation to GHS have been carried out. These activities include revision of legislation to align with the GHS; chemical database collection; illustrating of GHS labelling samples, seminars and training workshops for regulatory officers and business entities to strengthen understanding and effectively implementation of GHS, and awareness raising for consumers and stakeholders.

It is expected that GHS implementation in hazardous substances used in households and public health will be enforced by 2013-2014. The expected transition period will be 1 year for single substances and 5 years for mixtures. The example of single substances is, but not limited to, technical grade pesticides. It is noted that most of the hazardous substances in household and public health products are considered as mixtures.

**Good Manufacturing Practice (GMP) for Hazardous Substance Products
under the responsibility of Thai Food and Drug Administration**

Thai FDA has issued a policy to strengthen quality standards for manufacturing of hazardous substance products to comply with Good Manufacturing Practice (GMP). In 1997, GMP was firstly implemented on a voluntary basis. From 1998, many projects on GMP implementation have been conducted to promote and support the manufacturers to put GMP into practice. However, only few manufacturing establishments have met the GMP requirements and received the GMP certificate. The main impediments to GMP compliance was the manufacturers have lacked motivation and awareness to improve their production quality as GMP was a voluntary program.

Currently, Thai FDA is underway to implement hazardous substances GMP as a mandatory aspect by drafting the Notification of Ministry of Public Health on GMP. The subcommittee of hazardous substance manufacturing standards (GMP) under the responsibility of Food and Drug Administration is assigned to study and develop the GMP instructions and procedures with the appropriate scientific justification and taking into account the relevant international GMP standards. The mandatory GMP requirements will be clearly defined for practicable compliance and to minimize the individual inspector's discretion. As well, they will be applicable for any establishments with or without their own laboratory facilities. Implementation of the mandatory GMP will take priority to the high risk products and the high risk manufacturing processes.

Quality Management System

Thai FDA has issued the FDA general rules and standards for quality management system to ensure standards and conformities of its operations regarding health products under its responsibility. This quality management system shall maintain capability, consistency and equality in services as well as enhance the recognition from stakeholders (i.e., consumers, business sector, government sector and networking groups). In addition, the system is aimed to conform to the relevant international standards. Thai FDA has set up the policy on the quality management system as follows:

“FDA aims at improving services toward international standards,
with performance-oriented, transparent and fair”

The Hazardous Substance Control Group has implemented the FDA general rules and standards for quality management system since September 1st, 2009. The system covers product registration, permission, and issuance of GMP certificates. Officers and personnel have the commitment to assure that the system will run effectively and progressively, and will increase creditability and recognition from the public.

The Hazardous Substance Control Group has disseminated documents and information regarding the quality management system. These include, for examples, rules and conditions for permission, registration, notification of operations, notification of product information, and manufacturing and import of product samples (RL-H2-1); rules and conditions for issuance, surveillance and renewal of registration certificate, (RL-H2-2); rules and conditions for issuance, surveillance and renewal of manufacturing license (RL-H2-3); rules and conditions for issuance of hazardous substance GMP certificate (RL-H3-1); and rules and conditions for hazardous substance GMP inspection (RL-H3-2). Every hazardous substance product company is required to sign **the Letter of Agreement to Rules and Conditions (page 44)** to admit their rights and duties accordingly.

Letter of Agreement to Rules and Conditions

Written at

Date.....Month.....Year (B.E.).....

I, the undersigned

on behalf of

hereby agree that:

- 1) I shall comply with rules and conditions set by the Hazardous Substance Control Group, Food and Drug Administration, which shall include current and new and/or future additional rules and conditions.
- 2) I certify that all documents and information submitted to the Hazardous Substance Control Group, Food and Drug Administration are true, correct and up to date.

I hereby ratify and confirm that all acts and things that I/the grantee have done beyond this agreement shall be bound and responsible by me in all aspects.

As of Date.....Month.....Year (B.E.).....

Valid till the expiry date of registration and permission

Signature.....Principal

(.....)

