ERIA Research Project Report 2011, No. 15

STUDY ON THE FEASIBILITY OF AN INFORMATION INFRASTRUCTURE FOR THE FUTURE CHEMICALS MANAGEMENT SCHEME IN THE ASIAN REGION

Edited by
SARISAK SOONTORNCHAI

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March 2012

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ABBREVIATIONS AND ACRONYMS

ACVM	Agricultural Compounds and Veterinary Medicines
ACOP	Approved Code of Practice
AEC	The ASEAN Economic Community
AG-HCL	Advisory Group on Harmonisation of Classification and Labelling
ASEAN	Association of South‑East Asian Nations
CAS	Chemical Abstracts Service
CCID	Chemical Classification and Information Database
CEMS	Continuous Emission Monitoring Systems
CERT	Company Emergency Response Team Audit
CHRIP	Chemical Risk Information Platform
CMP	Chemical Management Programme
CMR	Chemicals in Main Regulations
COPPC	Code of Practice on Pollution Control
CPU	Central Processing Unit
CSCL	Chemical Substances Control Law
DEHP	Bis(2-ethyl(hexyl)phthalate)
DENR	Department of Environment and Natural Resources
DIW	Department of Industrial Works
ECHA	European Chemicals Agency
EHS	Environmentally Hazardous Substances
EIS	Environmental Impact Statement
EPA	Economic Partnership Agreement
EPMA	Environmental Protection and Management Act,
ERIA	Economic Research Institute for ASEAN and East Asia
ERIA WG	ERIA Working Group
EU	European Union
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration Act
FTA	Free Trade Agreement
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HDD	Hard Disk Drive
HES	Health and Safety in Employment Act
HSNO	Hazardous Substances and New Organisms
ICCM	International Committee on Composite Materials
IRR	Implementing Rules And Regulations
LAN	Local Area Network
J-CHECK	Japan Chemicals Collaborative Knowledge Database
LPG	Liquefied petroleum gas
MAFF	Ministry of Agriculture, Forest and Fisheries
MIME	Ministry of Industry,. Mines and Energy
MOIT	Ministry of Industry and Trade
MOM	Ministry of Manpower
NEA	National Environmental Agency
NEQA	National Environment Quality Act
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
ODS	Official Document System of the United Nations
OECD	Organization for Economic Co-operation and Development
OSHS	The Occupational Safety and Health Standards

PACS	Priority Assessment Chemicals Substance
PCB	Polychlorinated Biphenyl
PCL	Priority Chemical List
PD	Presidential Decree
PICCS	Philippine Inventory of Chemicals and Chemical Substances
QRA	Guidelines for Quantitative Risk Assessment
RA	Republic Act
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
RMA	Resource Management Act
SAICM	The Strategic Approach to International Chemicals Management
SCDF	Singapore Civil Defense Force
SDS	Safety Data Sheets
SQI	Small Quantity Importation
TA	Technical Assistance
TSCA	Toxic Substances Control Act
TPP	Trans-Pacific Partnership
UN	United Nations
UNCEDTG	United Nations Committee of Experts on the Transport of Dangerous Goods
UNTDG	United Nations Recommendation on the Transport of Dangerous Goods
VPN	Virtual Private Network
vPvB	very Persistent, very Bioaccumulative
WHO	World Health Organization
WSSD	World Summit on Sustainable Development

EXECUTIVE SUMMARY

1. Background and Objectives

At the World Summit on Sustainable Development (WSSD), which was held in Johannesburg in 2002, participating countries committed "to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment, using transparent science-based risk assessment procedures and science-based risk management procedures (WSSD 2020 goal)." All countries in the world need to take necessary measures to achieve this goal.

Following the commitment, Japan amended its major regulation for industrial chemicals, the "Chemical Substances Control Law (CSCL)" in May 2009. The European Commission has already introduced the REACH system, which places greater responsibility on industry to manage the risks that chemicals may pose to human health and the environment. The United States also announced in September 2009 that they would revise the US chemical regulation, TSCA (Toxic Substances Control Act). In the case of Asian countries, many of them started considering the revision of their chemical management systems. For example, the revised regulation on the registration of new chemicals came into force on October 15, 2010, in China.

Several different approaches have been taken to reach the same WSSD 2020 goal, as exemplified by the abovementioned stances taken by Japan, the EU, and the US. Their economic and social impacts differ according to each country's industrial

structure and the nature of the chemical supply chains shared among each region, especially East Asia. Therefore, in the research in the 2010 Fiscal Year, we analyzed the economic impact in cases where two types of risk-based chemicals management systems, the "No-data, No-market" Approach (covering all substances for risk assessment, e.g. EU-REACH) and "Prioritization-Led" Approach (covering only limited types of chemicals selected on a priority basis, e.g. amended CSCL of Japan), where introduced in each country in ASEAN or the surrounding region. As a result of the trial calculation for the total cost, the introduction of a "Prioritization-Led" Approach in each country individually was lower and the introduction of "No-data, No-market" Approach in each country individually was higher.

It was discussed that, in the future, for the efficient collection of chemical hazard data, which is costly and time consuming, the location of chemicals management systems and chemicals risk assessments will be critical. In other words, if a country that did not have a chemicals management system at present could share hazard data with other countries, it would be easier for that country to establish such a system and more easily achieve WSSD 2020 goal.

The supply chains of the manufacturing industries have been and are still expanding rapidly in ASEAN and East Asian countries. The amount of trade in chemicals among ASEAN+6 countries reached 137 billion dollars in 2009, which accounts for around 8.8% of the chemical trade in the world[1]. Clearly, it is very important for ASEAN and East Asian countries to cooperate each other closely in order to carry out appropriate quality controls throughout the life cycle of chemicals. The development of the chemical industry in the Asian region will be encouraged if

[1] Source: RIETI Trade Industry Database 2010, Research Institute of Economy, Trade and Industry (RIETI), Japan

all/many Asian countries have a harmonized chemical management system by using the same data.

From the abovementioned point of view, we would propose the research "Study on the feasibility of an information infrastructure for the future chemicals management scheme in the Asian region." This research will seek to answer how this information infrastructure, including a data center, should be established, on the basis of other examples, including existing chemicals databases and multilateral databases in other areas. It will take into account its economic impact and how an effective and efficient chemical management system in the region can be developed.

2. Findings and Conclusions

(1) Outline of the Information Infrastructure in ASEAN and Partner Countries

1) Target Setting

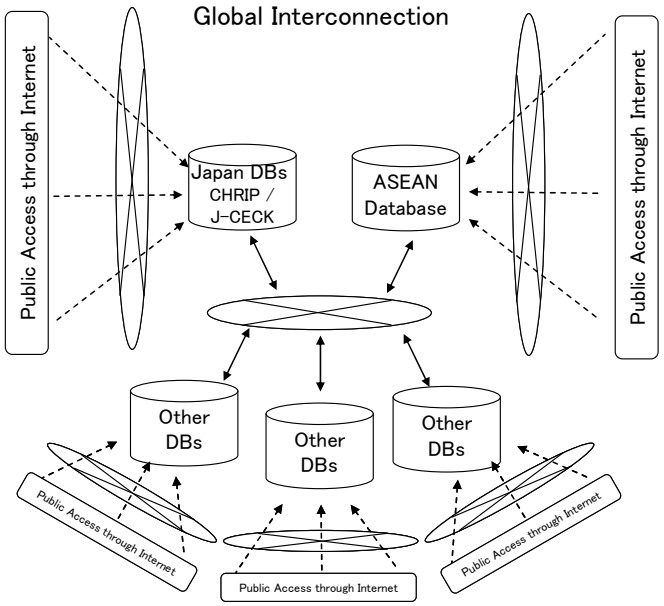
The ASEAN Chemical Safety Database pursues the achievement of the following targets, with the aim of establishing appropriate distribution of chemical substances with assured safety.

1. *To share information on chemical risks and hazards*
2. *To enhance transparency and reduce compliance risks and costs, through providing information on local regulations*
3. *To facilitate regulatory convergence among ASEAN and East Asian Countries*
4. *To reduce the cost of duplicative testing and the burden of assessment*

2) Previous Concept

The following figure illustrates the general schema of the ASEAN Chemical Safety Database examined until the last year. The ASEAN Chemical Safety Database is briefly summarized as follows.

- ✓ The ASEAN Chemical Safety Database shall be made accessible through the Internet, so that it can be utilized by the public at large.
- ✓ The ASEAN Chemical Safety Database shall design mutual links with databases constructed by ASEAN and databases in other countries so that the data can be used to best effect.
- ✓ The ASEAN Chemical Safety Database shall exchange data on chemical risk and hazard with databases constructed by ASEAN and CHRIP in Japan, in order to make use of information on chemical risk and hazard data.



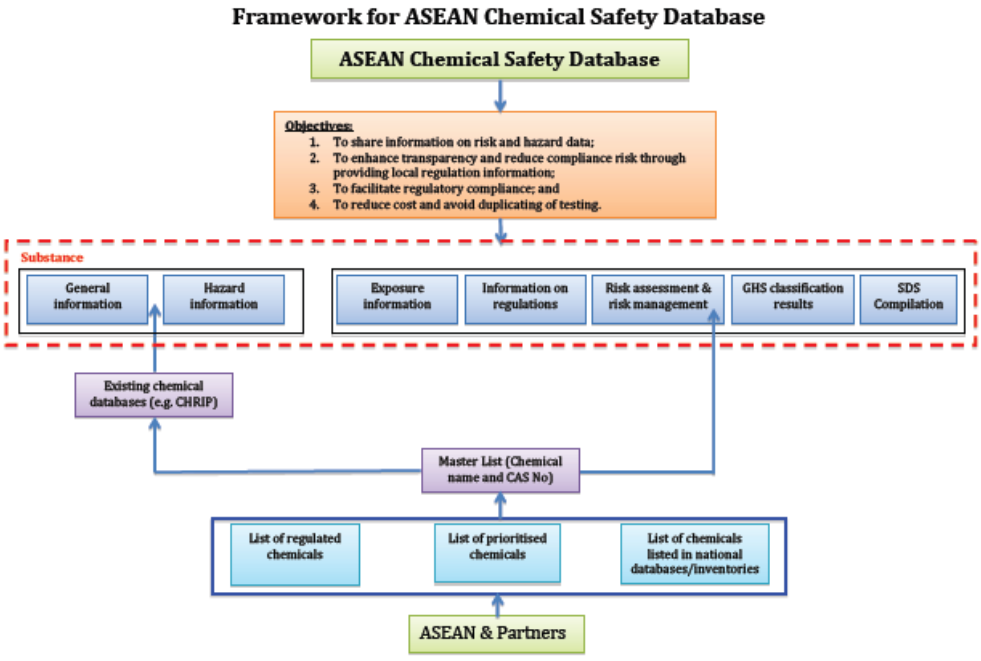
3) Information Items

The details of the information items are shown in the following Table. Here SDS is not the final information.

No.	Field	Specification
1	General Information	CAS No., Chemical Substance Name, Synonym, Structure, Total production amount (the 'total production amount' should be placed in item #4)
2	Information on Laws and Regulations of Each Country	Chemical Management Information
3	Information on Inventories, Regulations, etc.	UN No. and Classification, EINICS, REACH Candidate List, etc.
4	Exposure Information	Produced and Imported amounts of chemical substances, PRTR data, etc.
5	Physical-Chemical Properties	
6	Information on Hazard Assessments.	
7	Information on Environmental Toxicity	
8	Information on Toxicity to Humans	American Conference of Governmental Industrial Hygienists (ACGIH), Carcinogenicity Assessment, etc.
9	GHS classification results	Pictogram, Signal word, Hazard statement, Precautionary statement
10	SDS (Safety Data Sheet)*	Examples of SDS

Note: *with a note of "not final"

The framework of ASEAN Chemical Safety Database was discussed by the working group (WG) for the purpose of its achievement. The discussion result is shown in the following Figure.



The ASEAN Chemical Safety Database collects the lists of chemical substances from member countries in ASEAN and Partners. The possible information items to be collected are as follows:

- ✓ List of regulated chemicals
- ✓ List of prioritized chemicals
- ✓ List of chemicals in national databases/inventories.

The ASEAN Chemical Safety Database integrates these three lists and complies the list of CAS No. and chemical substance name. ASEAN Chemical Safety Database indicates the data of the table 3.1-1 corresponding to the above list. For the existing chemical substances in the list, it indicates general and hazard-related information.

4) Information Management in the Database

The WG discussed 4 cases of display for information output from databases. Case 1 that links to databases providing hazard information is displayed. Links to be displayed shall be set by manual works.

In Case 2, representative values in hazard-related information are displayed. The representative values shall be set manually.

Case 3 displays representative values of databases providing information on hazards if data can be provided automatically. If data cannot be provided, links to databases shall be displayed. Links to be displayed shall be set manually.

Lastly, Case 4 is a hybrid of Case 3 and Case 2. In Case 4, the data which cannot perform automatic registration in Case 3 is registered using the function of Case 2.

The following table is a summarized matrix of features on Case 1 to 4.

	Case 1	**Case 2**	**Case 3**	**Case 4**
Result Table	✘ Link	✓	✓	✓
Method of Data Input	Link	Manual	Auto	Manual/Auto
Modification of Database	✘	✘	✓	✘
Link to Regulation Pages	✓	✓	✓	✓
Authority Cost	C_A	2 C_A	C_A	C_A to 2 C_A
Operation Cost	C_O	3 C_O	C_O	C_O to 3 C_O

* C_A: Authority Cost in Case 1 and Case 3

* C_O: Operation Cost in Case 1 and Case 3

(2) Possible Impact of the ASEAN Chemical Safety Database

The possible impacts to the Government, Industry and ASEAN as a whole are as summarized in the following matrix.

Government	Industry	ASEAN as a whole
✓ Reduction of the testing cost ✓ Reduction of the cost for information gathering ✓ Improve the quality of information for risk assessment ✓ Increased transparency ✓ Harmonization of regulated chemicals ✓ Convergence of GHS classification result ✓ Improve health and environmental outcomes	✓ Reduction of the testing cost ✓ Reduction of the cost for information gathering ✓ Increased transparency ✓ Convergence of GHS classification result ✓ Reduction of the entry barrier for SMEs	✓ Contribution to the AEC Goal ✓ Contribution to the WSSD Target ✓ Harmonization of regulated chemicals ✓ Facilitation of trade ✓ Improve health and environmental outcomes

(3) Rough Roadmap for the ASEAN Chemical Safety Database

The following table summarizes rough roadmaps for the roles to be fulfilled by and information items to be implemented in the ASEAN Chemical Safety Database.

Although detailed discussion on primary objectives, information items, etc. in terms of the database was carried out, there has not been high level political agreement on the construction of the database. Therefore, the years themselves are not specified on the drafted roadmap. Instead, expressions such as Y1, Y2,… have been used to describe the year range for the roadmap of the database. This means that the construction of the database will start in the year that the political agreement is made (e.g., if agreement is made in 2012, Y1=2012).

It should be noted that the following roadmap simply summarizes the rough paths and tasks to be carried out and the approximate time periods; it should not be considered either final or conclusive.

		Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10
Items to be determined	Definition of the scope of service										
	Governing structure										
	Decision-making group										
	Operator and its location (to build a new entity/use existing)										
	Funding scheme / Human resource arrangement										
	Connection to other databases										
Benchmarks for the development of ASEAN Chemical Safety Database	Setting outline of the established database system										
	Planning for systemization										
	System development										
	Data feeding										
	Trial operation										
	Operation										
Cooperation from member countries	Provision of restricted chemicals lists in CAS No. base										
	Provision of hazard data (incl. GHS classification) / SDS sample										
	Contribution to the development and maintenance of the Database										
	Providing experts for direction setting										
	Providing human resource for development and maintenance										
	Monetary support										

Listed items in database	General information										
	Regulatory information / regulated chemicals										
	Risk Assessment Information										
	Exposure information										
	Information on hazards										
	GHS classification result										
	SDS repository										

(4) Toward Further Harmonization

1) Vision and Strategy for Regional Chemical Management

The ASEAN Chemical Safety Database will significantly contribute to the economic integration of the region and strengthen chemical management in a less burdensome manner, as discussed in the previous chapters. However, it is also recognized that the database and the management body of the database will provide a great opportunity for further harmonization in the area of chemical management.

Therefore, the future vision for sound regional chemical management is discussed. Although this attempt may seem to be ambitious, this vision and the following strategy could contribute to promoting further harmonization in this region.

To consider the vision for sound regional chemical management, it is necessary to revisit the goal of the ASEAN Economic Community (AEC). The AEC's goal is economic integration, and concepts such as single market, equitable economic development, and integration into the global economy are mentioned as possible ways of achieving this goal. On the other hand, chemical management schemes may work against economic integration. For example, if the convergence of GHS classification results is not adequately realized, this may hinder trade in ASEAN region. In this context, the further utilization of the database and the management body should be considered as a potential way of achieving further harmonization or convergence of the chemical management scheme in this region.

Therefore, the vision for the future of regional chemical management could be stated simply as follows:

To achieve greater economic integration through chemical management

To achieve this vision, the function of the database and a management body need to be discussed, and a deliberate strategy should be considered. Although this report does not contain a concrete strategy, several functions are discussed, and establishing an appropriate body is discussed. The ideas that are discussed here could be included in the final strategy.

The following are examples of possible functions for the body that have been discussed:

- ✓ Technical Assistance
- ✓ GHS Convergence
- ✓ One stop service
- ✓ Providing chemical management tools (e.g. risk assessment tool)

Furthermore, a management body that has the above functions requires an appropriate host organization. This is not in the scope of this study, but should be carefully reviewed, because establishing a new independent organization is costly owing to various reasons including required management such as human resources, etc. However, all the functions listed above are closely linked to each other and should be operated in a consistent manner. Thus, the management body of the database will be appropriate in helping us achieve the vision mentioned above. At some time in the future, the body may be referred to as a center (i.e., "ASEAN chemical management research center" or "ASEAN chemical management promotion center") if appropriate.

2) Criteria for Moving Forward

During the discussion regarding the future utilization of the management body, it was also discussed that, no matter how attractive and deliberate the strategy and vision seem to be, it is not appropriate to follow the primary strategy or move forward as originally planned. For the achievement of the vision, it is necessary to revisit or review the strategy in order to take the progress of the database project and changes of circumstances into account. From this point of view, the discussion of criteria for moving forward, including the criteria to establish a center as discussed in 6.1, may be useful for future consideration by the body or leaders in the region.

The followings are examples of the criteria for moving forward. If the criteria are satisfied, then a move to the next phase, including establishing a center, will become a realistic agenda to discuss.

- ✓ The development of the ASEAN Chemical Safety Database goes on as planned
- ✓ The appropriate management body of the ASEAN Chemical Safety Database is assigned, etc.

- ✓ (After the development of the Database) the ASEAN Chemical Safety Database is fully used and updated
- ✓ Appropriate business plan (including securing human and finance resources) to provide new functions is developed

3. Policy Recommendations

(1) Policy Implications from the Proposal of ASEAN Chemical Safety Database

As the first policy implication regarding the ASEAN Chemical Safety Database, when considering the qualitative advantages and quantitative cost benefits of constructing the Database, it is concluded that constructing the ASEAN Chemical Safety Database is efficient from both quantitative and qualitative aspects, and it is deemed worthy to move on to a detailed examination in the future.

