

Overview and updates of chemical regulations in Vietnam

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Summary of Topics

- 1 Chemical Regulations in Vietnam
- 2 Amendment of Decree 113/2017/ND-CP
- 3 New regulations on POP substances
- 4 Updates on National Chemical Inventory (NCI)
- 5 Future development of chemical compliance



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1. Chemical regulations in Vietnam

Vietnam Chemical Agency (Vinachemia) - Ministry of Industry and Trade (MOIT) is the main competent authority in chemical management

| Authorities | | Main roles |
|--|---|---|
| Ministry of Industry and Trade (MOIT)- Vietnam Chemical Agency (Vinachemia) |  | An organization plays central role in chemical regulations, including the Law on Chemicals and its subordinate legislations, responsible for production, import, export, trading; management of chemical accidents, existing chemical lists and new chemical substances. |
| Ministry of Natural Resources & Environment (MONRE) |  | An organization plays central role in measures for environmental problems. Relating to chemicals, MONRE is in charge of environmental accidents, environmental pollution, Stockholm Convention , and currently preparing a draft regulation for PRTR . |
| Ministry of Public Health (MOH) |  | An organization manages pharmaceuticals and food safety. Relating to chemicals, MOH is in charge of management of insecticidal and disinfectant chemicals and preparations for household and medical use; and responsible for regulations on chemical exposure at workplace . |
| Ministry of Labor, Invalids and Social Affairs (MOLISA) |  | An organization manages all labor-related field, including labor, occupational safety and health. Relating to chemicals, MOLISA is currently preparing technical standards on labor, occupational safety and health in using of hazardous substances . |



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1. Chemical regulations in Vietnam

Chemical

A substance (an element / a compound) or a mixture which is exploited or created by humans from natural or artificial raw materials.

Chemical production

An act of producing chemicals through chemical reactions or biochemical or physiochemical processes such as extraction, concentration, dilution and mixture and other physiochemical processes

Chemical trade

Sale, export and import of chemicals to provide chemicals on the market for profitable purposes.

New chemical

A chemical not yet listed in the National Chemical Inventory (NCI) or foreign chemical inventories recognized by Vietnamese competent state agencies

Chemical regulations in Vietnam target on substances and mixtures, not much on chemical products

Source: *Law on Chemicals 06/2007/QH12*



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1. Chemical regulations in Vietnam

Law on Chemicals 06/2007/QH12

The most basic law on chemical management, regulates on production/trading/use, chemical safety, chemical information and responsibilities of competent authorities

Decree 113/2017/ND-CP

On guidelines for implementation of certain articles of the Law on chemicals

Detailed regulations for **various chemical lists** on licenses, classification, plans/measures for chemical incident, safety training, declaration, etc.

⇒ Under amendment

Circular 32/2017/TT-BCT

On guidelines for implementation of certain articles of the Law on chemicals and Decree 113/2017/ND-CP

Forms and guidelines of labeling, MSDS, declaration, reports, license application, plans/measures, etc.