Date.....Month.....Year (B.E.).....

Frequently Asked Questions (FAQ)

1. **Q:** Can I submit the application for registration and permission at the same time?

A: It depends. If your storage or manufacturing location has yet to be inspected by our officials, you must submit the permission application together with the registration application; so that, we can inspect your site before issuing the hazardous substance registration certificate. If your storage or manufacturing location has once been approved, you can submit the permission application either with the registration application, or after receiving the hazardous substance registration certificate.

2. **Q:** I have two products containing the same chemicals, but they are different in percentages. Do I have to register these products separately?

A: Yes, you have to register both products separately because their formulations are dissimilar. The documents for registration are also different.

3. **Q:** Are the efficacy test and analysis of active ingredient (AI) content required for registration of technical grade or pre-mixed pesticides?

A: No, they are not required. Thai FDA requests the efficacy test and the quantitative analysis of AI for finished product pesticides only, not for technical grade or pre-mixed pesticides. In case of a finished product pesticide contains any of 61 chemicals listed in the list of hazardous substances required to be analyzed for AI contents (see the list of 61 hazardous substances in the appendix of Thai FDA announcement in regards of required documents list for hazardous substance registration B.E. 2552 (2009)), the report of quantitative analysis of AI is also needed.

4. **Q:** Would it be possible to use information published in academic articles or journals as an efficacy test evidence in order to register a product?

A: No, the efficacy test must be performed using your to-be registered products, except chlorine-containing products, for which you are allowed to use journal articles as the academic references.

5. **Q:** If the country of origin is not able to issue a certificate of free sale (CFS); because the product is produced for export only, what should I do?

A: In that case, you can use the CFS issued by the country of distribution. However, the content in the CFS must comply with the instructions given by Thai FDA. Also, the notification letter from the manufacturer must state the reasons why the country of origin cannot issue that CFS.

6. **Q:** Is the six-year validity period for the hazardous substance registration certificate of counted on a calendar year basis?

A: Yes, the validity of the hazardous substance registration certificate is counted on a calendar year basis. Therefore, the certificates, which were issued on January 2009, and November 2009, are valid until December 31st 2014.

7. **Q:** Do I need to register hazardous substances which are imported for donation only?

A: It depends. If the conditions of the donation fulfil the criteria stated in the section of the import exception according to Hazardous Substance Act B.E. 2535 (1992), you are exempted from registration. However, if the conditions of the donation do not fulfil such exception condition, depends on the type of your products, you must register, apply for the permission, or notify Thai FDA prior to import those substances.

8. Q: In which circumstances those two chemicals/products can use a similar trade name?

A: You can use a similar trade name with other products only if

1. The two products have a similar formula, or
2. The two products are totally different in kinds or types of the products, or
3. They are technical grade pesticides and use a common name or chemical name as their trade name.

However, Thai FDA is not responsible if any registered trade name is pirated.

The enterprises, themselves, have to take any legal actions by the civil law.

9. Q: If the company would like to put the product's expiry date on the labels, what condition and how long of the stability test should be applied?

A: Generally, the stability test will be performed at the normal condition and the expiry date will be issued according to the test duration. However, at the accelerated condition, the expiry date will be extrapolated longer than the actual test duration. At present, no specific criteria for the matters have been set.

10. Q: What data or information should be identified in quantitative analysis of AI and efficacy test reports?

A: The reports must contain:

1. Name of the tested product
2. Name of manufacturer
3. List of active ingredients, and their concentrations
4. Lot of manufacturing
5. Manufacturing date (Date/Month/Year)

11. Q: From which organizations does the Hazardous Substance Control Group accept the quantitative analysis of AI reports or efficacy test results?

A: Analysis of the active ingredient content: The applicant can submit the quantitative analysis of AI reports from the government sectors or private

sectors approved by Thai FDA (see details in the Thai FDA announcement on the topic of Private Laboratories for the Analysis of Hazardous Substances for Registration B.E. 2553 (2010)).