The main information to be gathered includes two aspects: information on laws and regulations and information on chemical properties and human health and environmental toxicity of chemical substances in each country. The information on laws and regulations is beneficial for both industrial circles considering starting production and exports to other countries and administrative government agencies using regulations in other countries as guidelines. Moreover, by summarizing and displaying existing toxicity information in a straight-forward list format, it becomes feasible for persons in charge of administrative government agencies to use the information when making decisions on control of substances in the future. Moreover, by making the information easily available, autonomous management within companies is promoted.

Finally, by displaying the information in a form that allows direct comparison, it is possible to expect a secondary effect where the rules on control substances in related countries will gradually converge toward a common understanding.

(2) Policy Implications from the Discussion on Further Harmonization

The discussion on further harmonization indicates large potential of policy implications.

The ASEAN summit held in 2007 clearly set a target for establishing the ASEAN community by 2015, and the target was affirmed repeatedly. Although chemical

management is not clearly mentioned in the documents relating to economic integration of the region, it is recognized that establishing the database and further harmonization will significantly contribute to economic integration in a timely manner.

In addition, enhancing further harmonization in ASEAN and East Asian countries is highly useful from a practical aspect, as explained in Chapter 6. For example, if the option to establish a new center (i.e., the ASEAN Chemical Management Research Center) for this purpose, or for another sustainable framework, could be established, this center would be able to become an entity that will provide benefits to many stakeholders. When considering the sustainable operation of the ASEAN Chemical Safety Database as well as the sophistication and the convergence of chemical substance management within the ASEAN region, the existence of a central player who can provide the opportunity for each ASEAN country to cooperate and can provide the leadership within the ASEAN region to promote chemical management is essential. Managing chemicals appropriately without hindering trade and investment poses challenges and may be costly for individual countries. On the other hand, if ASEAN and its partners countries work together through an appropriate mechanism, like the center that has been mentioned here, the future convergence of chemical management in the ASEAN and East Asian region will be more realistic, and this will ultimately lead to the activation of trading and FDI (Foreign Direct Investment) within the region.

For this reason, the discussions on further harmonization, discussed in chapter 6 of this report, will be able to play an important role in future ASEAN policies. Further elaboration of such concepts may be useful in order to accelerate economic integration through chemical management.

CHAPTER 1

Background and Scope of the Study

1. Background and Objectives

At the World Summit on Sustainable Development (WSSD), which was held in Johannesburg in 2002, participating countries committed "to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment, using transparent science-based risk assessment procedures and science-based risk management procedures" (WSSD 2020 goal). All countries in the world need to take the necessary measures to achieve this goal.

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priority basis, e.g. amended CSCL of Japan), where introduced in each country in ASEAN or the surrounding region. As a result of the trial calculation for the total cost, the introduction of a "Prioritization-Led" Approach in each county individually was lower and the introduction of "No-data, No-market" Approach in each county individually was higher.

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From the abovementioned point of view, we would propose the research "Study on the feasibility of an information infrastructure for the future chemicals management scheme in the Asian region." This research will seek to answer how this information infrastructure, including a data center, should be established, on the basis of other examples, including existing chemicals databases and multilateral databases in other areas. It will take into account its economic impact and how an effective and efficient chemical management system in the region can be developed.

[1] RIETI Trade Industry Database 2010, Research Institute of Economy, Trade and Industry (RIETI), Japan

2. Methodologies and Expected Policy Recommendation of the Study

2.1. Methodologies

The aim of the study is to analyze the feasibility of the establishment of an information infrastructure, including a data center in Asian countries or region.

This study first surveys the status of data on chemical hazard in each country (types and numbers, etc.), the situation of existing databases on chemicals, and the multilateral databases in other areas. The study also summarizes some conditions (language, operator, and data collection method, etc.) for operating the data center efficiently and estimates its operation cost. Based on this information, the study analyzes the effects, including economic impact, for both government and industry, in cases where the data center is established and where the chemical management system,[2] in which the risk assessment using the database is carried out, is established.

At the end of the study, a recommendation will be developed regarding the establishment of the data center and a chemical management system using the data center, which could be most effective and efficient in the Asian supply chain, and which could also help to achieve the WSSD 2020 goal.

2.2. Expected Policy Recommendation

- Identifying the most appropriate data center

  What should the most appropriate data center, which contributes to establishing a chemical management system in each Asian country and developing the supply chain in the Asian region, consist of.

- Identifying an effective, efficient chemical management system for a data center

  How can each country establish an effective, efficient chemical management system by analyzing ways of risk assessment using data in the data center and the development and learning technique of risk assessment.

[2] The study assumes that each country will introduce the “Prioritization-Led” Approach based on the result of trial calculation, which was the lowest on the total cost in the study in the 2010 Fiscal Year.

CHAPTER 2

Current Chemical Management System and Trading Amount in ASEAN and East Asia

1. Overview of Chemical Management Systems in ASEAN and East Asian Countries

1.1. Chemical Risk Management Regulations in Australia

Existing Legal Instruments on the Chemical Management

The Industrial Chemicals (Notification and Assessment) Act 1989 established the national inventory of Australia, in which all industrial chemicals available for use have been stored. Chemicals that are not in the inventory are subject to the new chemical requirement.

The following list is the existing legal instruments on chemical management, which covers industrial chemicals in Australia. This is mainly conducted at a national level, rather than a federal level.

A) Acts on industrial chemical management

- ✓ Industrial Chemicals (Notification and Assessment) Act 1989
- ✓ The Poisons Standard 2011
- ✓ Competition and Consumer Act 2010

B) Acts on labor protection

- ✓ Safe Work Australia Act 2008
- ✓ Model Work Health and Safety Act – under development
- ✓ Hazardous Substances Regulatory Package – under review

C) Acts on waste and recycle

- ✓ Hazardous Waste (Regulation of Exports and Imports) Act 1989
- ✓ Product Stewardship Bill 2011

D) Act on transport of hazardous material, shipping

- ✓ Carriage of Goods by Sea Act 1991

E) Acts on transport of hazardous material, aeronautical

- ✓ Civil Aviation Act 1988
- ✓ Civil Aviation Safety Regulations 1998

F) Acts on transport of hazardous material, rail and road

- ✓ Model Act on the Transport of Dangerous Goods by Road or Rail
- ✓ Australian Code for the transport of Dangerous Goods by Road and Rail – 7th edition
- ✓ National Transport Commission (Road Transport Legislation – Dangerous Goods Act) Regulations 2006

G) Acts on environment, general

- ✓ Environment Protection and Biodiversity Conservation Act 1999
- ✓ National Environment Protection Council Act 1994
- ✓ National Environment Protection Measures (ambient air quality, ambient marine, estuarine and fresh water quality, environmental impacts associated with waste, re-use and recycling of used materials, National Pollutant Inventory reporting)

H) Act on environment of water

- ✓ Environment Protection (Alligator Rivers Region) Act 1978

I) Act on environment of soil

- ✓ Pipeline Authority Act 1973

J) Acts on marine pollution

- ✓ Great Barrier Reef Marine Park Act 1975
- ✓ Australian Maritime Safety Authority Act 1990
- ✓ Environment Protection (Sea Dumping) Act 1989
- ✓ Petroleum (Submerged Lands) Act 1967
- ✓ Protection of the Sea (Civil Liability) Act 1981, Protection of the Sea (Powers of Intervention) Act 1981, Protection of the Sea (Prevention of Pollution from Ships) Act 1983, Protection of the Sea (Harmful Anti-fouling Systems) Act 2006, and Protection of the Sea (Civil Liability for Bunker Oil Pollution Damage) Act 2008

K) Acts on environment of atmosphere, global environment

- ✓ Ozone Protection and Synthetic Greenhouse Gas Management Act 1989, Ozone Protection and Synthetic Greenhouse Gas (Import Levy) Act 1995, and Ozone Protection and Synthetic Greenhouse Gas (Manufacture Levy) Acts 1995
- ✓ Fuel Quality Standards Act 2000; Fuel Quality Standards Regulations 2001 (petrol, diesel, biodiesel, autogas, ethanol)

List of Restricted Chemicals in Main Regulations

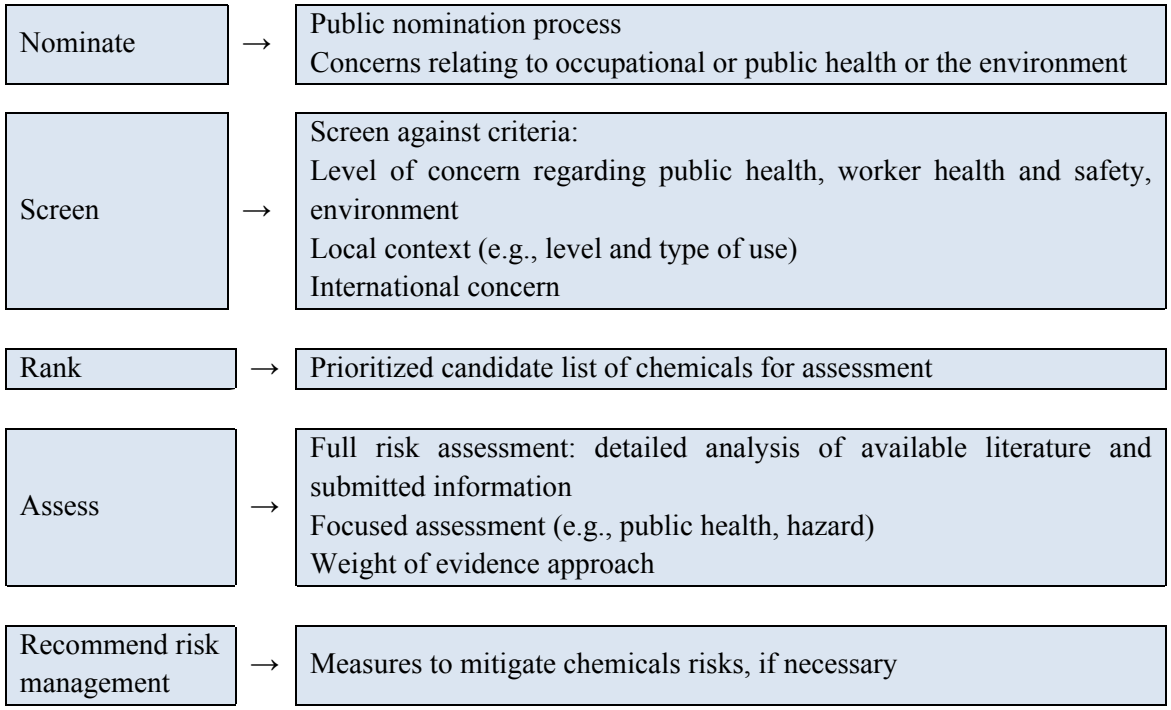
Table 1: List of Restricted Chemicals in Main Regulations in Australia

Law Name	Decree/Circular/Standard	Field	List
Industrial Chemicals (Notification and Assessment) Act 1989	Industrial Chemicals (Notification and Assessment) Regulations 1990	Chemical Management	Approx. 3,000 assessment reports on NICNAS website
Therapeutic Goods Act 1989	The Poisons Standard 2011	Public health	Schedules 5 and 6; Appendix C
Hazardous substances regulatory package	Model regulations for the control of hazardous workplace substances	Labor Safety	Schedule 2
	National Exposure standards for atmospheric contaminants in the Occupational environment 1995		Exposure standards for atmospheric contaminants in the occupational environment
	Model regulations for the control of scheduled carcinogenic substances 1995		Schedules 1 and 2
	National Standards (e.g. lead, mineral fibres)		SafeWork Australia website
	Approved Criteria for Classifying Hazardous Substances 2004		Hazardous substance information system
Competition and Consumer Act 2010	Mandatory standards (e.g. lead and DEHP in children's toys)	Consumer products	Product Safety Australia website

Basis of Selecting Restricted Chemicals; Conventional Approach

Australia has been transitioning from one scheme to another. The conventional approach is "stage-based"and is presented as follows. The chemicals that should be restricted are nominated, screened, ranked, assessed, and may be recommended for risk management.

Figure 1: Outline of the Conventional Basis of Selecting Restricted Chemicals

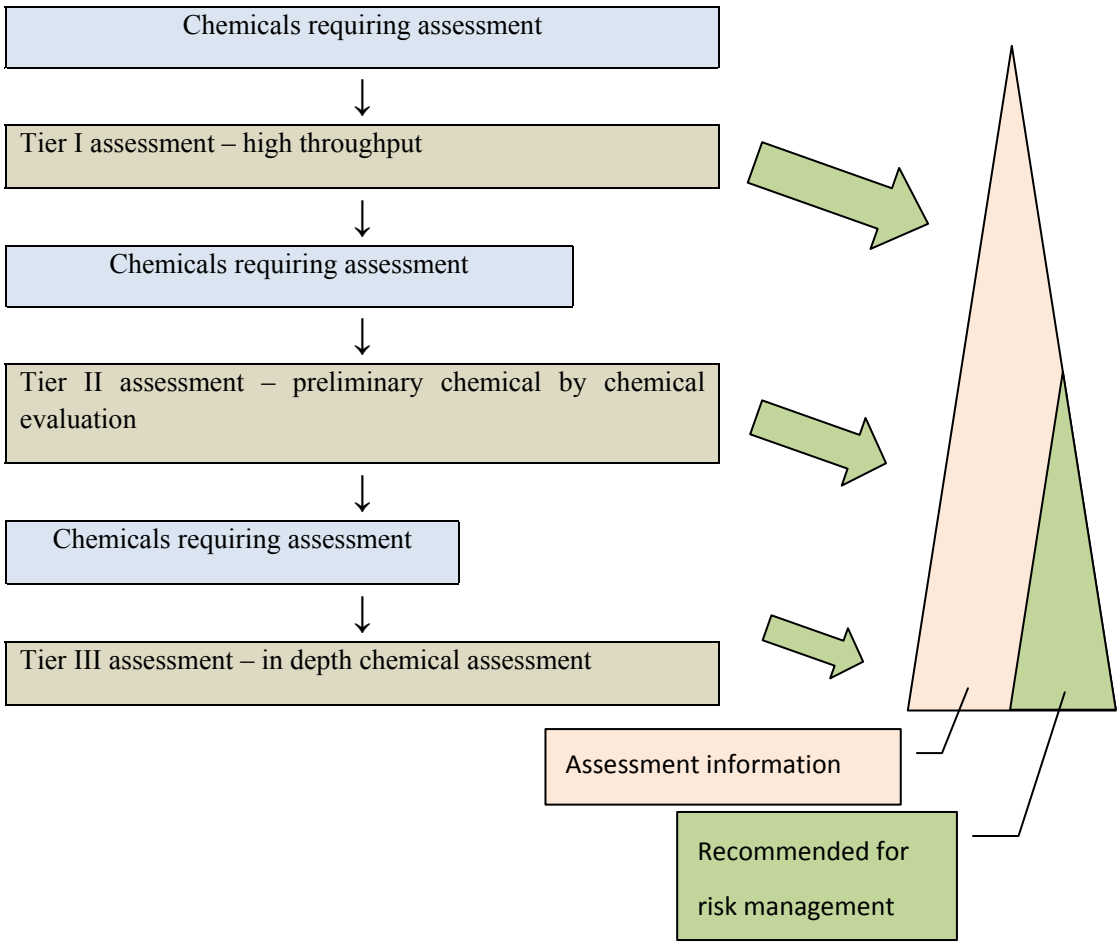


Basis of Selecting Restricted Chemicals; New Approach

A new approach can make an assessment much faster than can the conventional approach. Tier 1 is called "high throughput"and assesses the industrial chemicals by referring the list of concerned chemicals overseas. Tier 2 is chemical evaluation, with a predicted model of techniques. Some chemicals that need further examination go through in-depth assessment in Tier 3.

Criteria – impacts on public health, worker health and safety, and environment

Figure 2: Outline of the New Basis of Selecting Restricted Chemicals



Implementation Status of SDS and GHS

In Australia, SDS is implemented in the following regulation/standard.

- ❖ National Model Regulations for the Control of Workplace Hazardous Substances – 1994 (has been updated)
- ❖ National Standard for the Storage and Handling of Workplace Dangerous Goods – 2001 (currently being revised)

On the other hand, GHS is now under development. The detailed progress situation is as written below.

- ✓ Workplace – National Code of practice for the labeling of Workplace Chemicals – 2012
- ✓ Consumer products – under development
- ✓ Environment – labeling scheme under consideration

1.2. Chemical Risk Management Regulations in Cambodia

Existing Legal Instruments on the Chemical Management

The existing legal instruments on chemical management, which covers industrial chemicals in Cambodia, are as follows:

A) Acts concerning on industrial chemical management

- ✓ Law on the Management of Quality and Safety of Products and Services, 2000
- ✓ Law on Administration of Factory and Handicraft, 2006
- ✓ Sub-Decree on Classification and Labeling of Chemicals, 2009
- ✓ Sub-Decree on the Master List of Prohibited and Restricted Goods, 2007
- ✓ Declaration No. 110 on the Management and Control of Uses, Import, Export and Distribution of Chemical Substances in Industry Sector, 2004
- ✓ Technical Guidelines on Handling of Chemical and Hazardous Substances 2011

B) Acts concerning labor protection and criminal protection

- ✓ Law on Labor/Labor law, 1997
- ✓ Sub-Decree on the industrial Standardization of Cambodia No. 42, May 15, 2001
- ✓ Law on Strong Acid, 2011

C) Act on waste and recycling

- ✓ Sub-Degree No. 37, on Solid Waste Management, April 27, 1999
- ✓ Law on Pollution Control, 2012(Draft)

D) Act on hazardous material, security and accident prevention

- ✓ Sub-Decree No. 21 on the Facilitation of Trade through Risk Management of the Royal Government of Cambodia, 2006

E) Act on transportation of hazardous material

- ✓ Sub-Decree on the Management of Road and Transportation of Goods and Passengers

F) Acts on environment, general

- ✓ Law on Environmental Protection and Natural Resources Management; December 24, 1996
- ✓ Law on Protection of Natural Resource Areas, 1993
- ✓ Sub-Degree No. 72, on The Environment Impact Assessment Process August 11, 1999
- ✓ Joint Prakas/Notice on Tax Service for Control on the Report of Environment Impact Assessment, Monitoring and Evaluation.

G) Act on environment of atmosphere, global environment

- ✓ Sub Degree No. 42 on Air and Noise Pollution Control, July 10, 2000
- ✓ Sub-Decree No. 47 on the Ozone Layer Pollution and Depletion Management, 2005

H) Act on environment of water

- ✓ Sub-Degree No. 27, on Water Pollution Control, April 06, 1999

List of Restricted Chemicals in Main Regulations

Table 2: List of Restricted Chemicals in Main Regulations in Cambodia

Law Name	Decree/Circular/Standard	Field	List
Prakas On Management and Control of use, Importation, Exportation and Distribution of Chemical Substances in Industrial Fields	Certification on import, export, uses and distribution, 2004	Chemical Management	Article 2
The Labor Law, 1997		Workers safety Industrial Safety and Environment	
Law on the Management of Factory and Handicraft, 2006	Technical Guidelines on Risk Management & Risk Assessment		
Law on Environmental Protection and Natural Resource Management	Sub-Decree on Air Pollution	Environment Protection	ANNEX1, 2, 3, 4, 8
	Sub-Decree on Water Pollution Control		ANNEX 1
Cambodian Law on Protected Areas, 2008			

Basis of Selecting Restricted Chemicals

Cambodia follows guidelines of the WHO,FAO, International Convention and Protocol by taking into consideration the following:

- ✓ Terrorism, National and Regional Security
- ✓ Human, Animal and Plant Health
- ✓ Contamination to the environment

Cambodia takes measures on risk assessment and the receipt of third party notifications to regulate the following perilous chemicals: acids and radioactive materials, food colorants and additives, CFC, POPs, Potassium nitrate and Sarin or mustard gas.