⇒ Under amendment



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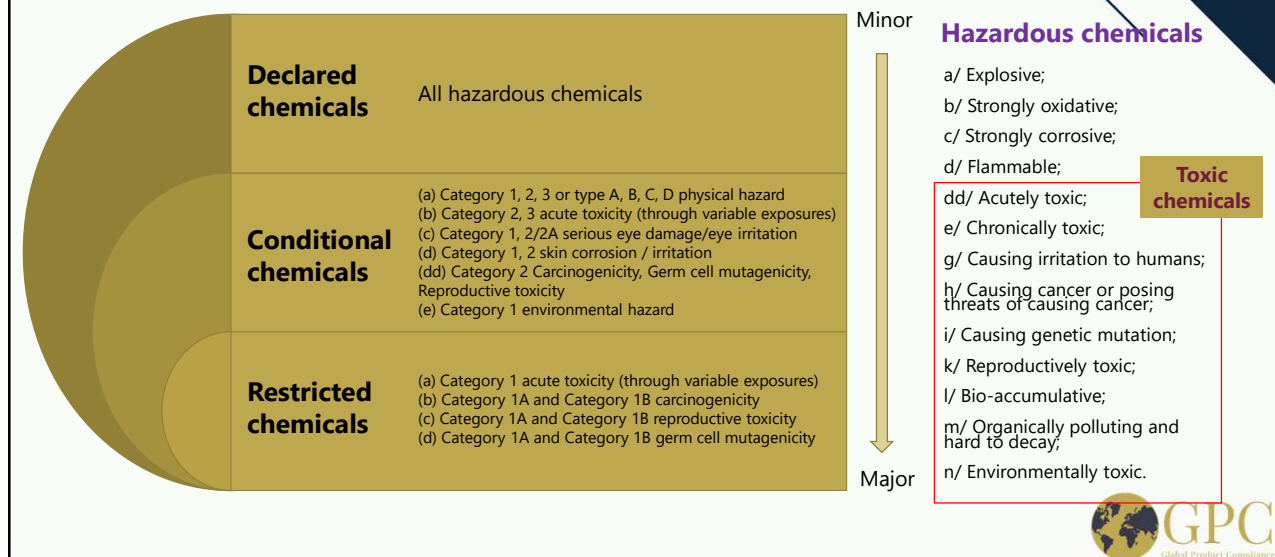
1. Chemical regulations in Vietnam

| Chemical List | Reference | Requirements |
|--|------------------------------------|--|
| Conditional industrial chemicals | Decree 113/2017/ND-CP Appendix I | • Certificates for production and trading of conditional industrial chemicals |
| Restricted industrial chemicals | Decree 113/2017/ND-CP Appendix II | • Licenses for production and trading of restricted industrial chemicals • Management of invoices related to sale and purchase of restricted industrial chemicals |
| Prohibited chemicals | Decree 113/2017/ND-CP Appendix III | • Licenses from Prime Minister for some special purpose (authorized to minister of MOIT) |
| Hazardous chemicals requiring incident prevention and response plan | Decree 113/2017/ND-CP Appendix IV | • Licenses for Plan from MOIT • Self-approved Measure by company |
| Declared chemicals | Decree 113/2017/ND-CP Appendix V | • Declaration on National Single Window before custom clearance |
| Hazardous chemicals | Law on chemicals Article 4 | • Material data sheet (SDS) |
| Toxic chemicals | Law on chemicals Article 4 | • Purchasing control paper |
| Industrial Precursors | Decree 73/2018/ND-CP Appendix I | • License for import / export from Minister of MOIT • Logbook for recording the industrial precursor chemical production |



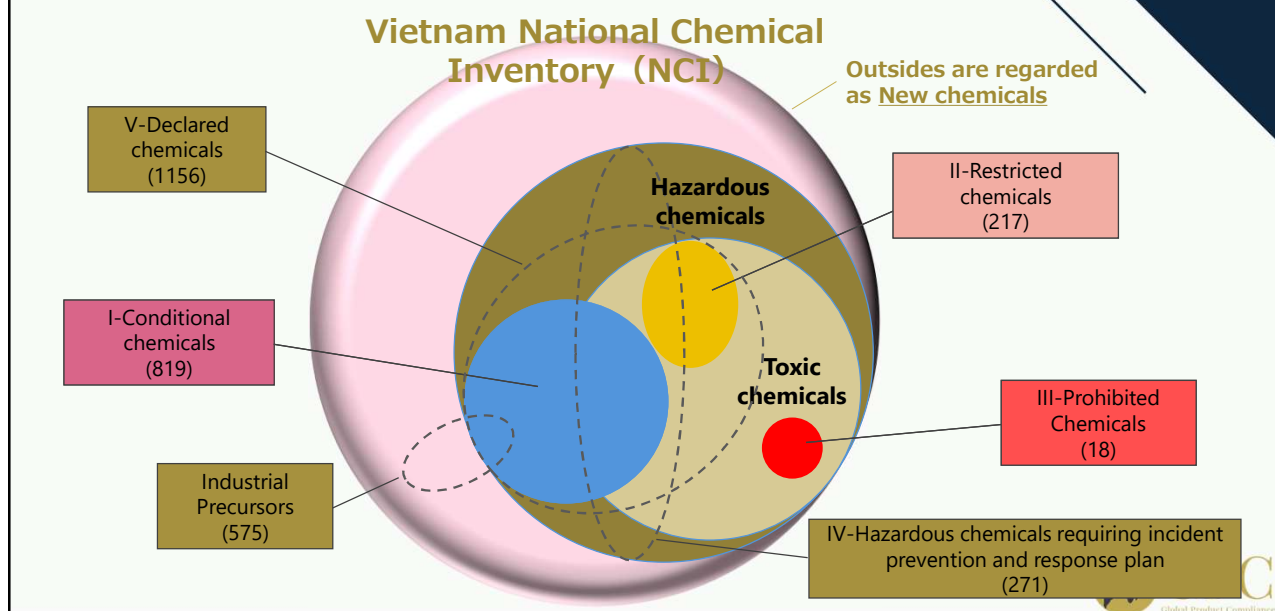
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1. Chemical regulations in Vietnam