Efficacy Test: Thai FDA has not specified agency to perform the efficacy tests; therefore:

- a. In case that, Thai FDA has set the procedure of efficacy tests, the applicant shall perform the test as stated in the procedure
- b. In case that, Thai FDA has not set the procedure of efficacy tests, the applicant shall submit your test protocols with the results. However, the protocols should correlate with indication or usage of your product.

12. **Q:** Is it required to submit quantitative analysis or efficacy test of chlorine releasing substance-containing products?

A: Yes, the results of quantitative analysis must be submitted together with the intensification reference for disinfection or efficacy test results.

13. **Q:** In the case of disinfectants, they are required to show the efficacy of the products against different kinds of micro-organisms. Can I submit the results from different tests?

A: Yes, you can but the tests must be done with the products from the same lot of production.

14. **Q:** My product is already certified by WHO using the results from my study. I would like to register this product in Thailand. Is this possible to register this product using the certificate issued by WHO without any efficacy test performed in Thailand?

A: In case that, it is a laboratory test and has the standard procedure of efficacy tests set by Thai FDA, your product must be tested according to the stated procedure. However, if it is a field test, it must be considered whether the conditions of that test (e.g. climate, species of pests) are similar to those in Thailand.

15. **Q:** Will I have to notify a 100% composition formula for the type 1 hazardous substance products in the Notification of Product Information of Type 1 Hazardous Substance (Wor Ohr./Sor Tor 5)?

A: Yes, you must notify a 100% composition formula and presented in %w/w, or %w/v. All substances must be listed using chemical names except for coloring and scent agents, which can be notified using common names and presented in total amount. For the chlorine-releasing disinfectants in swimming pool, please specify proportions in the form of available chlorine; such as, trichloroisocyanuric acid as available chlorine 90%w/w.

16. **Q:** I would like to export a type 1 hazardous substance. What should I do?

A: You can proceed without performing any product information notification or permission.

17. **Q:** Would it be possible to amend the amount of manufacturing/import/export per year (addition or reduction) stated in the permission license?

A: It depends. Increasing the permissive amount or volume of hazardous substances in all types of license cannot be done because the Ministerial Regulation on permission fee for hazardous substance B.E. 2552 (2009) set up the fee into four levels depending on permissive amount or volume of hazardous substances per year (see details in “Fee for Hazardous Substance Manufacturing/Import/Export License” page 27). Hence, adding the amount of business will affect the permission fee. Therefore, it cannot be endorsed on the permission license. If you want to increase the permissive amount or volume of hazardous substances, you must submit a new license application to comply with the fee issued by the ministerial regulation.

However, if you would like to decrease the amount of business per year, you can submit the amendment of permissive amount or volume of hazardous substances by endorsing at the back of the permission license at the OSSC.

Appendix

List of hazardous substances under responsibility of Thai Food and Drug Administration

(Based on the List 4 at the end of the Notification of Ministry of Industry on List of Hazardous Substances B.E. 2556 (2013))