Implementation Status of SDS and GHS

In Cambodia, SDS is implemented in the following regulation/standard.

- ❖ Regulation (Prakas) No. 110 of MIME on February 11, 2004, on the management and control of import-export and distribution of industrial chemical substances
- ❖ Regulation (Prakas) issued by MAFF, MoE and MoH

On the other hand, GHS is implemented in the following regulation/standard.

- ✓ In the Sub-decree on GHS Classification and Labeling of Chemicals in Cambodia, issued 2009:
  - ➢ Roadmap, National Implementation Strategy on GHS in Cambodia, 2009-2011

- National Report on the Status of Chemical Management in Cambodia, Dec. 2009
- Gov. Ordinance 345 for implementation of Sub-Decree No. 69 on Standards and Management of Agricultural Inputs
- Prakas No. 110 on Management and Inspection of Industrial Chemicals used, import, export and distribution
- Other trainings, workshops conducted, technical guidelines on handling of Chemical and Hazardous Substances and GHS and REACH Information System for use in the Industrial Sector (draft)

1.3. Chemical Risk Management Regulations in Japan

Existing Legal Instruments on the Chemical Management

Japan has a number of categories of legal instruments. In particular, the Poisonous and Deleterious Substances Control Act and Industrial Safety and Health Act requires inventories. Manufacturers cannot produce chemicals that are not included in these inventories.

The existing legal instruments on chemical management covering industrial chemicals in Japan are as follows:

A) Acts concerning chemical management

- ✓ Poisonous and Deleterious Substances Control Act
- ✓ Act on Special Measures against Dioxins
- ✓ Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.
- ✓ Act on Confirmation, etc., of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

B) Acts concerning on Industrial Safety and Health

- ✓ Labor Standards Act
- ✓ Industrial Safety and Health Act

C) Acts on waste and recycling

- ✓ Act on Control of Export, Import and Others of Specified Hazardous Wastes and Other Wastes
- ✓ Waste Management and Public Cleansing Act

- ✓ Act on Special Measures concerning Promotion of Proper Treatment of PCB Wastes
- ✓ Act on the Promotion of Effective Utilization of Resources
- ✓ Law Concerning the Promotion of Procurement of Eco-friendly Goods and Service by the State and Other Entities

D) Act on hazardous material, security and accident prevention

- ✓ Fire Service Act
- ✓ Explosives Control Act
- ✓ High Pressure Gas Safety Act
- ✓ Act on the Securing of Safety and the Optimization of Transaction of Liquefied Petroleum Gas

E) Acts on transportation of hazardous material, shipping

- ✓ Ship Safety Act
- ✓ Act on Port Regulations
- ✓ Maritime Traffic Safety Act

F) Acts on transportation of hazardous material, aeronautical

- ✓ Civil Aeronautics Act

G) Acts on transportation of hazardous material, rail and road

- ✓ Road Act
- ✓ Road Transportation Act
- ✓ Road Transport Vehicle Act
- ✓ Railway Business Act

H) Acts on transportation of hazardous material, mailing

- ✓ Postal Act
- ✓ Act on Correspondence Delivery by Private Business Operators

I) Act on environment, general

- ✓ Basic Environment Act

J) Acts on environment of atmosphere, global environment

- ✓ Air Pollution Control Law
- ✓ Act on the Quality Control of Gasoline and Other Fuels
- ✓ Act Concerning Special Measures for Total Emission Reduction of Nitrogen Oxides and Particulate Matter from Automobiles in Specified Areas
- ✓ Act on the Regulation, etc., of Emissions from Non-road Special Motor Vehicles
- ✓ Act on the Protection of the Ozone Layer Through the Control of Specified Substances and Other Measures
- ✓ Act on Ensuring the Implementation of Recovery and Destruction of Fluorocarbons concerning Designated Products
- ✓ Act on the Promotion of Global Warming Countermeasures
- ✓ Act on the Promotion of Contracts of National Governments and Other Entities Involving Due Care for the Reduction of Greenhouse Gas Emission
- ✓ Offensive Odor Control Law
- ✓ Building Standards Act
- ✓ Act on Maintenance of Sanitation in Buildings

K) Acts on the environment of water

- ✓ Water Pollution Control Law
- ✓ Act on Special Measures concerning Conservation of Lake Water Quality

- ✓ Act on Special Measures concerning Conservation of the Environment of the Seto Inland Sea
- ✓ Water Supply Act
- ✓ Act on Special Measures concerning Water Quality Conservation at Water Resources Area in Order to Prevent the Specified Difficulties in Water Utilization
- ✓ Sewerage Act
- ✓ Law concerning Special Measures for Compensation of Minamata Disease
- ✓ Hot Springs Act

L) Act on environment of soil

- ✓ Soil Contamination Countermeasures Act
- ✓ Agricultural Land Soil Pollution Prevention Act

M) Acts on marine pollution

- ✓ Act on the Prevention of Marine Pollution and Maritime Disasters

List of Restricted Chemicals in Main Regulations

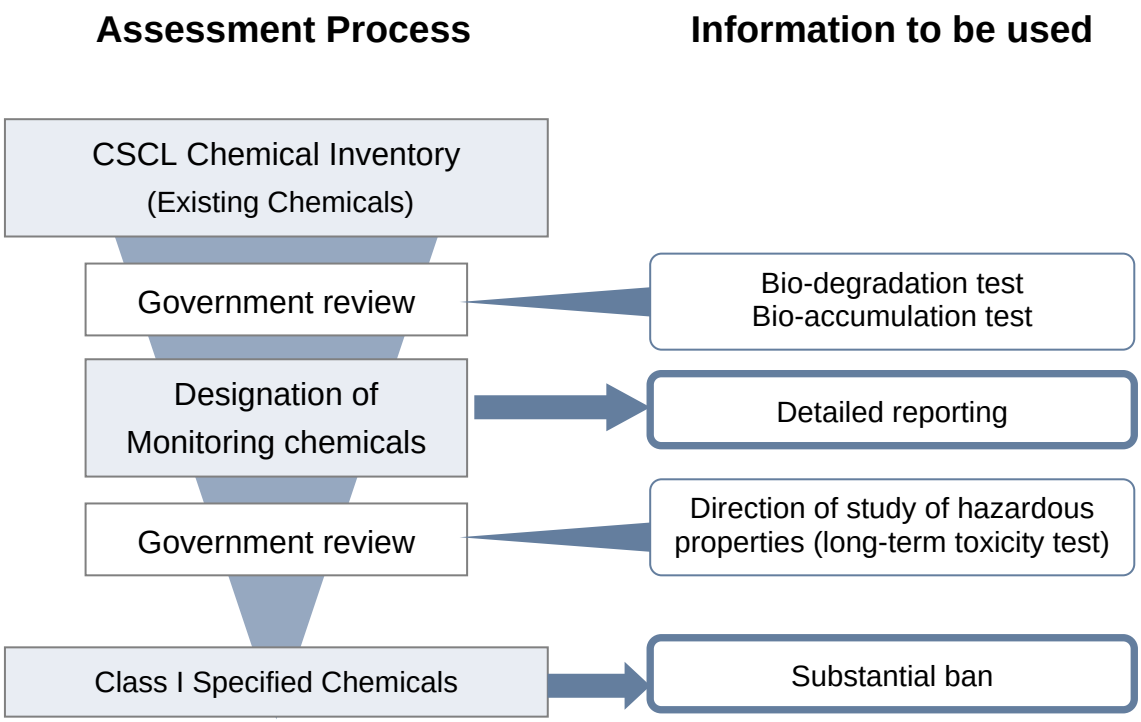
Table 3: List of Restricted Chemicals in Main Regulations in Japan

Law Name	Decree/Circular/Standard	Field	List
Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (CSCL)	Order for Enforcement of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.	Chemical Management	Article 1, 1–2, 3, 5
Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof	Order for Enforcement of the Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof		Appended Tables 1, 2
Poisonous and Deleterious Substances Control Act			
Industrial Safety and Health Act	Enforcement Order of the Industrial Safety and Health Act	Labor Safety	Appended Table 3
Law on Environmental Protection		Environment Protection	
Air Pollution Control Law			
Water Pollution Control Law			
Soil Contamination Countermeasures Act			

Basis of Selecting Restricted Chemicals in the CSCL Monitoring and Class I

The Chemical Substance Control Law (CSCL) has two categories of chemicals to be regulated. The first category is PBT (Persistent Bioaccumulative and Toxic) chemicals. Japan has 20,000 listed chemicals on its CSCL Chemical Inventory, and this list covers many CAS No. The government picks up chemicals with PBT properties based on the following process. An overview of the assessment process for this first category is described as follows:

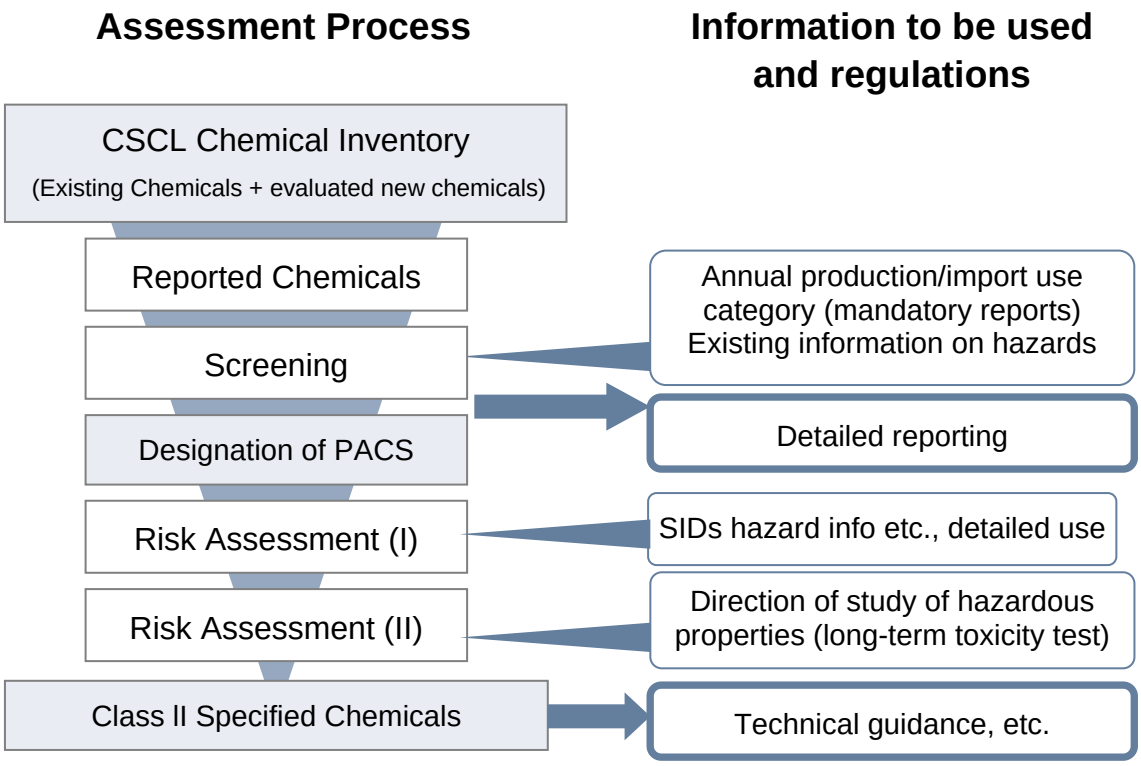
Figure 3: Basis of Selecting Restricted Chemicals in the CSCL Monitoring and Class I



Basis of Selecting Restricted Chemicals in the CSCL PACCs and Class II

Chemicals that are not bioaccumulated are addressed in this category througha prioritized risk assessment approach. The chemicals covered in this category are not only existing chemicals, as described in the previous Figure, but also evaluated new chemicals. The overview of the assessment process of this category is described as follows:

Figure 4: Basis of Selecting Restricted Chemicals in the CSCL PACCs and Class I



Implementation Status of SDS and GHS

In Japan, SDS is implemented in the following regulation/standard. These three laws cover the different lists of chemicals.

- ✓ Act on Confirmation, etc., of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (PRTR Law)
- ✓ Poisonous and Deleterious Substances Control Law
- ✓ Industrial Safety and Health Law

On the other hand, GHS is implemented in Industrial Safety and Health Law, and the industrial standard is available

- ✓ GHS Classification Results
  - ➢ Uploaded at http://www.safe.nite.go.jp/ghs/list.html

1.4. Chemical Risk Management Regulations in Malaysia

Existing Legal Instruments on Chemical Management

The existing legal instruments on chemical management, which covers industrial chemicals in Malaysia, are as follows:

A) Acts concerning chemical management

- ✓ Occupational Safety and Health (Classification, Packaging and Labeling of Hazardous' Chemicals) Regulations, 1997
- ✓ Occupational Safety And Health (Use And Standards Of Exposure Of Chemicals Hazardous To Health) Regulations, 2000

B) Acts concerning on Industrial Safety and Health

- ✓ Occupational Safety and Health Act, 1994
- ✓ Occupational Safety And Health (Employers' Safety And Health General Policy Statements) (Exception) Regulations, 1995
- ✓ Factories and Machinery Act 1967

C) Acts on waste and recycling

- ✓ Environmental Quality (Scheduled Wastes) Regulations 2005 (amended in 2007)
- ✓ Environmental Quality (Prescribed Premises) (Scheduled Wastes Treatment And Disposal Facilities) Regulations, 1989
- ✓ Environmental Quality (Prescribed Premises) (Scheduled Wastes Treatment And Disposal Facilities) Order, 1989 (amended in 2006)

D) Acts on hazardous material, security and accident prevention

- ✓ Fire service Act, 1988

- ✓ Explosive Act, 1957
- ✓ Occupational Safety And Health (Control of Industrial Major Accident Hazards) Regulations, 2000
- ✓ Occupational Safety And Health (Notification of Accident, Dangerous Occurrence, Occupational Poisoning and Occupational Disease) Regulations, 2004

E) Act on transportation of hazardous material, shipping

- ✓ Petroleum (Safety Measures) (Transportation Of Petroleum By Water) Regulations, 1985

F) Act on transportation of hazardous material, aeronautical

- ✓ Civil Aviation Act, 1969

G) Act on transportation of hazardous material, rail and road

- ✓ Road Transport Act, 1987

H) Act on transportation of hazardous material, mailing

- ✓ Postal Service Act, 1991(Amendment in 2001)

I) Act on transportation of hazardous material, pipelines

- ✓ Petroleum (Safety Measures) (Transportation Of Petroleum By Pipelines) Regulations, 1985

J) Act on environment, general

- ✓ Environmental Quality Act, 1974
- ✓ Environmental Quality (Prescribed Activities)(Environmental Impact Assessment) Order, 1987

K) Acts on environment of atmosphere, global environment

- ✓ Environmental Quality (Clean Air Regulations), 1978
- ✓ Environmental Quality (Dioxin and Furan) Regulations, 2004
- ✓ Environmental Quality (Control of Emission from Diesel Engines) Regulations, 1996

L) Act on environment of water

- ✓ Environmental Quality (Industrial Effluent) Regulations, 2009
- ✓ Environmental Quality (Sewage) Regulations, 2009

M) Act on environment of soil

- ✓ Environmental Quality (control of Pollution from Solid Waste Transfer Station and Landfill) Regulations, 2009

N) Act on Marine Pollution

- ✓ Environmental Quality (Delegation of Powers on Marine Pollution Control) Order, 1994
- ✓ Environmental Quality (Prohibition on the Use of Controlled Substances in Soap, Synthetic Detergent and Other Cleaning) Order, 1995

List of Restricted Chemicals in Main Regulations

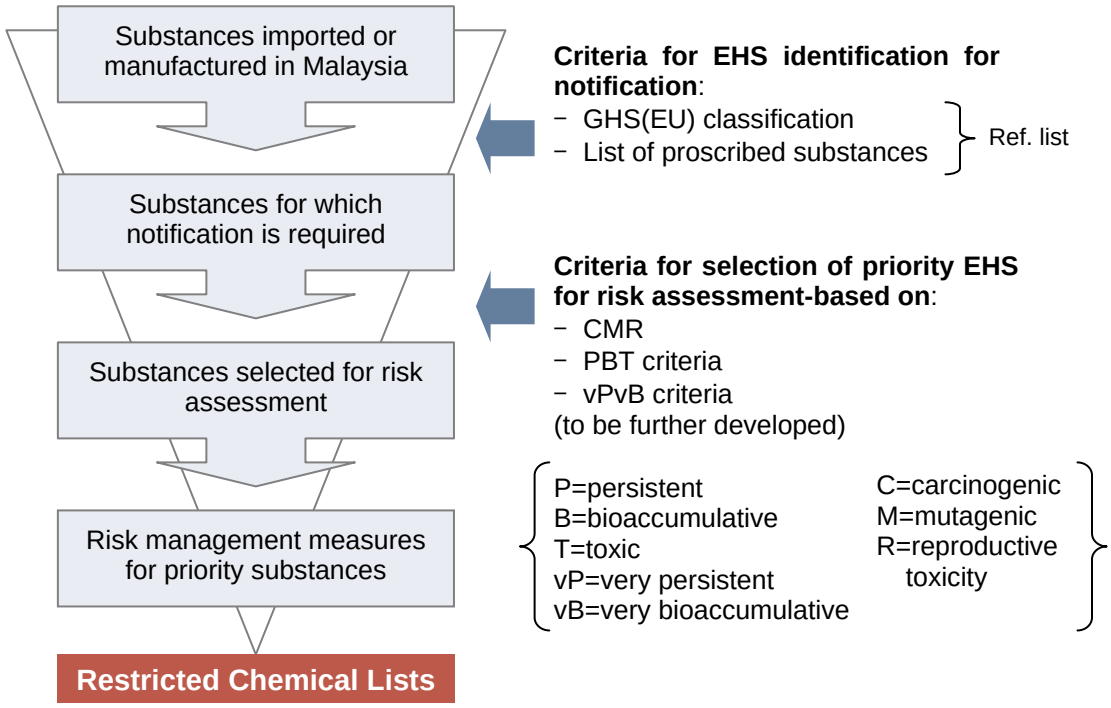
Table 4: List of Restricted Chemicals in Main Regulations in Malaysia

Law Name	Decree/Circular/Standard	Field	List
Environmentally Hazardous Substances (EHS) Notification and Registration Scheme (draft)		Chemical control	EHS and CMR Reference List
Factory Act	Factories and Machinery (Mineral Dust) Regulations 1989		Silica, Mineral dust
	Factories and Machinery (Lead) Regulations 1984	Labor safety	Lead
Occupational Safety and Health Act	Occupational Safety and Health (Classification, Packing and Labeling of Hazardous Chemicals) Regulations 1997	Labor Safety	Table I
	Occupational Safety and Health (Use and Standards of Exposure of Chemicals Hazardous to Health) Regulations 2000		Schedule 1 Schedule 2
	Occupational Safety and Health (Control of Industrial Major accident Hazards) Regulations 2000		Schedule 2
Poison Act	Poison (Psychotropic Substances) Regulations 1989 Poison (Sodium Hydroxide) Regulations 1962	Poison Regulations	Second Schedule
Environmental Quality Act	Environmental Quality (Clean Air) Regulations 1978	Environment Protection	Regulation 26, 27, THIRD SCHEDULE
	Environmental Quality (Industrial Effluent) Regulations 2009		FIFTH SCHEDULE
	Environmental Quality (Sewage) Regulations 2009		SECOND SCHEDULE

Basis of Selecting Restricted Chemicals

Environmentally Hazardous Substances (EHS) is defined as substances which are classified as hazardous under GHS classification and listed as hazardous under the proscribed list of international convention. EHS imported and manufactured are required to be notified under the EHS Notification and Registration Scheme. The lists of hazardous chemicals known as EHS Reference List and CMR Reference List are two lists of dangerous substances which were adopted from the EU Directive. Certain criteria will be used for selecting EHS of concerned such as CMR, PBT criteria, vPvB criteria. This selected EHS will go through the risk assessment process in order to enable the Malaysian government to come out with the risk management measures.