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1. Chemical regulations in Vietnam



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2. Amendment of Decree 113/2017/ND-CP

Amended and Supplemented Points

- A. Supplementation of prohibited chemicals
- B. Supplementation of restricted chemicals
- C. Chemicals requiring special control at importation
- D. Exemption types of product not covered by Decree 113
- E. Exemption cases of concentration limit value
- F. Determination of expiration for licenses
- G. Extension of deadline for annual chemical report
- H. Revision of GHS classification categories
- I. Practical exercises of chemical accident prevention and response measures/plans

4 groups of substances subject to Chemical Weapon Convention will be added to the list of prohibited chemicals

The following 6 substances subject to Stockholm Convention will be added to the list of restricted chemicals

- Hexabromocyclododecane
- Chlordecone
- Pentachlorobenzene (PeCB)
- Polychlorinated naphthalene (PCN)
- Decabromodiphenyl ether (DBDE)
- Perfluorooctanoic acid (PFOA) and its salts

Persistent Organic Pollutants (POPs)

- Nitrous oxide (N₂O)
- Cyanide (CN⁻)
- Mercury and mercury compounds



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2. Amendment of Decree 113/2017/ND-CP

D. Exemption types of chemical product not covered by Decree 113 (Amended at Decree 17/2020/ND-CP)

- Pharmaceuticals; germicidal and insecticidal preparations; cosmetics;
- Feeds; veterinary drugs; agrochemicals; organic fertilizers, biofertilizers, chemical fertilizers that are mixed fertilizers, organic mineral fertilizers, bio-mineral fertilizers; products used for preservation and processing of agricultural products, forestry products, fishery products and foods;
- Radioactive substances; building materials; paints, printing ink;
- Household adhesives and cleaning products;
- Gasoline, oil; condensate and naphta used for gasoline and oil processing.

⇒ **Not requiring certificates/licenses of production and trading for conditional/restricted chemicals; or import declaration**



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2. Amendment of Decree 113/2017/ND-CP

E. Exemption cases of concentration limit value

Hazardous chemical mixtures include component substances with the content **below than 0.1%** in the following list:

- Appendix I: List of conditional chemicals; or
- Appendix II: List of restricted chemicals; or
- Appendix V: List of declared chemicals

⇒ **Not requiring certificates/licenses of production and trading for conditional/restricted chemicals; or import declaration**



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2. Amendment of Decree 113/2017/ND-CP

Other amendment points

| Amended Points | Contents |
|---|--|
| F. Application of expiration for licenses | Licenses for production and trading of restricted industrial chemicals No expiration ⇒ Expiration of 5 years |
| G. Extension of deadline for annual chemical report | January 15 th ⇒ February 15th (report on National Chemical Database: chemicaldata.gov.vn) |
| H. Revision of GHS classification categories | Table of main categories are mixed by GHS from Rev. 2 (2007) to Rev. 7 (2017) ⇒ Main categories of GHS Rev. 2 (2007) |
| I. Practical exercises of chemical accident prevention and response measures/plan | Organize practical exercises annually with attendance of specialized authorities |



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3. New regulations on POP substances