List 4.1 List of chemical names

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
1	1-(p-methoxyphenyl)-2-methyl-1,3-propanediol-methylene ether	5689-72-5	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
2	1,1,1-trichloroethane or methyl chloroform	71-55-6	4	In household or public health products
3	1,1,2-trichloroethane	79-00-5	3	In products used for erasing, correcting, or dissolve chemicals used for erasing or correcting or dry cleaning clothes and textile products
4	1,2,3,4-tetrahydro-2-naphthol	530-91-6	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
5	1,3-dichloro-5,5-dimethylhydantoin	118-52-5	3	In products used for bleaching or swimming pool anti-infection/deodorization
6	2,4,5-TCP or 2,4,5-trichlorophenol	95-95-4	4	
7	2,4-dinitroanisole	119-27-7	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
8	2-nitro-2-methyl-1,3-propanediol	77-49-6	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
9	2-nitro-2-ethyl-1,3-propanediol butyraldehyde acetal	5702-40-9	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
10	2-phenylcyclohexanol	1444-64-0	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
11	2-phenylethyl-alpha-hydroxy isobutyrate	10290-01-4	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
12	4-nitrodiphenyl	92-93-3	4	
13	4-aminodiphenyl	92-67-1	4	
14	cyclohexane carboxylic acid	98-89-5	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
15	boric acid	10043-35-3	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
16	hydrocyanic acid or hydrogen cyanide	74-90-8	4	In household or public health products
17	glutaraldehyde	111-30-8	3	In household or public health products intended to kill germs on floors, walls and sanitary wares or other materials
18	crimidine	535-89-7	4	In household or public health products intended to get rid of rodents
19	crufomate	299-86-5	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
20	chlordimeform	6164-98-3	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
21	chlordecone	143-50-0	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
22	chlordan	57-74-9	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
23	chlorthiophos	21923-23-9	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
24	chlorpyrifos	2921-88-2	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
25	chlorpyrifos-methyl	5598-13-0	2	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
26	chlorfenvinphos [(Z) - + (E) - isomers]	470-90-6	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
27	chlormephos	24934-91-6	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
28	chloranil	118-75-2	4	
29	chlorobenzilate	510-15-6	4	
30	chloroform or trichloromethane	67-66-3	4	In hazardous substance products for household and public health
31	chlorophacinone	3691-35-8	3	In household or public health products intended to get rid of rodents

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
32	quintozene or PCNB	82-68-8	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
33	copper arsenate hydroxide	16102-92-4	4	
34	solid carbon dioxide or dry ice	124-38-9	1	
35	carbon tetrachloride or tetrachloromethane	56-23-5	4	In household or public health products used for erasing, correcting, or dissolve chemicals used for erasing or correcting or dry cleaning clothes and textile products
36	carbaryl	63-25-2	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
37	calomel	10112-91-1	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
38	kelevan	4234-79-1	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
39	coumatetralyl	5836-29-3	3	In household or public health products intended to get rid of rodents
40	coumaphos	56-72-4	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
41	coumatfuryl	117-52-2	3	In household or public health products intended to get rid of rodents
42	capsaicin	404-86-4	4	In products used in order to temporarily inhibit human bodily functions for self-defense or to harm others

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
43	captafol	2425-06-1	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
44	calcium arsenate	7778-44-1	4	
45	calcium hypochlorite	7778-54-3	1	In products used for swimming pool anti-infection/deodorization
46	crotoxyphos	7700-17-6	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
47	cholecalciferol	67-97-0	2	In household or public health products intended to get rid of rodents
48	kinoprene	37882-31-8	3	In household or public health products intended to inhibit, prevent and get rid of insects by insects' growth regulation
49	jodfenphos	18181-70-9	2	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
50	sulfuramid	4151-50-2	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
51	zinc phosphide	1314-84-7	4	In household or public health products intended to get rid of rodents
52	scillitroside	507-60-8	3	In household or public health products intended to get rid of rodents
53	silvex	93-72-1	4	