Figure 5: Identification and Evaluation Scheme for EHS



Implementation Status of SDS and GHS

In Malaysia, SDS is implemented in the following regulation/standard:

- ❖ Occupational Safety and Health (Classification, Packaging, and Labelling of Hazardous Chemicals) Regulations, 1997.
- ❖ Malaysian Standard MS 1804:2008: GHS For Classification, Labelling of Chemicals – Specification For The Classification, Labelling and Formulation Of Safety Data Sheet For Chemical Products.
- ❖ Guidelines For The Formulation Of A Chemical Safety Data Sheet
- ❖ CLASS (Classification, Labelling and Safety Data Sheet) Regulations 201X

On the other hand, GHS is implemented in the following regulation/standard:

- ✓ Malaysian Standard MS 1804:2008: GHS For Classification, Labelling of Chemicals – Specification for the Classification, Labelling and Formulation of Safety Data Sheets For Chemical Products.
- ✓ The translation of the GHS Purple Book into national language is completed (based on the 3rd Revision).

1.5. Chemical Risk Management Regulations in New Zealand

New Zealand's Chemical Control Legislation

In New Zealand, there is a single legislative framework covering the management of all substances with hazardous properties – the **Hazardous Substances and New Organisms (HSNO) Act, 1996**. The hazardous substances part of this legislation regulates the introduction (import and/or manufacture) and use of new chemicals and chemical products, and the use of existing chemicals and chemical products.

For hazardous substances, the HSNO Act brings together the management of all the adverse effects of a substance under one Act and one authority. Before this law was introduced, individual hazardous substances were controlled under a number of separate laws such as the 1957 Explosives Act, the 1974 Dangerous Goods Act, the 1979 Toxic Substances Act, the 1979 Pesticides Act and parts of the 1967 Animal Remedies Act. The HSNO Act repealed all these individual laws and brought the management of all hazardous substances together under one law.

Other Chemical Control Legislation in New Zealand

A) Agricultural Compounds and Veterinary Medicines (ACVM) Act, 1997

Hazardous substances that are pesticides and veterinary medicines are also regulated under the ACVM Act. For these substances, the HSNO Act addresses risks to human health and the environment, and registration under the ACVM Act addresses risks to trade, animal welfare, biosecurity, and chemical residues in food.

B) Health and Safety in Employment (HSE) Act 1992 and Regulations

The purpose of the HSE Act is to promote the prevention of harm to all persons at work and other persons in or around a place of work. The HSNO Act sets out the controls and conditions for the safe use of hazardous substances, and where these are used in the workplace, there are general requirements under the HSE Act to identify the chemicals used and to take steps to ensure that they are used safely.

C) Transport Laws

New Zealand's transport legislation, covering the transport of hazardous substances on land, sea, and air, generally follows international transport agreements in terms of the safe transportation of hazardous substances:

- **The Land Transport Rule: Dangerous Goods 2005 (Rule 45001/1)** sets out the requirements for the safe transport of dangerous goods on land in New Zealand. The Rule covers the packaging, identification and documentation of dangerous goods, the segregation of incompatible goods, transport procedures, and the training and responsibilities of those involved in the transport of dangerous goods. The Rule's requirements are applied according to the nature, quantity and use of the goods.
- **The Maritime Rules Part 24A Carriage of Cargoes – Dangerous Goods** sets out the responsibilities of seafarers, ship owners, shippers, consolidators and packers with respect to dangerous goods to be carried by sea.
- **The Civil Aviation Rules Part 92** prescribes rules governing the carriage of dangerous goods by air. It includes the packaging, marking, and labelling requirements of dangerous goods, and the operators' training and operating responsibilities.

D) The Gas Act, 1992

The Gas Act 1992 provides for the setting of standards concerning the design, construction, installation, importation, or manufacture of distribution systems, gas installations, fittings, or gas appliances. The purposes of this Act are (a) to provide for the regulation, supply, and use of gas in New Zealand; (b) to provide for the regulation of the gas industry in New Zealand; (c) to protect the health and safety of members of the public in connection with the supply and use of gas in New Zealand; and (d) to promote the prevention of damage to property in connection with the supply and use of gas in New Zealand.

E) Ozone Layer Protection Act 1996 and Ozone Layer Protection Regulations 1996

New Zealand's commitments under the Montreal Protocol on substances that deplete the Ozone Layer are contained in the Ozone Layer Protection Act 1996 and the Ozone Layer Protection Regulations 1996.

The Ozone Layer Protection Act sets out the broad controls for ozone-depleting substances, while the Ozone Layer Protection Regulations contain the rules relating to specific substances.

F) The Imports and Exports (Restrictions) Act, 1988, and the Imports and Exports (Restrictions) Prohibition Order (No. 2), 2004

The Imports and Exports (Restrictions) Act and Regulations make up the domestic legislation which implements the Basel Convention in New Zealand, aimed at managing the transboundary movement of hazardous waste.

G) Resource Management Act, 1991 (RMA)

The HSNO Act sets controls on hazardous substances, which apply regardless of location. The RMA allows local authorities to manage the effects of the use of hazardous substances in specific locations in relation to sensitive environments or conditions – for example where there are schools, hospitals, lakes, or earthquake-prone areas.

The HSNO Act Framework

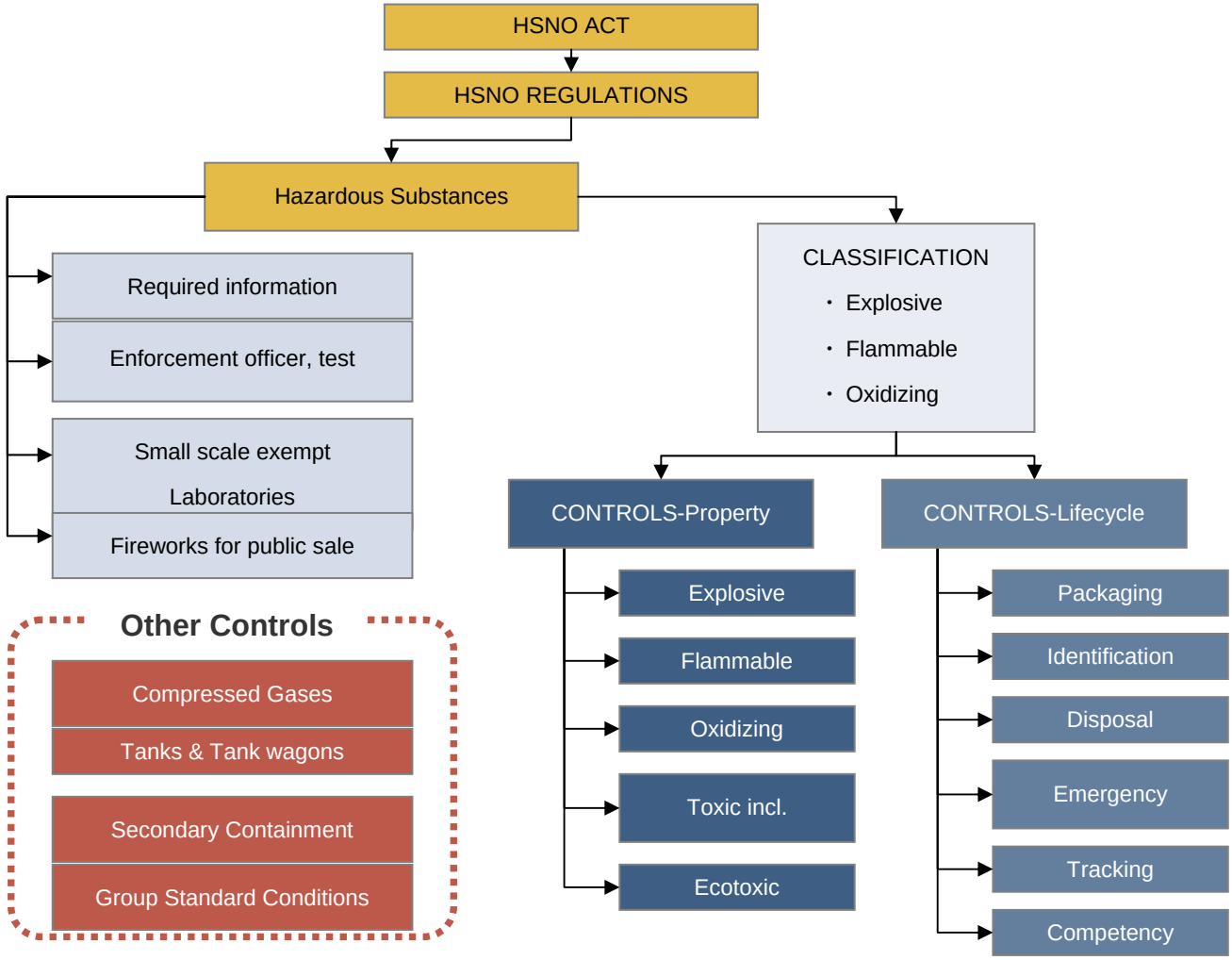
The purpose of the HSNO Act is to protect human health and the environment by preventing or managing any harmful effects of hazardous substances and new organisms.[1] For hazardous substances, the HSNO Act covers the full lifecycle of a substance – controls and conditions are assigned to approved substances, which set out requirements for how they can be contained, labeled, stored, used, transported, or disposed of. The HSNO Act covers a broad range of chemicals with hazardous properties:

- Explosives (including fireworks and detonators)
- Dangerous goods (substances that are flammable, oxidising and corrosive)
- Pesticides and veterinary medicines
- Toxic substances
- Cosmetics and other consumer products available to the general public
- Gases under pressure (including compressed air and LPG)

[1] The HSNO Act also covers the introduction of new organisms (species coming into New Zealand for the first time). A new organism can include a plant, an animal, a micro-organism or a genetically modified organism.

It also covers mixtures and finished products, in addition to single chemical substances as well as the requirements for the certification and approval of people and equipment relating to hazardous substances (such as bulk storage tanks and tank wagons, burners, dispensers, vaporizers, and compressed gas cylinders).

Figure 6: HSNO Legislative Framework



A) HSNO Regulations:

Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001

Hazardous Substances (Classification) Regulations 2001

Hazardous Substances (Personnel Qualifications) Regulations 2001

Hazardous Substances (Classes 1 to 5 Controls) Regulations 2001

Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001

Hazardous Substances (Identification) Regulations 2001

Hazardous Substances (Packaging) Regulations 2001

Hazardous Substances (Disposal) Regulations 2001

Hazardous Substances (Emergency Management) Regulations 2001

Hazardous Substances (Tracking) Regulations 2001

Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004

Hazardous Substances (Compressed Gases) Regulations 2004

Hazardous Substances (Exempt Laboratories) Regulations 2001

Hazardous Substances (Fireworks, Safety Ammunition, and Other Explosives Transfer) Regulations 2003

Hazardous Substances (Fireworks) Regulations 2001

Hazardous Substances and New Organisms (Methodology) Order 1998

B) What is a hazardous substance?

Under the HSNO Act, a hazardous substance is any substance that has one or more of the following hazardous properties exceeding specified thresholds:

- explosiveness
- flammability

- toxicity (including chronic toxicity)
- capacity to oxidise
- corrosiveness (to human tissue or metal)
- ecotoxicity

The hazardous property thresholds are based on the GHS (Globally Harmonised System of Classification and Labelling) and are set out in the HSNO *Hazardous Substances Minimum Degrees of Hazard Regulations*.

Examples of hazardous property threshold levels:

- If a substance has an LD50 (oral) of less than or equal to 5000 mg/kg, it is a hazardous substance because it triggers the threshold for **oral toxicity**
- If a substance has a flash point (closed cup) of less than or equal to 93°C, it is a hazardous substance, because it triggers the threshold for **flammability**

Any substance can trigger more than one hazardous property threshold.

C) Classifications – type and degree of hazard

The classification criteria for the HSNO Act hazardous properties are set out in the *Hazardous Substances (Classification) Regulations 2001*. These regulations prescribe for each intrinsic hazardous property a number of degrees or types of hazard. When a substance is assessed, it is assigned one or more classifications that reflect the type and degree of hazard.

The classification scheme specifies a degree of hazard for each hazardous property, made up of:

- numbered classes (for example, class 6), indicating the intrinsic hazardous property
- numbered subclasses (for example, subclass 6.1), indicating the type of hazard

- lettered categories (for example, category A) indicating the degree of hazard.

The hazard classification scheme follows as closely as possible the GHS (Globally Harmonised System of Classification and Labelling) for hazard classification.

For physical hazards, (explosiveness, flammability, oxidising capacity) the classification system follows agreements of the United Nations Committee of Experts on the Transport of Dangerous Goods (UNCEDTG).

For biological hazards, (toxicity, ecotoxicity and some corrosives), the classification system follows the schemes agreed by the OECD Advisory Group on Harmonisation of Classification and Labelling (AG-HCL), as part of the GHS.

Examples of Classifications:

3.1A – Flammable liquids: very high hazard

3.1B – Flammable liquids: high hazard

3.1C – Flammable liquids: medium hazard

3.1D – Flammable liquids: low hazard

6.7A – Substances that are known or presumed human carcinogens

6.7B – Substances that are suspected human carcinogens

D) Controls – assigned to manage the risk

Each hazardous property classification triggers a number of controls aimed at managing the adverse effects of a substance. If a substance has more than one hazardous property (for example, it is toxic and flammable), then controls will be assigned to manage both its toxicity and its flammability.

There are two general types of controls:

Hazardous property controls, applying to:

- Biological hazards – aim to limit exposure of people or the environment to the adverse effects of the substance;
- Physical hazards – aim to avoid initiation of the hazard (for example, by keeping ignition sources away from flammable substances).

Life cycle controls, relating to:

- Packaging and containment (for example, packages and bulk containers being strong, durable, and resistant to their contents)
- Identification – information on labels, signs, documentation, advertising, and safety information for workers
- Competency of handlers – requiring appropriately trained people to be in charge of highly hazardous substances
- Emergency preparedness – ensuring information or equipment is on hand to deal with emergencies
- Tracking – systems for locating highly hazardous substances
- Disposal – to be done in a way which does not create damage or harm

Approved Chemicals

No hazardous substance shall be imported or manufactured except in accordance with an approval issued under the HSNO Act.

All hazardous substances must have an approval:

- Single component chemicals (for example, acetone, toluene)
- Chemical products and mixtures (for example, pesticide formulations, cleaning products)

Hazardous substance approvals:

- Are not specific to an approval holder – an approved substance can be used by any person as long as the controls are complied with
- Are valid until the approval is declined through the reassessment process
- Can cover single component substances ("pure" chemicals) as well as chemical products that are hazardous
- Can cover substances that have been grouped together according to a common characteristic (for example, they are of a similar type or nature, or have a common use) under Group Standard approvals.

Registers and Lists

Link to registers and lists:

http://www.epa.govt.nz/search-databases/Pages/default.aspx

A) Register of Controls on Approved Substances

The register of approved substances sets out the controls that have been assigned to each substance.

B) Chemical Classification and Information Database (CCID)

The Chemical Classification and Information Database (CCID) details the chemicals classified in accordance with the HSNO Classification regulations. The CCID can be used by industries to classify formulated products to enable their substances to be assigned to a group standard. It can also be used to assist industries to design less hazardous products by providing classification information on potential alternative components.

The CCID provides chemical identification information, hazard classifications, and classification data. The information may also be useful for the preparation of labels and safety data sheets:

- Chemical Abstracts Service (CAS) Registry Number
- Name and synonyms
- United Nations Dangerous Goods (UN) Number and UN Class (where applicable)
- HSNO approval number (if the chemical has HSNO approval)
- Selected information on physical property
- Hazard classifications
- Classification data - each hazard classification is based upon classification data. The CCID includes references to the source of this data, where possible.

C) New Zealand Inventory of Chemicals

Group Standards impose a condition that requires notification to the Authority of the presence of any new chemical in products approved under that standard.

The chemicals listed on the Inventory of Chemicals are those chemicals present in New Zealand (compiled from the list of components of toxic substances notified under old legislation and any newly notified chemicals).

The inventory currently on the EPA website has limited functionality. The development of a searchable web-based database is currently underway. The search function will be based on CAS number, with limited searching on chemical names. The design includes the ability to then directly make an application for listing a new chemical component by emailing in the completed form. Note that notifications also require the submission of data on the hazard of the new chemical component.

D) Register of Controls on Approved Substances

The register of approved substances sets out the controls that have been assigned to each substance.

E) Safety Data Sheets (SDS)

Safety data sheets (SDSs) are a key element of the HSNO control framework – they provide information on the hazards of the substance and how it should be safely used, stored, transported and disposed of. SDSs also describe emergency procedures, such as what to do in the event of a spill or fire.

It is the responsibility of the importer or manufacturer to supply an SDS. SDSs must include information under each of the following headings:

1. Product and company identification
2. Hazard(s) identification
3. Composition and information on ingredients
4. First-aid measures
5. Fire-fighting measures
6. Spillage, accidental release measures
7. Handling and storage
8. Exposure controls and personal protection
9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations

14. Transport information

15. Regulatory information

16. Other information

SDSs in the above format, which meets the requirements of overseas jurisdictions, are acceptable, but some additional information is required, including:

- Name and contact details of the NZ supplier and NZ emergency contact details (Section 1 of the SDS)
- HSNO regulatory information, including the HSNO approval number or title of the group standard approval, if relevant (Section 15 of the SDS)

This can be provided by adding a front sheet or over-sticker to the SDS. Further information is available on the EPA website:

http://www.epa.govt.nz/hazardous-substances/about/HSNO-controls/Pages/Safety-data-sheets.aspx

F) Labelling

Manufacturers and importers must ensure that the label provides information in accordance with the hazards of the substance. Labels should include information on the hazards of the substance, disposal requirements, and emergency management procedures (for example, first aid).