Decree 08/2022/ND-CP (Article 38-41)

1. Hexabromodiphenyl ether (HBDE)
2. Tetrabromodiphenyl ether, pentabromodiphenyl ether (PBDE)
3. Perfluorooctanesulfonic acid (PFOS), Perfluorooctanesulfonyl fluoride (PFOSF)
4. Hexabromocyclododecane (HBCDD)
5. Polychlorinated naphthalene (PCN)
6. Decabrominated diphenyl ether (DBDE)
7. Short chain chlorinated paraffins (SCCP)
8. Perfluorooctanoic acid (PFOA), and PFOA related compounds

Production, Use, Import

Apply for **exemption registration** to MONRE

Exemption registration for use of POPs required the following information:

- Name, CAS RN, HS code of POPs
- Planned use amount per year
- Use purpose and method
- Environmental protection requirements (storage warehouse, fire prevention, waste treatment, etc.)

For import of POPs: The **approval notice of exemption registration** by the authority must be presented during customs clearance. Additionally, the quantity and name of POPs per Lot must be reported to MONRE and General Department of Vietnam Customs.

Producers and Importers of POPs are required to conduct conformity assessment of POPs

Labeling

Comply with **Environmental Technical Standard** for permissible amount of POPs in raw materials, fuels, products and equipment.

New National technical standard (QCVN) is under development

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3. New regulations on POP substances

| | MONRE | MOIT |
|----------------------|---|--|
| Regulatory name | Draft of National Technical Standard (QCVN) for permissible concentration of POPs in raw materials, fuels, products and equipments. | Draft of Decree amending and supplementing Decree 113/2017/ND-CP on guidelines for implementation of Law on chemicals |
| Regulated substances | <ul style="list-style-type: none"> • Hexabromodiphenyl ether (HBDE) • Tetrabromodiphenyl ether, Pentabromodiphenyl ether (PBDE) • Perfluorooctanesulfonic acid (PFOS), Perfluorooctanesulfonyl fluoride (PFOSF) • Hexabromocyclododecane (HBCDD) • Decabrominated diphenyl ether (DBDE) • Short chain chlorinated paraffins (SCCP) • Perfluorooctanoic acid (PFOA), and PFOA related compounds | <p>The following substances are added to the list of restricted chemicals.</p> <ul style="list-style-type: none"> • Hexabromocyclododecane • Chlordecone • Pentachlorobenzene (PeCB) • Polychlorinated naphthalene (PCN) • Decabrominated diphenyl ether (DBDE) • Perfluorooctanoic acid (PFOA) and its salts <p>※HBCDD, PBDE, PFOS, SSCP are already in the list of restricted chemicals.</p> |
| Concentration limit | Concentration limits are specifically applied to each substance | The substance which content in the mixture is equal to or more than 0.1% will be subject to this regulation. |
| Requirements | Businesses that import, produce, trade or use raw materials, fuels, products, equipment containing POPs are required to apply MONRE. | The above 6 substances are designated as "Restricted Chemicals" and required a license for production/trading approved by MOIT. |



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4. Updates on National Chemical Inventory

- Overall list of existing chemical substances in Vietnam
- In 2012, Prime minister approved Decision 768/QĐ-TTg on plan for compilation of national chemical inventory (NCI) and national chemical database (NCDBS)

| STT | Tên chất | CAS |
|-----|---------------------------------------|-----------|
| 1 | Formaldehyde | 50-00-0 |
| 2 | 2,4-Dinitrophenol | 50-02-2 |
| 3 | Hydrochloric acid | 7647-01-0 |
| 4 | 2,4-Dinitrophenol | 50-06-4 |
| 5 | Phenol | 108-95-2 |
| 6 | Chlorine | 7782-42-5 |
| 7 | Carbon | 7440-74-6 |
| 8 | Phenol | 108-95-2 |
| 9 | Water | 7732-18-5 |
| 10 | Hexane | 110-54-3 |
| 11 | 1,1,1-Trichloro-2,2,2-trifluoroethane | 102-93-3 |
| 12 | 2,4-Dinitrophenol | 50-06-4 |

Documents need for nomination in NCI

- Chemical name (IUPAC)
- CAS number
- Safety Data Sheet (SDS)
- Documents approved that the chemicals are being used in Vietnam (purchase contract, import invoices, etc.)