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
54	cis-bicyclo(2,2,1-heptene-2,3-dicarboxylic acid)methyl ester	5826-73-3	2	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
55	sec-butyl mercaptan or 2-butanethiol	513-53-1	4	In products used in order to temporarily inhibit human bodily functions for self-defense or to harm others
56	safole	94-59-7	4	
57	sodium fluoride	7681-49-4	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
58	sodium hypochlorite	7681-52-9	1	In products used for swimming pool anti-infection/deodorization
59	cycloheximide	66-81-9	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
60	cyclohexyl acetoacetate	6947-02-0	2	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
61	cyanophos	2636-26-2	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
62	DDT or 1,1,1-trichloro-2,2-bis (4-chlorophenyl) ethane	50-29-3	4	
63	DBCP or 1,2-dibromo-3-chloropropane	96-12-8	4	
64	dieldrin	60-57-1	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
65	DEET or N,N-diethyl-3-methylbenzamide	134-62-3	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
66	decabromobiphenyl	13654-09-6	4	
67	di(phenylmercury)dodecyl succinate or di(phenylmercury)dodecyl(-3-succinate	27236-65-3	4	
68	dichlorvos	62-73-7	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
69	dicofof	115-32-2	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
70	dicrotophos	141-66-2	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
71	dinitroresol or DNOC	534-52-1	4	In household or public health products
72	dibutyl phthalate	84-74-2	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
73	diflubenzuron	35367-38-5	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
74	diphacinone	82-66-6	3	In household or public health products intended to get rid of rodents
75	difenacoum	56073-07-5	3	In household or public health products intended to get rid of rodents
76	dimethyl phthalate	131-11-3	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
77	dimetilan	644-64-4	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
78	dioxcarb	6988-21-2	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
79	dioxathion	78-34-2	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
80	diazinon	333-41-5	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
81	diethyl phthalate	84-66-2	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
82	diethylene glycol monobutyl ether acetate	124-17-4	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
83	di-isopropyl tartrate	2217-15-4	2	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
84	tetrachlorinphos	22248-79-9	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
85	tetrachloroethane or acetylene tetrachloride or 1,1,2,2-tetrachloroethane	79-34-5	4	In household or public health products
86	trichlorfon	52-68-6	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
87	tris(2,3-dibromopropyl)phosphate	126-72-7	4	

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
88	toxaphene or camphechlor	8001-35-2	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
89	thanite	115-31-1	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
90	TDE or DDD or 1,1-dichloro-2,2-bis (4-chlorophenyl) ethane	72-54-8	4	
91	temephos	3383-96-8	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
92	tert-butyl mercaptan or 2-methyl-2-propanethiol	75-66-1	4	In products used in order to temporarily inhibit human bodily functions for self-defense or to harm others
93	thallium sulfate	7446-18-6	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
94	norbormide	991-42-4	3	In household or public health products intended to get rid of rodents
95	dibutyl-DL-malate	6280-99-5	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
96	n-butyl mercaptan or 1-butanethiol	109-79-5	4	In products used in order to temporarily inhibit human bodily functions for self-defense or to harm others
97	n-propyl cinnamate	7778-83-8	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
98	naled	300-76-5	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
99	citronella oil	8000-29-1	1	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
100	naphthalene	91-20-3	2	In products used in households or for public health purposes in order to inhibit, prevent, control, repel, and get rid of insects or other pests or for deodorization
101	naphthylamine	134-32-7	4	
102	<i>Bacillus thuringiensis</i>	68038-71-1	3	In products, which their active ingredients come from or are produced by microbial, to diminish or prevent human harms by get rid of mosquitoes or insects' larvae
103	bis(chloromethyl)ether	542-88-1	4	
104	BHC or benzene hexachloride or HCH or hexachlorocyclohexane	608-73-1	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
105	beta-HCH or 1,3,5,2,4,6-hexachlorocyclohexane	319-85-7	4	
106	benzidine	92-87-5	4	
107	benzyl benzoate	120-51-4	2	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
108	bendiocarb	22781-23-3	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
109	barium carbonate	513-77-9	3	In household or public health products intended to get rid of rodents

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
110	brodifacoum	56073-10-0	3	In household or public health products intended to get rid of rodents
111	bromadiolone	28772-56-7	3	In household or public health products intended to get rid of rodents
112	bromophos	2104-96-3	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
113	bromophos-ethyl	4824-78-6	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
114	paris green	12002-03-8	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
115	plifenate	21757-82-4	2	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
116	<i>p</i> -(<i>n</i> -propoxy)benzaldehyde	5736-85-6	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
117	paraquat dichloride	1910-42-5	4	
118	<i>p</i> -dichlorobenzene or 1,4-dichlorobenzene	106-46-7	3	In products used in households or for public health purposes in order to inhibit, prevent, control, repel, and get rid of insects or other pests or for deodorization
119	parathion	56-38-2	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
120	parathion-methyl	298-00-0	4	