The labelling requirements are based on the GHS. The pictograms, signal words, and hazard and precautionary statements are derived from the substance's hazard classifications, and are based on the proposals presented to the UN GHS Committee. A labelling guide for manufacturers and importers is available from the EPA website:

http://www.epa.govt.nz/Publications/hsnogen-labelling-guide.pdf

G) Implementation of the GHS in New Zealand

New Zealand implemented the United Nations GHS in 2001. The Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001 and the Hazardous Substances (Classification) Regulations 2001 are based on proposals for the GHS, as developed in late 2000.New Zealand effectively has one legislative framework (HSNO Act) and one competent authority (the Environmental Protection Authority) for the management of all hazardous substances over all sectors. Correspondingly, when GHS was adopted into the HSNO regulations in 2001, all of the GHS classification "building blocks" were adopted, regardless of type and sector of use. However, under the HSNO Act, the "building block" approach can effectively be applied through the ability of the EPA to vary the controls attached to a particular hazard classification category.

Since the Hazardous Substances regulations have not been updated since they came into force in July 2001, there are now differences in a number of areas between the criteria in the HSNO regulations and the GHS. A discussion document setting out the options for addressing these differences was released early last year, but no legislative changes to the classification framework have yet been made.

Information Needs on Chemical Management

Because of the Group Standards framework, the majority of new and existing hazardous substances used in industry are covered by an existing group standard approval. The EPA provides information to industry through the Chemical Classification and Information Database (CCID), to assist them to self-classify their chemicals and chemical products.

1.6. Chemical Risk Management Regulations in the Philippines

Existing Legal Instruments on the Chemical Management

The existing legal instruments on the chemical management, which covers industrial chemicals in the Philippines, are as follows:

A) Acts concerning chemical management

- ✓ An Act to Control Toxic Substances and Hazardous And Nuclear Wastes, Providing Penalties For Violations Thereof, and for Other Purposes (RA 6969)
- ✓ Implementing Rules and Regulations of RA 6969 (DAO 1992–29)
- ✓ Temporary Banning of the Importation and Use of Endosulfan (DMC 2009–02)
- ✓ Prescribing Additional Requirements for the Issuance of the Priority Chemical List (PCL) Compliance Certificate (DAO 2007–23)
- ✓ Revised Priority Chemical List (DAO 2005–27)
- ✓ Priority Chemicals List (DAO 1998–58)
- ✓ Toxic Chemical Substances for Issuance of Chemical Control Orders (DAO 2005–05)
- ✓ Chemical Control Order for Polychlorinated Biphenyls (PCBs) (DAO 2004–01)
- ✓ Chemical Control Order for Asbestos (DAO 2000–02)
- ✓ Chemical Control Order for Mercury and Mercury Compounds (DAO 1997–38)
- ✓ Chemical Control Order for Cyanide and Cyanide Compounds (DAO 1997–39)
- ✓ Scope of Compliance Monitoring for Industrial Chemicals and Toxic Substance Under Title II of Republic Act 6969 (MC 2003–011)
- ✓ Delegation of Authority to the EMB Regional Offices to Issue “Permit to Issues Permit to Transport” for Hazardous Wastes, and “Certification” and “Importation Clearance” for Chemicals and Chemical Substances (DMC 2002–02)

- ✓ Act Creating the Fertilizer and Pesticide Authority, 1977 (PD 1144)

B) Acts concerning industrial safety and health

- ✓ Labor Code of the Philippines, 1974 (PD 442)
- ✓ Occupational Safety and Health Standards:
- ✓ Rule 1090 – Hazardous Materials
- ✓ Rule 1140 – Explosives
- ✓ Rule 1150 – Materials Handling and Storage
- ✓ Rule 1950 – Pesticides and Fertilizers
- ✓ Consumer Act of the Philippines (Republic Act (RA) 7394)
- ✓ Food and Drug Administration (FDA) Act, 2009 (RA 9711)
- ✓ Food, Drug and Cosmetic Act, 1963 (RA 3720)
- ✓ Comprehensive Dangerous Drugs Act, 2002 (RA 9165)

C) Acts on waste and recycling

- ✓ An Act to Control Toxic Substances and Hazardous and Nuclear Wastes, Providing Penalties for Violations Thereof, and for Other Purposes (RA 6969)
- ✓ Implementing Rules and Regulations of Republic Act 6969 (DAO 1992–29)
- ✓ Philippine Ecological Solid Waste Management Act, 2000 (RA 9003)
- ✓ Implementing Rules and Regulations of Republic Act 9003 (DAO 2001–34)
- ✓ Technical Guidelines for Municipal Solid Waste Disposal (DAO 1998–49)
- ✓ Guideline on the Use of Alternative Fuels and Raw Materials in Cement Kilns (DAO 2010–06)
- ✓ Procedural Manual Title III of DAO 92-29 " Hazardous Waste Management" (DAO 2004–36)

- ✓ Order Amending Annex A of DAO 94-28 Interim Guidelines for the Importation of Recyclable Materials Containing Hazardous Substances (DAO 1997–28)
- ✓ Delegation of Authority to EMB Regional Offices of Various Requirements of DAO 2004–01 Which Includes Issuance of "PCB Registration Certificates" and "Importation Clearance" for Non-PCB Equipment (DMC 2007–03)
- ✓ Delegation of Authority to the EMB Regional Offices to Issue "Permit to Transport" for Hazardous Wastes, and "Certification" and "Importation Clearance" for Chemicals and Chemical Substances (DMC 2002–12)

D) Acts on hazardous material, security, public safety and accident prevention

- ✓ Revised Fire Code of the Philippines of 2008 – An Act Establishing a Comprehensive Fire Code of the Philippines, Repealing Presidential Decree 1185, and for other Purposes (RA 9514)
- ✓ Act Regulating the Sale, Manufacture, Distribution, and Use of Firecrackers and Other Pyrotechnic Devices, 1992 (RA 7183)
- ✓ Act Defining and Penalizing Certain Prohibited Acts Involving Petroleum and/or Petroleum Products, Including Shortselling and Adulteration of Petroleum Products, 1983 (PD 1865)

E) Acts on environment, general

- ✓ Decree Establishing an Environmental Impact Statement (EIS) System Including Other Environmental Management Related Measures and for Other Purposes (PD 1586)
- ✓ Implementing Rules And Regulations (IRR) for the Philippine Environmental Impact System (EIS) System (DAO 2003–30)
- ✓ Law Providing for the Revision of Republic Act 3931, Commonly Known as the Pollution Control Law, and for other Purposes, 1976 (PD 984)

F) Acts on environment of atmosphere, global environment

- ✓ Philippine Clean Air Act of 1999 – An Act Providing for a Comprehensive Air Pollution Control Policy and for Other Purposes (RA 8749)

- ✓ Implementing Rules and Regulations for Clean Air Act or RA 8749 (DAO 2000–81)
- ✓ Policy on Compliance and Permitting for Industrial Facilities Relating to Air Quality (MC 2007–003)
- ✓ Guidelines on the Requirements for Continuous Emission Monitoring Systems (CEMS) and Other Acceptable Protocols, Thereby Modifying and Clarifying Certain Provisions of Section 5, Rule X Of Dao 2000-81 and Other Related Provisions (DA 2007–22)
- ✓ Revised Emission Standards for Motor Vehicles Equipped With Compression-Ignition and Spark-Ignition Engines (DAO 2007–27)
- ✓ Interim Guidelines on Regulation for Industrial Facilities Using Bunker Oil (DAO 2007–30)
- ✓ Revised Emission Standards for In-Use Motor Vehicles Equipped With Spark-Ignition and Compression-Ignition Engines (DAO 2003–51)
- ✓ Hydrocarbon Standards for Motorcycle (DAO 2003–25)
- ✓ Implementing Rules and Regulations (IRR) for Mandating the Phase-Out of Leaded Gasoline as One of the Means of Solving Air Pollution (DAO 1998–47)
- ✓ 1998 Revised Rules and Regulations for the Prevention, Control and Abatement of Air Pollution from Motor Vehicles (DAO 1998–46)
- ✓ Order Mandating the Phase-Out of Leaded Gasoline as One of the Means of Solving Air Pollution (EO 1997–446)
- ✓ List of Alternatives to Ozone Depleting Substances (DMC 2005–03)
- ✓ Registration of Dealers, Re-Sellers and Retailers of Ozone Depleting Substances (ODS) (DMC 2005–23)
- ✓ Revised Chemical Control Order for Ozone Depleting Substances (DAO 2004–08)
- ✓ Code on Sanitation of the Philippines, 1975 (PD 856)

G) Acts on environment of water

- ✓ The Clean Water Act -An Act Providing for a Comprehensive Water Quality Management and for other Purposes, 2004 (RA 9275)
- ✓ Revised Industrial EcowatchSystem Amending Implementing Guidelines of DAO 98–51 Series of 1998 (DAO 2003–26)
- ✓ Revised Effluent Regulations, 1990, Revising and Amending the Effluent Regulations of 1982 (DAO 1990–35)
- ✓ Philippine Standards for Drinking Water, 1993, Under the Provision of Chapter Ii, Section 9 of PD 856, Otherwise Known as the Code on Sanitation of the Philippines (DAO 1994–26a)
- ✓ The Water Code of the Philippines and its IRR (PD 1067)
- ✓ An act creating the LAGUNA LAKE DEVELOPMENT AUTHORITY Prescribing Its Powers, Functions and Duties, Providing Funds Thereof, and for Other Purposes (RA 4850)
- ✓ Strict Implementation of the 50 Meters Buffer Zone in Aerial Spraying (MC 2009–14)
- ✓ Procedural Manual for the Designation of Water Quality Management Areas (MC 2009–15)
- ✓ Amending Revised Procedural Manual for DAO 03–30 on the Classification of the Fast-Food Stores, Restaurants and Similar Quick-Service Establishments (EMB MC 2009–002)
- ✓ Issuance of the Ambient Water and Effluent Quality Monitoring Manuals (EMB MC 2008=–008)

H) Act on marine pollution

- ✓ Revised Coast Guard Law, 1974 (PD 601)

List of Restricted Chemicals in Main Regulations

Table 5: List of Restricted Chemicals in Main Regulations in Philippines (1)

Law Name	Decree/Circular/Standard	Field	List
Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990 (Republic Art 6969)			
	DENR Administrative Order DAO 1992–29 Implementing Rules and Regulations of Republic Act 6969	Chemical Management	DAO 2005–27 – Priority Chemical List
	Chemical Control Orders		DAO 97–38 (CCO for Mercury and Mercury Compounds), 97–39 (CCO for Cyanide and Cyanide Compounds), 2000–02 (CCO for Asbestos), 2004–01 (CCO for Polychlorinated Biphenyls (PCBs), 2000–18 and 2004–08 (CCO for ODS)
	JOINT DTI-DENR-DOF-DOH-DILG-DOTC ADMINISTRATIVE ORDER for the Adoption and Implementation of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS)		
	(3rd draft) Rules and Procedures for the Safety Date Sheet (SDS), Labeling Requirements and Hazards Classification under DENR Administrative Order No. 29, Series of 1992 of RA 6969 for the Adoption and Implementation of the GHS		Annex 2

Table 5: List of Restricted Chemicals in Main Regulations in Philippines (2)

Law Name	Decree/Circular/Standard	Field	List
The Philippine Labor Code	The Occupational Safety and Health Standards (OSHS), 1978	Labor Safety	Table 8, 8a, 8b
	Draft amendments to Rule 1090 of the Occupational Safety and Health Standards (OSHS) entitled "Hazardous Materials" for GHS implementation in the workplace	Environment Protection	Article 19, 21, 30, 31, 32
Clean Air Act of 1999, RA No. 8749 (Act providing for a Comprehensive Air pollution Control Policy and for Other Purposes)	Implementing Rules and Regulations for RA 8749 (DAO 2000-81)		
Clean Water Act (RA No. 9275) An Act Providing for a Comprehensive Water Quality Management and for other purposes	Implementing Rules and Regulations of the Philippine Clean Water Act of 2004 (Republic Act No. 9275)（DAO 2005–10） DAO 1990–35 Revised Effluent Regulations of 1990, Revising and Amending the Effluent regulations of 1982		Table 1

Basis of Selecting Restricted Chemicals

A) Criteria for inclusion in the priority chemical list

Primary Consideration:

- ✓ Bio-accumulative
- ✓ Persistence
- ✓ Toxicity

Secondary Consideration:

- ✓ Actual volume Use
- ✓ Importation

B) Guidelines and Classification of Restricted Chemicals / Pesticides

Guidelines on restricted pesticides

A restricted pesticide is covered by two basic guidelines:

- ✓ They may not be allowed for distribution, sale and use in certain crops and/or areas of the country
- ✓ They may be used only by and under the supervision of certified applicators, or under such conditions as the FPA Administrator may require

Classifications on restricted pesticides

The list of restricted pesticides is categorized as follows:

- ✓ Those that are not for importation, except in cases of emergency. Such cases are to be determined by the Authority
- ✓ Those to be used for ***termite control only***
- ✓ Those to be used under ***specific limitations***

- ✓ Fumigants and other chemicals for use only by ***certified fumigators***

Implementation Status of SDS and GHS

In the Philippines, SDS is implemented in the following regulation/standard:

- ✓ The Act to Control Toxic Substances and Hazardous And Nuclear Wastes, Providing Penalties For Violations Thereof, and For Other Purposes (RA 6969)
    - ➢ SDS is a requirement in the application for issuance of PMPIN, SQI, PCL and PICCS clearance or compliance certificate

In the Philippines, GHS is implemented in the following regulation/standard:

- ✓ Implemented in the JOINT DTI-DENR-DOF-DOH-DILG-DOTC ADMINISTRATIVE ORDER for the Adoption and Implementation of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

1.7. Chemical Risk Management Regulations in Singapore

Existing Legal Instruments on the Chemical Management

There is no chemical inventory and chemical notification process in Singapore. In Singapore, hazardous chemicals are regulated by different authorities and on a list basis, as follows:

- **National Environment Agency (NEA)** licenses the import, storage, usage, sales, and supply and disposal of prescribed hazardous substances listed under the "Environmental Protection And Management (Hazardous Substances) Regulations" (EPMA). The EPMA is more concerned with environmental health.
- **Singapore Civil Defense Force (SCDF)** regulates the transport and storage of petroleum and bulk flammable substances.
- **Ministry of Manpower (MOM)** issues the Factory license, and regulates the Workplace, Safety and Health (WSH) Act.

The existing legal instruments on chemical management, which includes industrial chemicals in Singapore, are as follows:

A) Acts concerning chemical management

- ✓ Environmental Protection and Management Act (EPMA)
- ✓ Air Emissions Standard
- ✓ Code of Practice on Pollution Control (COPPC)
- ✓ Environmental Pollution Control

- ✓ Fire Safety Regulations, 2005 (for petroleum and other flammable materials)
- ✓ Guidelines for Quantitative Risk Assessment (QRA) Study for Installations which Store, Transport or Use Hazardous Substances
- ✓ Company Emergency Response Team Audit (CERT)
- ✓ Guidelines for Open Plant Structures in Oil, Chemical and Process Industries
- ✓ Strategic Goods Control List
- ✓ National Authority (Chemical Weapons Convention)
- ✓ Arms and Explosives Act
- ✓ Misuse of Drug Act and Regulations
- ✓ Medicines Act and Regulations
- ✓ Approved Code of Practice SS 586 Part 2 – Specification for hazard communication for hazardous chemicals and dangerous goods – Globally harmonized system of classification and labeling of chemicals – Singapore's adaptions
- ✓ Approved Code of Practice SS 586 Part 3 – Specification for hazard communication for hazardous chemicals and dangerous goods – Preparation of safety data sheets (SDS)
- ✓ Chemical Weapons (Prohibition) Act
- ✓ Workplace Safety and Health Act
- ✓ Chemical Management Program (CMP)

B) Acts that are related to chemical management

- ✓ International Maritime Organization Testing Requirements for Electrical Grading of Chemicals
- ✓ WSH Safety and Health Management System and Auditing Regulations

List of Restricted Chemicals in Main Regulations

Table 6: List of Restricted Chemicals in Main Regulations in Singapore

Law Name	Decree/Circular/Standard	Fields	List
Environmental Protection Management Act (Cap.94A)		Chemical control	SECOND SCHEDULE
	Environmental Protection and Management (Hazardous Substances) Regulations		2
Workplace Safety and Health Act (Cap. 354A)		Labor Safety	
	Workplace Safety and Health (General Provisions) Regulations 2006		FIFTH SCHEDULE PART II
Fire Safety Act (Cap. 109A)			34. THE SCHEDULE
	Fire Safety (Petroleum and Flammable Materials) Regulations 2005		2
Environmental Protection Management Act （Cap. 94A）		Environmental Protection	
	Environmental Protection and Management (Air Impurities) Regulations		THE SCHEDULE Regulation 4
	Environmental Protection and Management (TRADE EFFLUENT) Regulations		9, 10

Basis of Selecting Restricted Chemicals

- ✓ Proposals for restricting chemicals are managed by the respective government agencies regulating chemical controls.
- ✓ Selection is based on health, safety and environment, and security concerns for both the industry and the community.
- ✓ The requirements of international conventions or protocols to which Singapore is party are another basis for consideration.

Implementation Status of SDS and GHS

In Singapore, GHS is implemented in the following regulation/standard.

- ✓ Aligned SS 586 with GHS requirements has been endorsed as an Approved Code of Practice (ACOP) on 26 January 2011, and came into effect on 15 February, 2011
- ✓ Capacity-building through training and promotion through awareness seminars
- ✓ The GHS website is now available on the WSH website. GHS information leaflets (4 types – GHS Fact Sheet, SDS, Labeling, and Classification) and posters are available on the WSH website
- ✓ A virtual GHS expert group, which includes GHS experts from Japan and UN TDG expert based in Australia was established to serve immediate needs
- ✓ A national GHS task force has conducted a number of GHS Awareness workshops over the last few years
- ✓ The SCIC also coordinates and conducts GHS Users and Classification courses in Singapore

The timeline is as follows:

Table 7: Timeline of Implementation of GHS

Phase	Timeline	Target Industry	Requirement
1A	Feb 2012	All Chemical Manufacturers & Suppliers	Preparation of GHS SDSs & Labels for Single Substances
2A	End 2012	All Users of Chemicals	GHS Labeling of Containers for Single Substances.
1B	Mid 2015	All Chemical Manufacturers & Suppliers	Preparation of GHS SDSs & Labels for Mixtures.
2B	Mid 2015	All Users of Chemicals	GHS Labeling of Containers for Mixtures.