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4. Updates on National Chemical Inventory

The system has been opened 5 times since 2016 Sep

1st Draft : Dec, 2015 > 3,000 substances

2nd Draft : Dec, 2016 > 5,000 substances

3rd Draft : Mar, 2017 > 30,000 substances

4th Draft : June, 2020 > 41,000 substances

5th Draft : April, 2021 > 52,000 substances

Dec, 2018: Official announcement of NCDBS

Not all of substances in the Draft are "approved"

3 status of applied substances

- Lack of evidence;
- Under examination; or
- Approved in Draft NCI

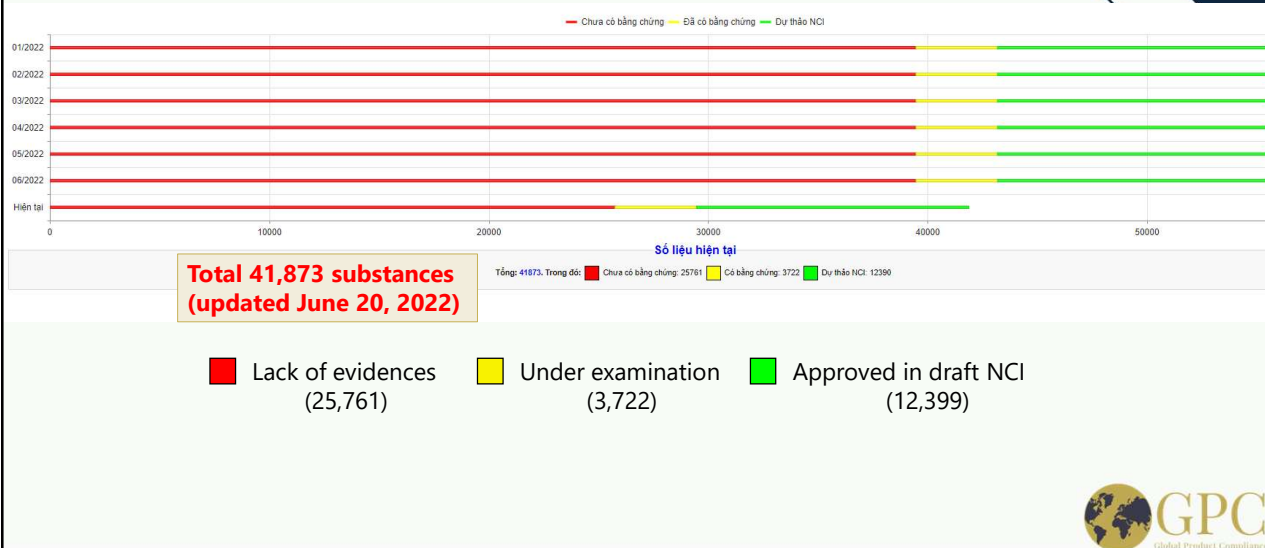
(5th Opening of the NCI system: Oct 16th, 2020 ~ Apr 15th, 2021)



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4. Updates on National Chemical Inventory

Status of Vietnam NCI (Present)



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4. Updates on National Chemical Inventory

Draft regulations on management of new chemicals

“New chemical substance”

A chemical substance not yet listed in the national chemical inventory (NCI) or foreign chemical inventories recognized by Vietnamese competent state agencies

“Foreign chemical substance”

A chemical substance not yet listed in the nation chemical inventory (NCI) but already listed in foreign chemical inventories recognized by Vietnamese competent state agencies