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
121	<i>p</i> -methoxybenzyl alcohol	105-13-5	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
122	<i>p</i> -isopropylphenylethyl alcohol	10099-57-7	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
123	pinone	83-26-1	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
124	pirimiphos-methyl	29232-93-7	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
125	PAVA or pelargonic acid vanillylamide or N-[(4-Hydroxy-3-methoxyphenyl) methyl] nonanamide	2444-46-4	4	In products used in order to temporarily inhibit human bodily functions for self-defense or to harm others
126	pentachlorophenate sodium or pentachlorophenoxide sodium	131-52-2	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
127	pentamethylene dipropionate	10025-09-9	2	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
128	polychlorinated terphenyl or PCT	61788-33-8	4	
129	prothiofos	34643-46-4	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
130	propoxur	114-26-1	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
131	propetamphos	31218-83-4	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
132	promecarb	2631-37-0	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
133	piperonyl cyclohexanone	12261-99-3	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
134	piperonyl butoxide or piperonyl ether butoxide	51-03-6	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
135	pyrinuron or pirimil	53558-25-1	4	
136	pyrethrins	8003-34-7	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
137	fluoroacetamide	640-19-7	4	In household or public health products intended to get rid of rodents
138	fluoroacetate sodium	62-74-8	4	In household or public health products intended to get rid of rodents
139	phoxim	14816-18-3	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
140	phosphorus	7723-14-0	4	
141	phosphamidon	13171-21-6	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
142	phosphine	7803-51-2	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
143	phosmet	732-11-6	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
144	fipronil	120068-37-3	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
145	PMO or phenylmercuric oleate	104-60-9	4	
146	phenylmercury acetate	62-38-4	4	
147	fenchlorphos	299-84-3	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
148	phenthoate	2597-03-07	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
149	fenthion	55-38-9	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
150	fenoxycarb	72490-01-8	2	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
151	fenitrothion	122-14-5	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
152	flocoumafen	90035-08-8	3	In household or public health products intended to get rid of rodents
153	malathion	121-75-5	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
154	mecarbam	2595-54-2	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
155	methoxychlor	72-43-5	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
156	methacrifos	62610-77-9	2	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
157	methanol or methyl alcohol	67-56-1	1	If used as solvents in household products
158	methanol or methyl alcohol	67-56-1	4	In injected or spray products and in products contacting skin or food while being used
159	methanol or methyl alcohol	67-56-1	4	Concentration > 1%v/v in products used as fuel for cooking or food warming
160	methamidophos	10265-92-6	4	
161	methyl bromide or bromomethane	74-83-9	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
162	methiocarb	2032-65-7	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
163	methoprene	40596-69-8	3	In household or public health products intended to inhibit, prevent and get rid of insects by insects' growth regulation
164	methomyl	16752-77-5	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
165	mevinphos	7786-34-7	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
166	monocrotophos	6923-22-4	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
167	mirex	2385-85-5	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
168	red squill	507-60-8	3	In household or public health products intended to get rid of rodents
169	rotenone	83-79-4	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
170	ryania	15662-33-6	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
171	lindane or gamma-hexachlorocyclohexane or γ -HCH	58-89-9	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests except in medication products used as second line treatment for curing scabies and pediculosis in human
172	lead arsenate	7784-40-9	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
173	warfarin	81-81-2	3	In household or public health products intended to get rid of rodents
174	vinyl chloride monomer or monochloroethene	75-01-4	4	If used as propellants in injected or spray products