1.8. Chemical Risk Management Regulations in Thailand

Existing Legal Instruments on Chemical Management

The existing legal instruments on chemical management, covering industrial chemicals in Thailand, are as follows;

A) Acts concerning chemical management

- ✓ Hazardous Substance Act B.E.2535, 1992
- ✓ Factory Act B.E.2535, 1992
- ✓ The Custom Act B.E.2534, 1991
- ✓ Enhancement and Conservation of National Environmental Quality Act B.E.2535, 1992
- ✓ Public Health Act B.E.2535, 1992
- ✓ Armament Control Act, B.E. 2530, 1987
- ✓ Disaster Prevention and Mitigation Act B.E.2550, 2007

B) Acts concerning Industrial Safety and Health

- ✓ The Factory Act, 1992
- ✓ Occupational Safety, Health and Environmental at Work Act B.E.2554, 2011
- ✓ The Industrial Estate Authority of Thailand Act, 1979
- ✓ Public Health Act B.E.2535, 1992

C) Acts on waste and recycling

- ✓ Factory Act B.E.2535, 1992
- ✓ Hazardous Substance Act B.E.2535, 1992

D) Acts on the transportation of hazardous material

- ✓ The Land Transportation Act B.E.2535, 1992
- ✓ Hazardous Substance Act B.E.2535, 1992

E) Acts on the environment, general

- ✓ Enhancement and Conservation of National Environmental Quality Act B.E.2535, 1992
- ✓ Factory Act B.E. 2535, 1992

F) Acts on the environment of the atmosphere, global environment

- ✓ Enhancement and Conservation of National Environmental Quality Act B.E. 2535, 1992

G) Acts on environment of water

- ✓ The Navigation on the Thai Territorial Water Act, 1913
- ✓ Enhancement and Conservation of National Environment Quality Act (NEQA) B.E.2535, 1992
- ✓ Factories Act B.E.2535, 1992
- ✓ Navigation in Thai Waterways Act (Volume14)as amended in 1992
- ✓ Public Health Act B.E.2535, 1992
- ✓ Cleanliness and Tidiness of the Country ActB.E.2535, 1992

List of Restricted Chemicals in Main Regulations

Table 8: List of Restricted Chemicals in Main Regulations in Thailand (1)

Law Name	Regulation, year	Fields	List
Hazardous Substance Act B.E.2535, 1992 Ministry of Industry	Ministerial Notification on the list of Hazardous Substances No.2 B.E.2543, 2000	Chemical Management	List Kor& List Khor
	Ministerial Notification on the list of Hazardous Substances B.E.2546, 2003		List Kor& List Khor
	Ministerial Notification on the list of Hazardous Substances No.3 B.E.2548, 2005		List Kor
	Ministerial Notification on the list of Hazardous Substances No.4 B.E.2549, 2006		List Kor&List Khor
	Ministerial Notification on the list of Hazardous Substances No.5 B.E.2549, 2006		List Kor& List Khor
	Ministerial Notification on the list of Hazardous Substances No.6 B.E.2552, 2009		List Kor
	Ministerial Notification on the list of Hazardous Substances No.7 B.E.2553, 2010		
	Ministerial Notification on Designation of a specialized person responsible for the safety of hazardous substance storage under authorization of DIW at the hazardous substance business facility. B.E.2551, 2010		Article

Table 8: List of Restricted Chemicals in Main Regulations in Thailand (2)

Law Name	Regulation, year	Fields	List
	Notification of DIW on Guideline for warehousing of Hazardous substances B.E.2551, 2010		Appendix
	Ministerial Notification on land transportation of hazardous material B.E.2546, 2003	Transportation of hazardous material	UNTDG
Factory Act B.E.2535, 1992 Ministry of Industry	Ministerial Notification order to enforce of the Act on the industrial waste management B.E.2548, 2005	Industrial Waste	Appendix 1-2
	Ministerial Notification No.2 B.E.2535, 1992 order to enforce of the Act on the environment industrial (waste water)	Environment	Article No.2
	Ministerial Notification order to enforce of the Act on the environment B.E.2549, 2006 (industrial air pollution)		Article No.3
	Ministerial Notification order to enforce of the Act on the environment B.E.2548, 2005 (industrial air pollution from the used oil)		Article No.2
	Notification of the Ministry of Industry: Level of impurities in the emission of factories B.E.2548, 2005		Appendix

Table 8: List of Restricted Chemicals in Main Regulations in Thailand (3)

Law Name	Regulation, year	Fields	List
Armament Control Act,B.E. 2530, 1987 Ministry of Defense	Ministerial Notification order to enforce the Act on Armament Control	Chemical Management	Article No.2.2 chemical in war implement. Article No.2.3chemical use in the mixture of explosive materials.
	Royal Decree controlling the exportation of arms armament and war implements B.E.2535, 1992		Appendix No.6
Occupational Safety, Health and Environment at Work Act B.E.2554, 2011 Ministry of Labor	Ministerial Regulation on the Prescribing of Standards for Administration and the Management of Occupational Safety, Health and Work Environments in Relation to Hazardous Chemical Substances B.E.XXXX[2]	Labor Safety	Ongoing process
The Land Transportation ActB.E.2522, 1979 Ministry of Transportation	Notification of Department of Land Transportation B.E.2543, 2000:Type and Class of Hazardous Substance	Transport of hazardous material	UNTDG
	Notification of Department of Land Transportation B.E.2553, 2010: Type and Class of Hazardous Substance require Driver license Type 4		Article

[2] As of March 2012, this regulation is under legislative process. Establishment year is to be determined.

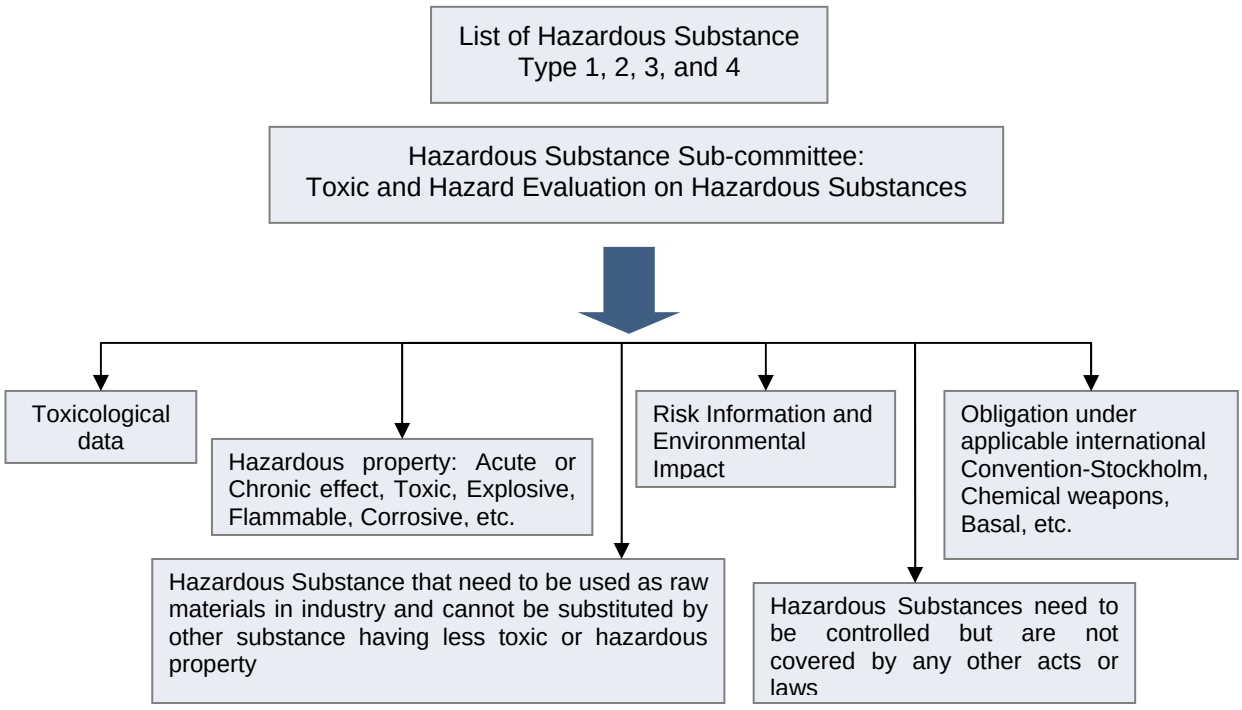
Table 8: List of Restricted Chemicals in Main Regulations in Thailand (4)

Law Name	Regulation, year	Fields	List
Enhancement and Conservation of National Environmental Quality Act Ministry of Science, Technology and Environment,	Notification of the Ministry of Science, Technology and Environment, No.3, B.E.2539, 1996, issued under the Enhancement and Conversation of the National Environmental Quality Act	Environmental Protection	Appendix
	Notification of Pollution Control Department on monitoring value for volatile organic compounds in 24 hours B.E.2551, 2008		Article 1
	Ministerial Notification on criteria of emission standard from industries B.E.2549, 2006		Article 2
	Notification of National Environment Committee No.30 on monitoring values for volatile organic compounds in the atmosphere within 1 year.B.E.2550, 2007		Article 1

Basis of Selecting Restricted Chemicals

Chemical substances must be under specific national procedure, as follows:

Figure 6: Basis of Selecting restricted Chemicals n Thailand



Implementation Status of SDS and GHS

In Thailand, SDS is implemented in the following regulation/standard:

- ❖ Hazardous Substance Act B.E.2535, 1992 (to be approved by the Minister of Industry, which complies with the GHS)

On the other hand, GHS is implemented in the following regulation/standard:

- ✓ Hazardous Substance Act B.E.2535, 1992 (to be approved fromthe Minister of Industry)
- ✓ GHS Classification Results will be available on http://www.diw.go.th by December 2011

1.9. Chemical Risk Management Regulations in Vietnam

Existing Legal Instruments on the Chemical Management

The existing legal instruments on the chemical management covering industrial chemicals in Vietnam are as follows:

A) Acts concerning industrial chemical management

- ✓ **Chemical Law**, 2007 (enforced 2008)
- ✓ **Decree No. 26/2011/ND-CP**, April 8 2011, amended and supplemented some articles of Decree No. 108/2008/ND-CP,October 7 2008,details and guides the implementation ofsome articles ofChemicalLaw
- ✓ **Decree No. 15/2010/ND-CP** on administrative punishment in the production, trading of fertilizers, March 1, 2010
- ✓ **Decree No. 90/2009/ND-CP** on administrative punishment of chemical activity, October 20, 2009
- ✓ **Decree No. 108/2008/ND-CP:** "Detailed regulation and guideline of implementation of several articles in Law of chemicals," October 2008
- ✓ **Decree No. 68/2005/ND-CP** on chemical safety, May 20, 2005
- ✓ **Decree 27/ND/CP** allowing the use and trade of explosive industrial materials, 20 April, 1995
- ✓ **Circular 28/2010/TT-BCT**,guiding the implementation of Chemical Law, June 28, 2010, and Decree 108/2008/ND-CP, October 7, 2008
- ✓ **Circular 30/2011/TT-BCT**,providing temporary regulation on the limitation of some hazardous chemicals in electrical and electronic products, August 10, 2011

B) Documents on Industrial Safety and Health

- ✓ Labor law

C) Documents on environment, general

- ✓ Environmental Protection Law

D) Documents on Waste and recycle

- ✓ Decree No. 67/2003/ND-CP, regulating waste water management, June 13, 2003
- ✓ Decree 59/2007/NĐ-CP, regulating solid waste management, April 9, 2007

E) Documents on Hazardous material, security and accident prevention

- ✓ Safety law for production, use, storage and transportation of dangerous chemicals

F) Documents on transport of hazardous material, shipping)

- ✓ Decree No. 13/2003/ND-CP, listing hazardous goods for land transportation, February 19, 2002

G) Documents on the environment, including atmosphere, global environment, water, soil

- ✓ QCVN 05:2009/BTNMT National regulation on ambient air
- ✓ QCVN 06:2009/BTNMT National regulation on some hazardous substances in ambient air.

List of Restricted Chemicals in Main Regulations

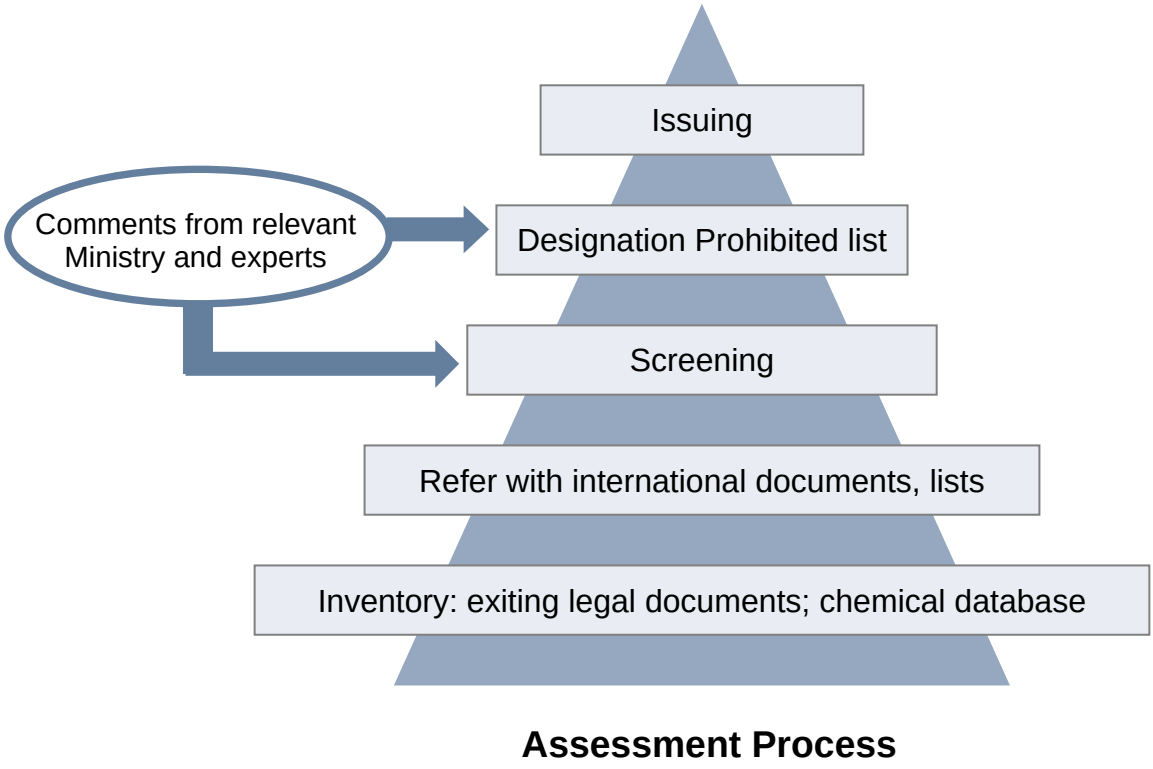
Chemicals management

Decree 108/2008/ND-CP, appendix III, List of restricted Chemicals

Next steps: Relevant ministries will issue the guidance documents on permission for import, export, production and using Restricted Chemicals for special purposes.

Basis of Selecting Restricted Chemicals

Figure 8: Assessment Process



Implementation Status of SDS and GHS

In Vietnam, SDS is implemented in the following regulation/standard:

- ❖ Decree No. 108/ND-CP/2008 and Decree No. 26/ND-CP/2011

Next steps: MOIT will issue the Circular guidance on Chemicals Declaration, and SDS will be a major part of that Circular

On the other hand, GHS is implemented in the following regulation/standard:

Dissemination:

- ✓ Awareness Raising Seminar on GHS and GHS implementation. Vinachemia, in cooperation with Sweden Chemicals Agency, held a workshop entitled "guidelines for implementation of chemicals classification and labeling in global harmonized system" in Hanoi and Ho Chi Minh City
- ✓ Participation in training courses in other countries such as Japan, Singapore, and Indonesia.

Legal documents:

- ✓ The guidance classification and labeling for chemicals was issued at the end of 2011.
- ✓ Road map: 2 years for substances (2011–2013)
- ✓ Road map: 4 years for mixtures (2011–2015)

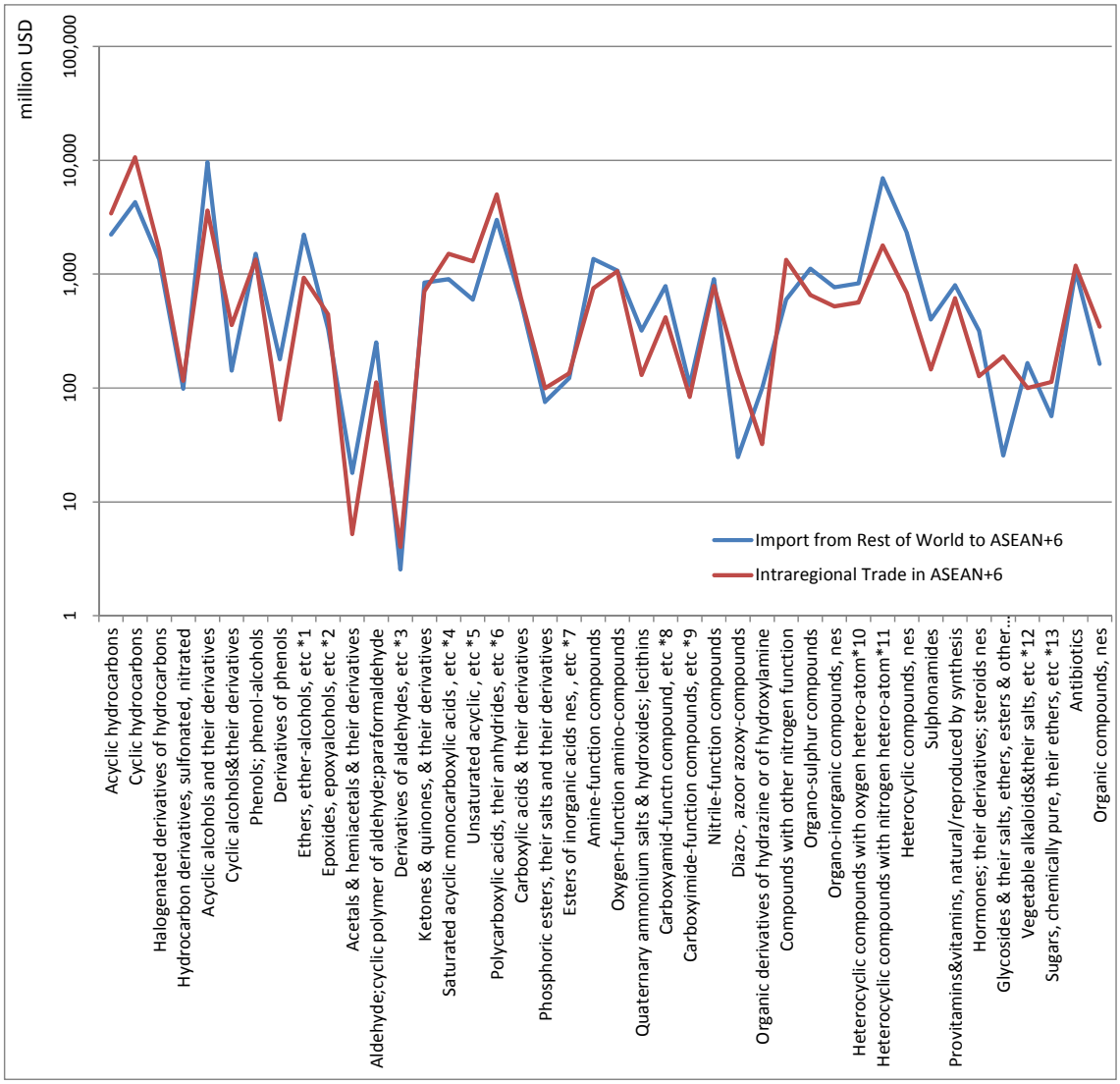
Next steps: Setup National Action plan for GHS implementation

2. Overview of the Trading Amount of Chemical Substances in ASEAN and East Asian Countries

2.1. Chemical Substance Trading in ASEAN and East Asian Countries in Brief

The values of imported chemical substances in 42 segments (based on HS code) are mostlythe same as those of the values of intraregional trades in ASEAN+6 (Figure 9). The significant difference is shown in the value of Diazo-, azoor azoxy-compounds, Glycosides and their salts, and Heterocyclic compounds.