Basic regulations

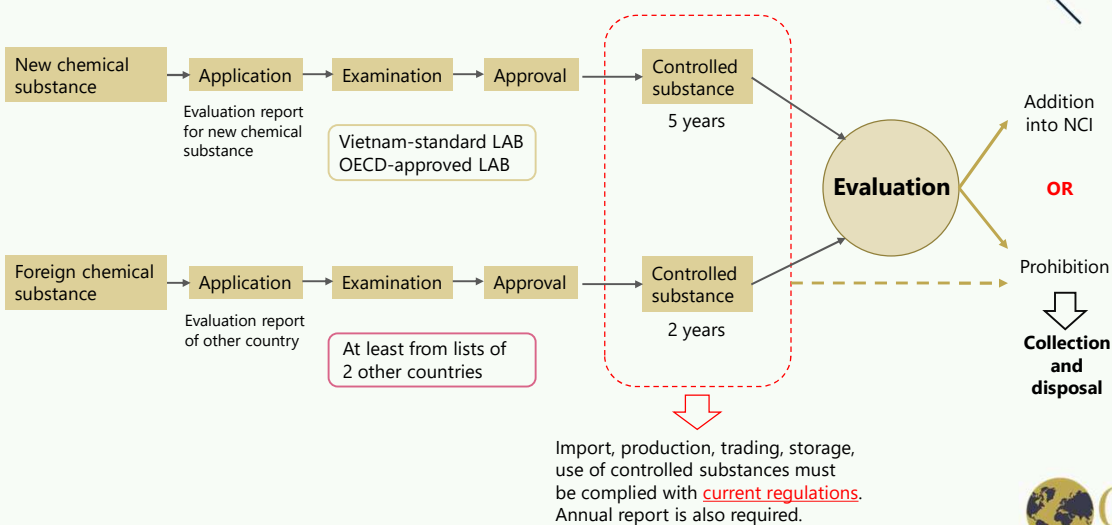
Before distribution (including import) and use of new chemical substances in Vietnam, it is essential to obtain "[New Chemical Substance Registration Approval Form](#)" issued by the competent authority through a management procedure.



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4. Updates on National Chemical Inventory

Draft of Decree on management of new chemicals



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4. Updates on National Chemical Inventory

Exemption cases for registration of new chemical substances

- For national purpose (security, national defense, response to disasters or emergencies, etc.)
- **Volume per one-time import is small**
- Production volume is small
- Ingredients extracted from natural products
- **Impurities in the mixture is less than 1%**
- Chemical materials for production of medicines, pesticides, insecticides, etc. that are permitted for distribution in Vietnam
- **Polymers**

What is the acceptable quantity/volume?

Only impurities ?
What about intentional additives ?

The exemption rules for polymers are based on the EU regulations?

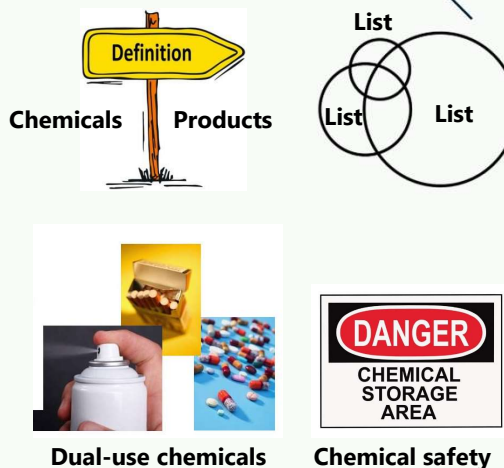


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5. Future development of chemical compliance

Problems of current regulations

- Lack of clear definitions of “chemical substances” and “product”.
- Limitation in chemical management in various lists of chemical substance. There are lists are excess or deficient, many lists overlap to each other.
- Functions of various authorities are duplicated, difficult to clarify responsibilities, particularly on management of dual-use chemicals.
- No emphasis on chemical security related to management of dual-use chemicals for the ban on the production of chemical weapons.
- No guidance on safety of production, trading, use, storage transportation and distance of chemicals.



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5. Future development of chemical compliance

Amendment of Law on Chemicals

- Completion of the National Chemical Inventory (NCI)**
- Life cycle management of chemical substances**
- Chemical safety**
 - To enact technical standards for chemical safety
- Application of evaluation of chemical risk**
- Management of chemical substances in products**
 - To regulate the content of chemicals in products
 - To ban specific chemical substances
 - To apply evaluation of chemical risk for products
- Development of chemical industry**
- Management of dual-use chemical substances**



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