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
175	skunk oil	-	4	In products used in order to temporarily inhibit human bodily functions for self-defense or to harm others
176	schradan or octamethylpyrophosphoramide or OMPA	152-16-9	4	
177	strychnine sulfate	60-41-3	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
178	strobane or polychloroterpenes	8001-50-1	4	
179	oxydemeton-methyl	301-12-2	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
180	octabromobiphenyl	27858-07-7	4	
181	o-dichlorobenzene or 1,2-dichlorobenzene	95-50-1	4	
182	azamethiphos	35575-96-3	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
183	acetophenone,4-methoxy-3-methyl	10024-90-5	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
184	amitraz	33089-61-1	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
185	amitrole	61-82-5	4	
186	aldrin	309-00-2	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
187	aldicarb	116-06-3	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
188	alpha,alpha'-dimethyl-alpha-carbobutoxy-dihydro-gamma-pyrone	532-34-3	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
189	alpha-chlorohydrin	96-24-2	3	In household or public health products intended to get rid of rodents
190	imidacloprid	105827-78-9	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
191	EDB or 1,2-dibromoethane	106-93-4	4	
192	ethanethiol or ethyl mercaptan or ethyl sulfhydrate	75-08-1	4	In products used in order to temporarily inhibit human bodily functions for self-defense or to harm others
193	ethion	563-12-2	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
194	EPN or ethyl <i>p</i> -nitrophenyl phenylphosphorothioate	2104-64-5	4	
195	ethanol,2,2'-thiodi-,diacetate	4275-28-9	2	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
196	ethylcyanocyclohexyl acetate	1331-45-9	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
197	ethyl hexyleneglycol or ethyl hexane diol or ethohexadiol	94-96-2	4	

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
198	ethylene glycol n-butyl ether or ethylene glycol mono butyl ether or 2-butoxy ethanol	111-76-2	3	In household or public health products intended to clean floors, walls and sanitary wares or other materials
199	ethylene dichloride	107-06-2	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
200	ethylene oxide or 1,2-epoxyethane	75-21-8	4	Except for anti-microbial purposes in health care facilities
201	Ethyl N,N-dipropyl succinamate	10143-31-4	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
202	n-propyl N,N-diethyl succinamate	5834-84-4	2	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
203	N-sec-butyl phthalimide	10108-61-9	2	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
204	endrin	72-20-8	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
205	endosulfan	115-29-7	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
206	N-butyl-1,2,3,6-tetrahydronaphthalimide	2021-19-4	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
207	MGK or 1,4,4a,5a,6,9,9a,9b-octahydrodibenzofuran-4a-carbaldehyde	126-15-8	4	
208	ergocalciferol	50-14-6	3	In household or public health products intended to get rid of rodents

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
209	ANTU or 1-naphthylthiourea	86-88-4	4	In household or public health products intended to get rid of rodents
210	asbestos : amosite	12172-73-5	4	
211	omethoate	1113-02-6	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
212	isazofos	42509-80-8	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
213	isodrin	465-73-6	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
214	isobenzan	297-78-9	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
215	isopropyl cinnamate	7780-06-5	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
216	hexachlorobenzene	118-74-1	4	
217	hexabromobiphenyl	36355-01-8	4	
218	diethylhexahydrophthalate	10138-59-7	2	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
219	heptachlor	76-44-8	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
220	heptenophos	23560-59-0	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
221	2-phenylethyl 3-hydroxy propanoate	10138-63-3	2	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
222	hydramethylnon	67485-29-4	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
223	hydrogen peroxide	7722-84-1	3	In household or public health products intended to kill germs on floors, walls and sanitary wares or other materials
224	hydroprene	41096-46-2	3	In household or public health products intended to inhibit, prevent and get rid of insects by insects' growth regulation

List of hazardous substances under responsibility of Thai Food and Drug Administration
(Based on the List 4 at the end of the Notification of Ministry of Industry on List of Hazardous Substances B.E. 2556 (2013))