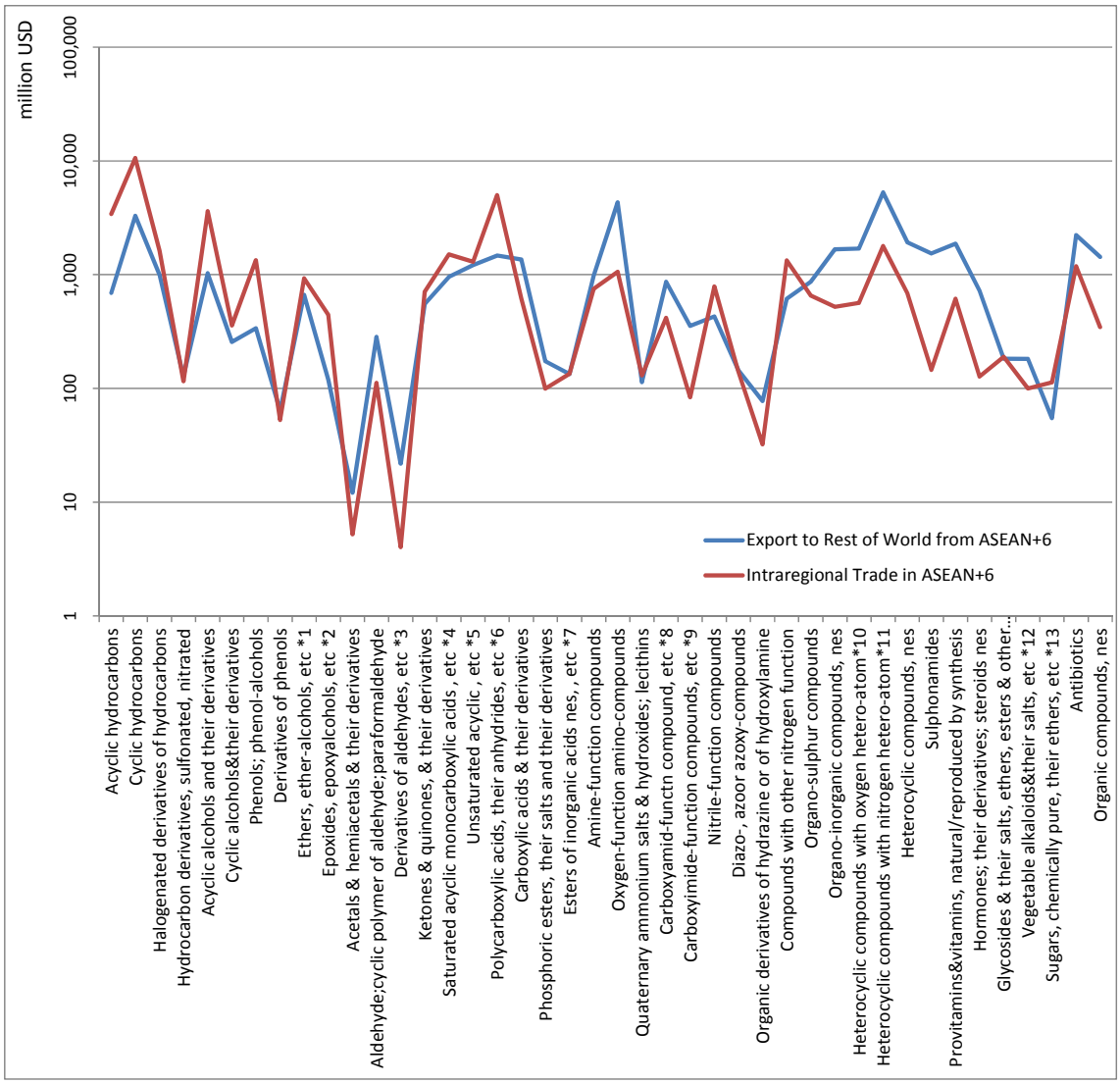
Figure 9: Amount of import from intraregional trade and rest of the world to ASEAN+6



Source: UN comtrade

Just as in the result in Figure 9, the values of exported chemical substances in 42 segments are similar to the values of intraregional trade in ASEAN+6 (Figure 10). The significant differences are shown in Glycosides and their salts, Acyclic alcohols and their derivatives, Phenols, Epoxides, Derivatives of aldehydes, Polycarboxylic acids, Oxygen-function amino-compounds, Carboxyimide-function compounds, Sulphonamides, Hormones, and Organic compounds. Here, a significant difference is recognized if the difference rate (=export/intraregional) is more than 300%, or less than 30%.

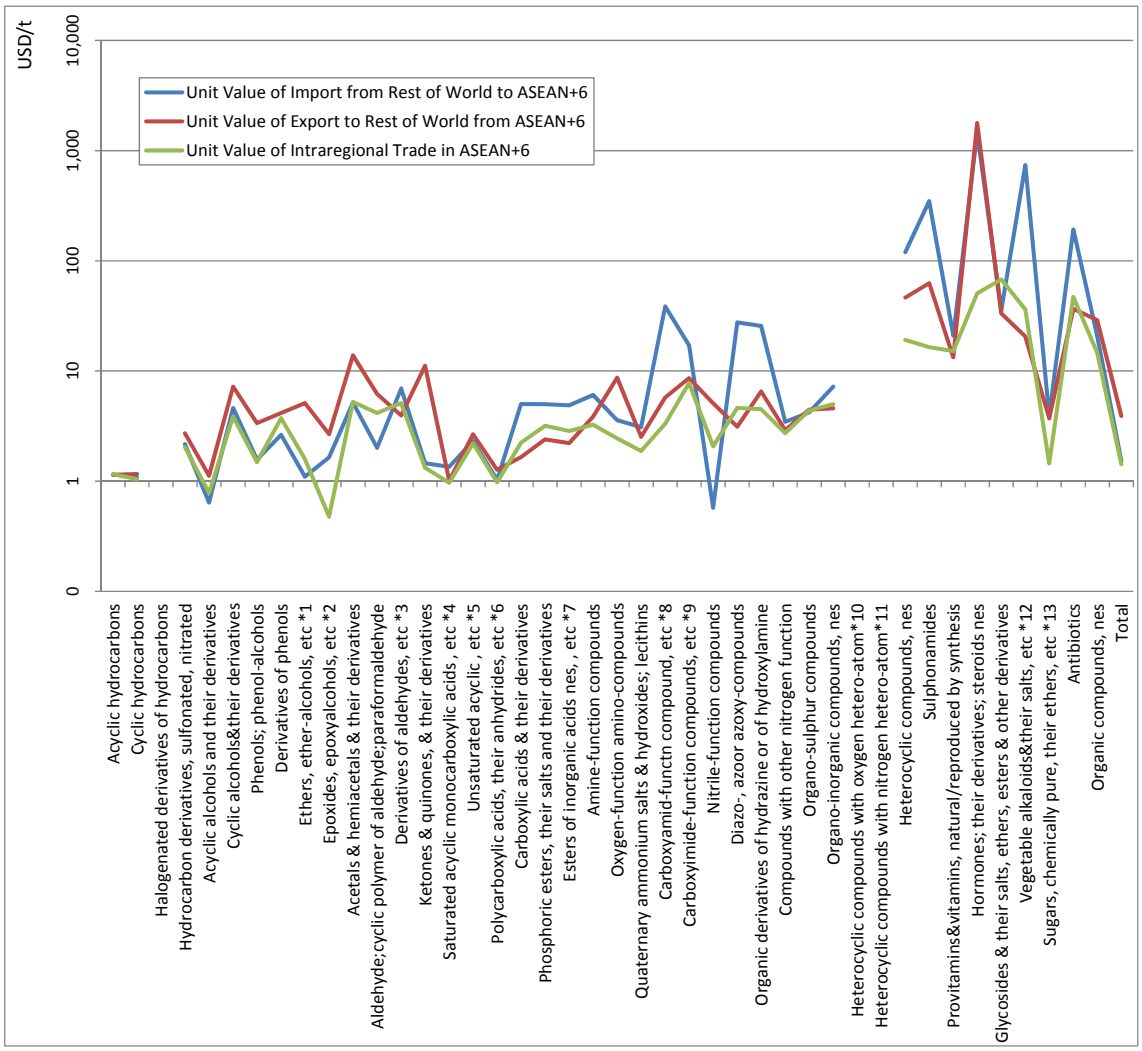
Figure 10: Amount of exports from ASEAN+6 to intraregional trade and rest of the world



Source: UN comtrade

Lastly, the unit values (=USD/t) of each of the 42 segmented chemicals for import/export/intraregional trade were calculated as shown in Figure 11. The most remarkable point is that the unit value of export to rest of world from ASEAN+6 is about 3.9 USD/t,whereas that of import and intraregional trade is around 1.5 USD/t. This result indicates that the companies in ASEAN+6 import/trade intra-regionally cheap chemicals and export highly valued chemicals to rest of the world.

Figure 11. Comparison of the Unit Cost of the Intraregional Trade and Others



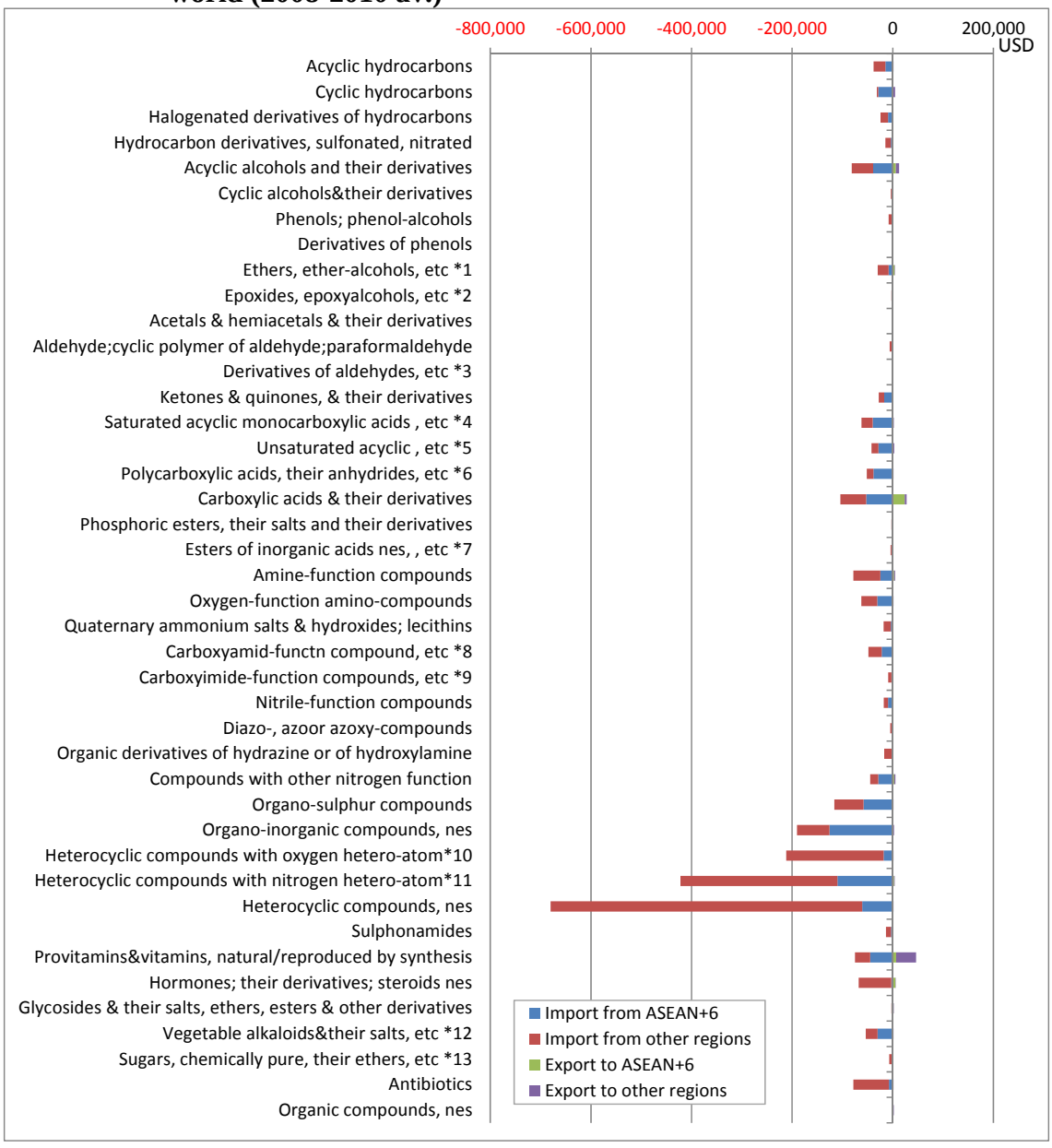
Source: UN comtrade

2.2. Chemical Substance Trading in Australia

Trading of Chemical Goods

In Australia, the imported value is much higher than that of exported value in the field of organic chemical goods, and especially the import of the Heterocyclic compounds is of high value (Figure 12).

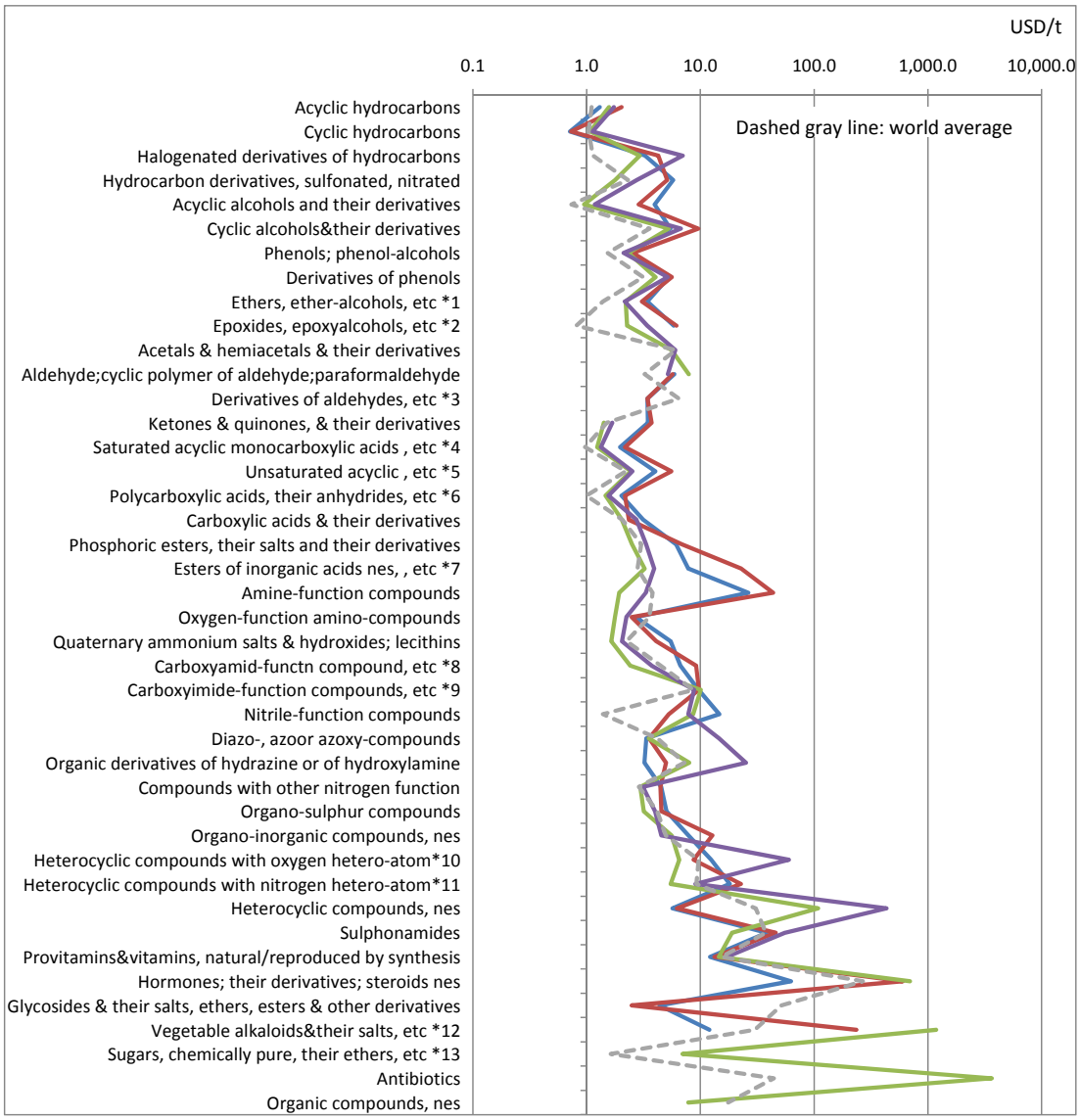
Figure 12: Value of import (negative) and export (positive) to ASEAN+6 and world (2008-2010 av.)



Source: UN comtrade

The difference of unit costs for importing and exporting, with respect to the goods criteria is shown in Figure 13. Although some items show large differences (e.g. "Hydrocarbon derivatives, sulfonated, nitrated" or "Heterocyclic compounds, nes"), these differences are mainly because the exported volume of these items is quite small. Therefore, these differences do not necessarily reflect a difference in the industrial structure.