List 4.2 List of chemical groups

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
1	dichloroisocyanuric acid and its salts	-	1	In products used for swimming pool anti-infection/deodorization
2	trichloroisocyanuric acid and its salts	-	1	In products used for swimming pool anti-infection/deodorization
3	fluoroacetic acid and its salts	-	4	In household or public health products intended to get rid of rodents
4	acids	-	3	In household or public health products intended to kill germs, clean floors, walls and sanitary wares or other materials or intended to unblock sewer pipes and clogged drains
5	chlorhexidine salts	-	3	In household or public health products intended to kill germs, clean floors, walls and sanitary wares or other materials or intended to unblock sewer pipes and clogged drains
6	soluble cyanide salts	-	4	In household or public health products
7	chlorofluorocarbons	-	4	If used as propellants in injected or spray products except in medication products or products making skin cool
8	alkalis	-	3	In household or public health products intended to kill germs, clean floors, walls and sanitary wares or other materials or intended to unblock sewer pipes and clogged drains

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
9	nonylphenol ethoxylate	-	3	In household or public health products intended to kill germs, clean floors, walls and sanitary wares or other materials or intended to unblock sewer pipes and clogged drains
10	polyalkylene glycol stearate	-	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
11	pyrethroids	-	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
12	insect growth regulators	-	2	In household or public health products intended to inhibit, prevent and get rid of insects by insects' growth regulation
13	microbial larvicides	-	2	In products, which their active ingredients come from or are produced by microbial, to diminish or prevent human harms by get rid of mosquitoes or insects' larvae
14	mercury compounds	-	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects, fungi or other pests
15	amphoteric surfactants	-	3	In household or public health products intended to kill germs, clean floors, walls and sanitary wares or other materials or intended to unblock sewer pipes and clogged drains
16	anionic surfactants	-	1	In household or public health products intended to kill germs, clean floors, walls and sanitary wares or other materials or intended to unblock sewer pipes and clogged drains except powdered detergents

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
17	cationic surfactants	-	3	In household or public health products intended to kill germs, clean floors, walls and sanitary wares or other materials or intended to unblock sewer pipes and clogged drains
18	nonionic surfactants except nonylphenol ethoxylate	-	1	In household or public health products intended to kill germs, clean floors, walls and sanitary wares or other materials or intended to unblock sewer pipes and clogged drains except powdered detergents
19	alkyl cyanoacrylate	-	1	In household or public health products intended to bind surfaces of materials
20	aldehydes	-	3	In household or public health products intended to kill germs, clean floors, walls and sanitary wares or other materials or intended to unblock sewer pipes and clogged drains
21	ethyl ester of epoxy methylphenyl acrylic acid	-	3	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
22	chlorine and chlorine releasing substances	-	3	In household or public health products intended to kill germs, clean floors, walls and sanitary wares or other materials or intended to unblock sewer pipes and clogged drains
23	cadmium and cadmium compounds	-	4	
24	dinoseb and dinoseb salts	88-85-7	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests
25	pentachlorophenol and its salts	-	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
26	phenols and phenolic compounds	-	3	In household or public health products intended to kill germs, clean floors, walls and sanitary wares or other materials or intended to unblock sewer pipes and clogged drains
27	dyes	-	4	In food products or food additives
28	arsenic and arsenic compounds	-	4	In household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests

List of hazardous substances under responsibility of Thai Food and Drug Administration

(Based on the List 4 at the end of the Notification of Ministry of Industry on List of Hazardous Substances B.E. 2556 (2013))

List 4.3 List of product groups or purpose of use

No.	Hazardous substances	CAS No.	Hazardous Substances Type	Condition
1	Household or public health products intended to get rid of rodents	-	2	
2	Household or public health products intended to inhibit, prevent, control, repel, and get rid of insects or other pests	-	2	
3	Household or public health products intended to kill germs, clean floors, walls and sanitary wares or other materials or intended to unblock sewer pipes and clogged drains	-	2	
4	Household or public health products used for bleaching or swimming pool anti-infection/deodorization	-	2	
5	Household or public health products used for erasing, correcting, or dissolve chemicals used for erasing or correcting or dry cleaning clothes and textile products	-	2	
6	Products containing any active ingredient used in order to temporarily inhibit human bodily functions for self-defense or to harm others	-	4	