Figure 13: Unit value of Import and Export (2008-2010 average)



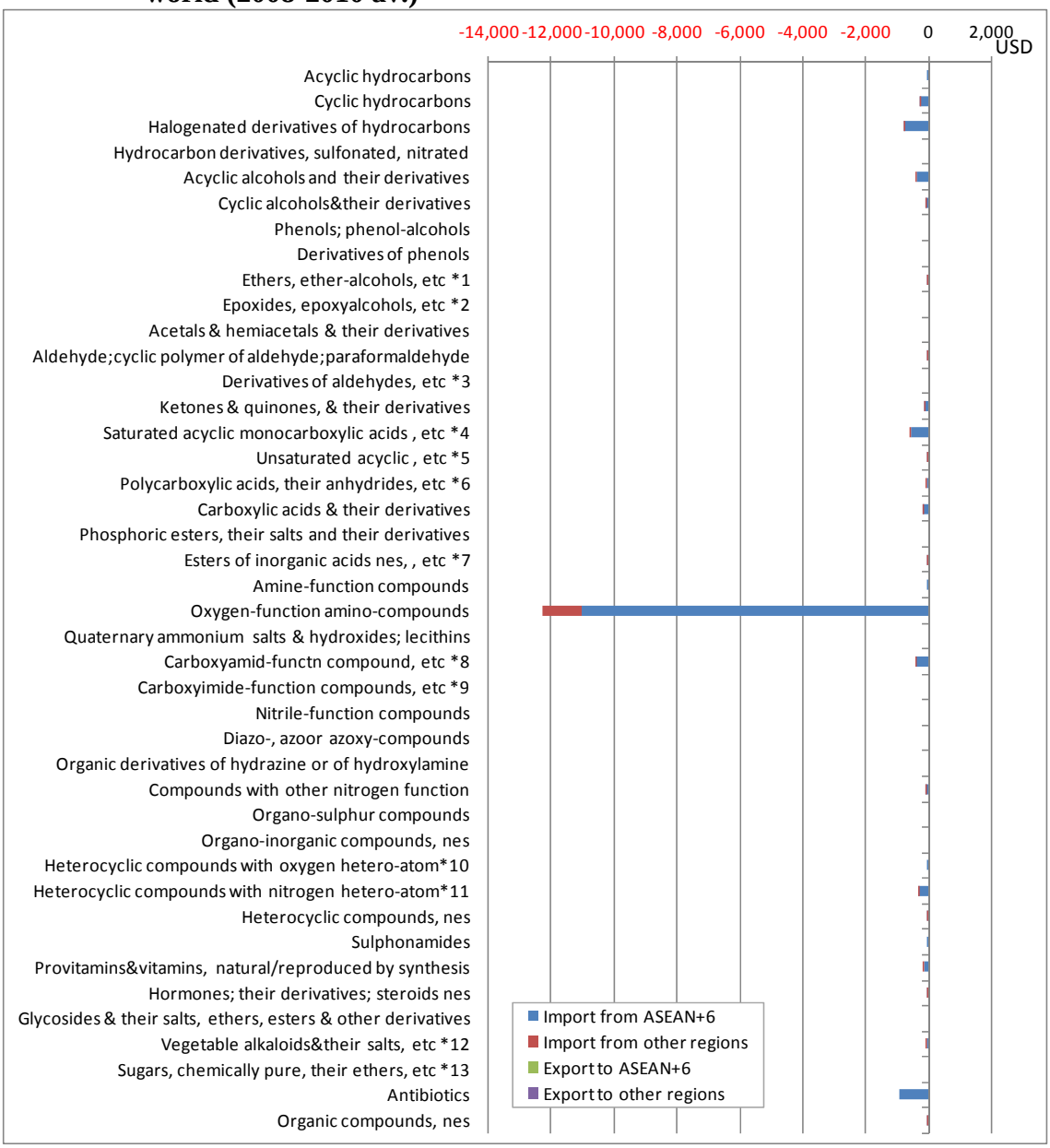
Source: UN comtrade

2.3. Chemical Substance Trading in Cambodia

Trading of Chemical Goods

In Cambodia, the imported value is higher than that of exported value in the field of organic chemical goods, and, in particular, the import of the Oxygen-function amino-compounds is of high value (Figure 14).

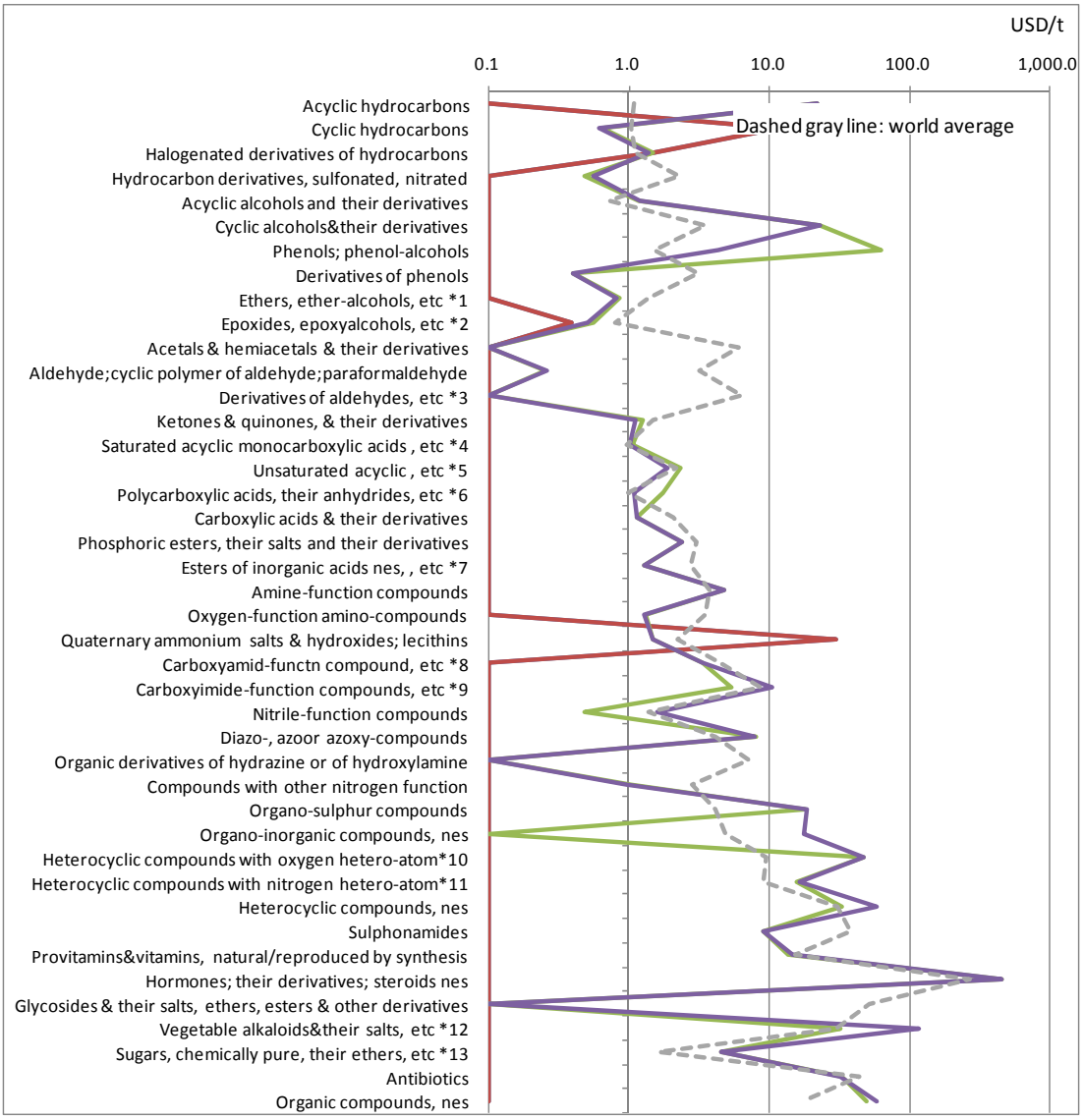
Figure 14: Value of import (negative) and export (positive) to ASEAN+6 and world (2008-2010 av.)



Source: UN comtrade

The difference of unit costs for importing and exporting, with respect to the goods criteria, is shown in Figure 15. Although some items show large differences, these differences are mainly because the exported volume of these items is quite small. Therefore, these differences do not necessarily reflect a difference in industrial structure.

Figure 15: Unit value of Import and Export (2008-2010 average)



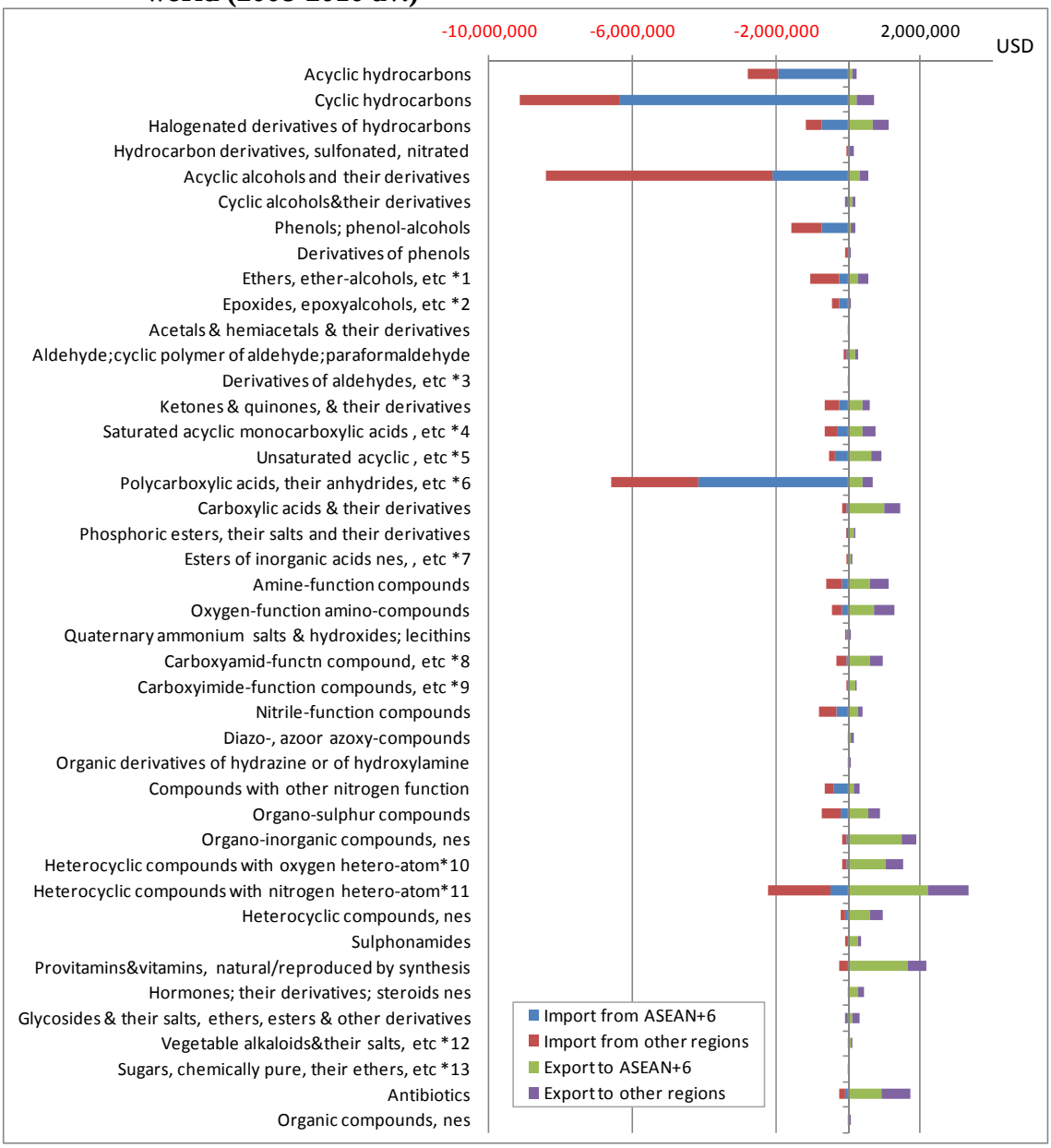
Source: UN comtrade

2.4. Chemical Substance Trading in China

Trading of Chemical Goods

In China, exported value is generally higher than imported value in the field of organic chemical goods, although some chemical compounds record high imported values (e.g., Cyclic hydrocarbons, Acyclic alcohols and their derivatives, Polycarboxylic acids, their anhydrides, etc.).

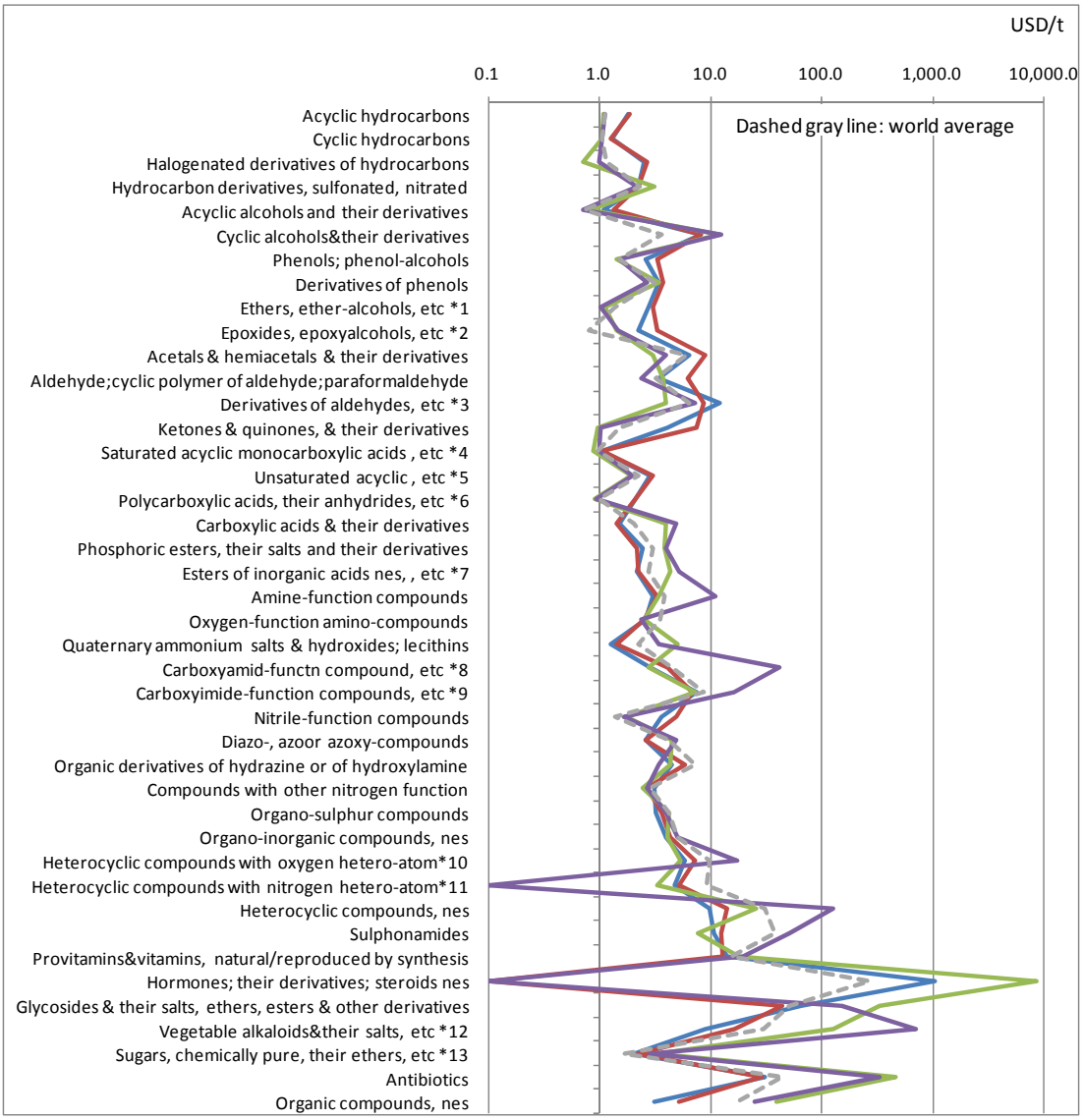
Figure 16: Value of import (negative) and export (positive) to ASEAN+6 and world (2008-2010 av.)



Source: UN comtrade

The difference of unit costs for importing and exporting with respect to the goods criteria is shown in Figure 17. Although some items show large differences (e.g., "Hormones; their derivatives; steroids nes"), these differences are mainly because the exported volume of these items is quite small. On the other hand, some chemical compounds (e.g., antibiotics) record a higher value for the exported compounds with a certain volume of exports.

Figure 17: Unit value of Import and Export (2008-2010 average)



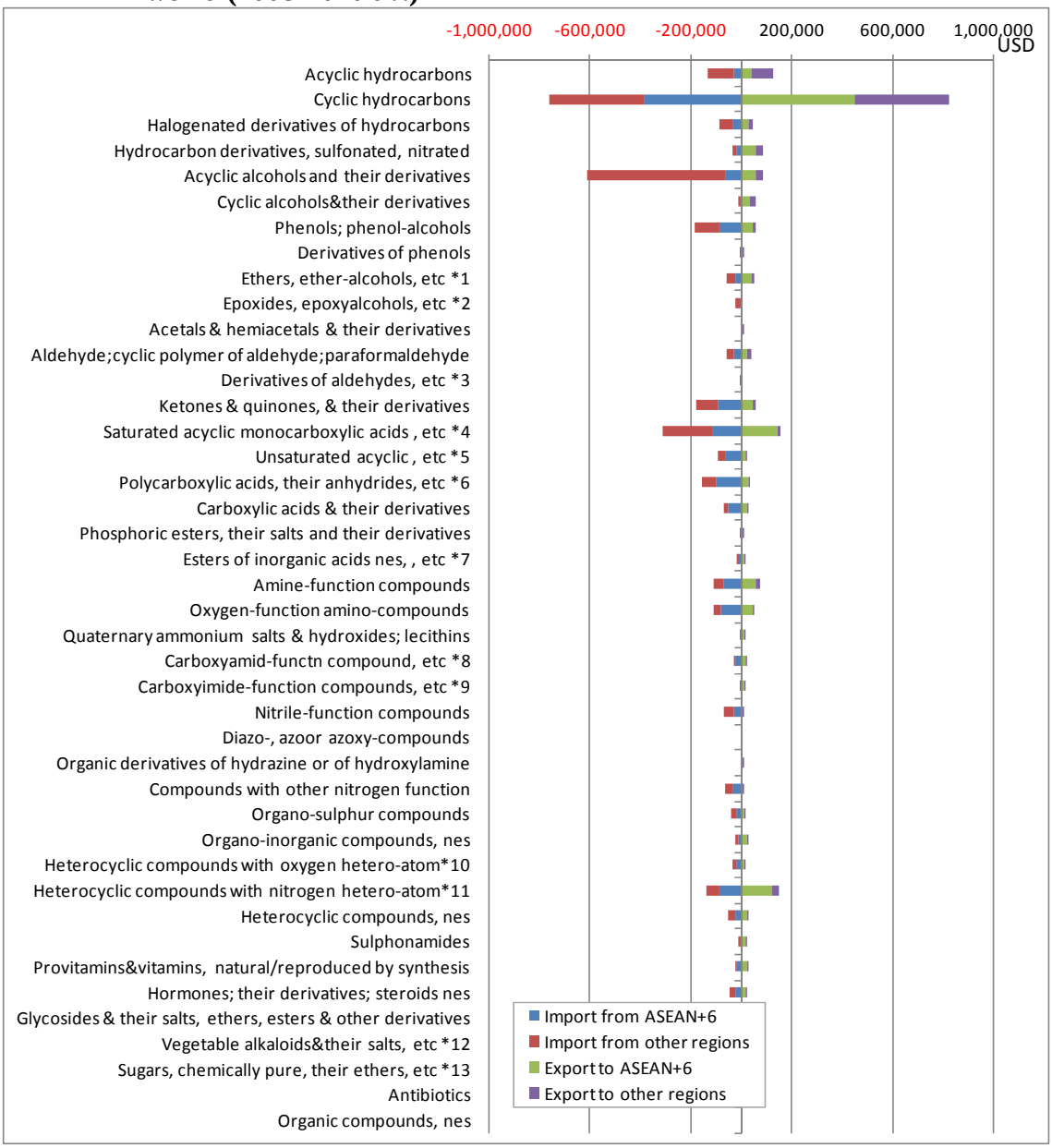
Source: UN comtrade

2.5. Chemical Substance Trading in India

Trading of Chemical Goods

In India, the imported value is generally higher than that of exported value in the field of organic chemical goods. In particular, cyclic hydrocarbons record the highest volume of exports as well as of imports.

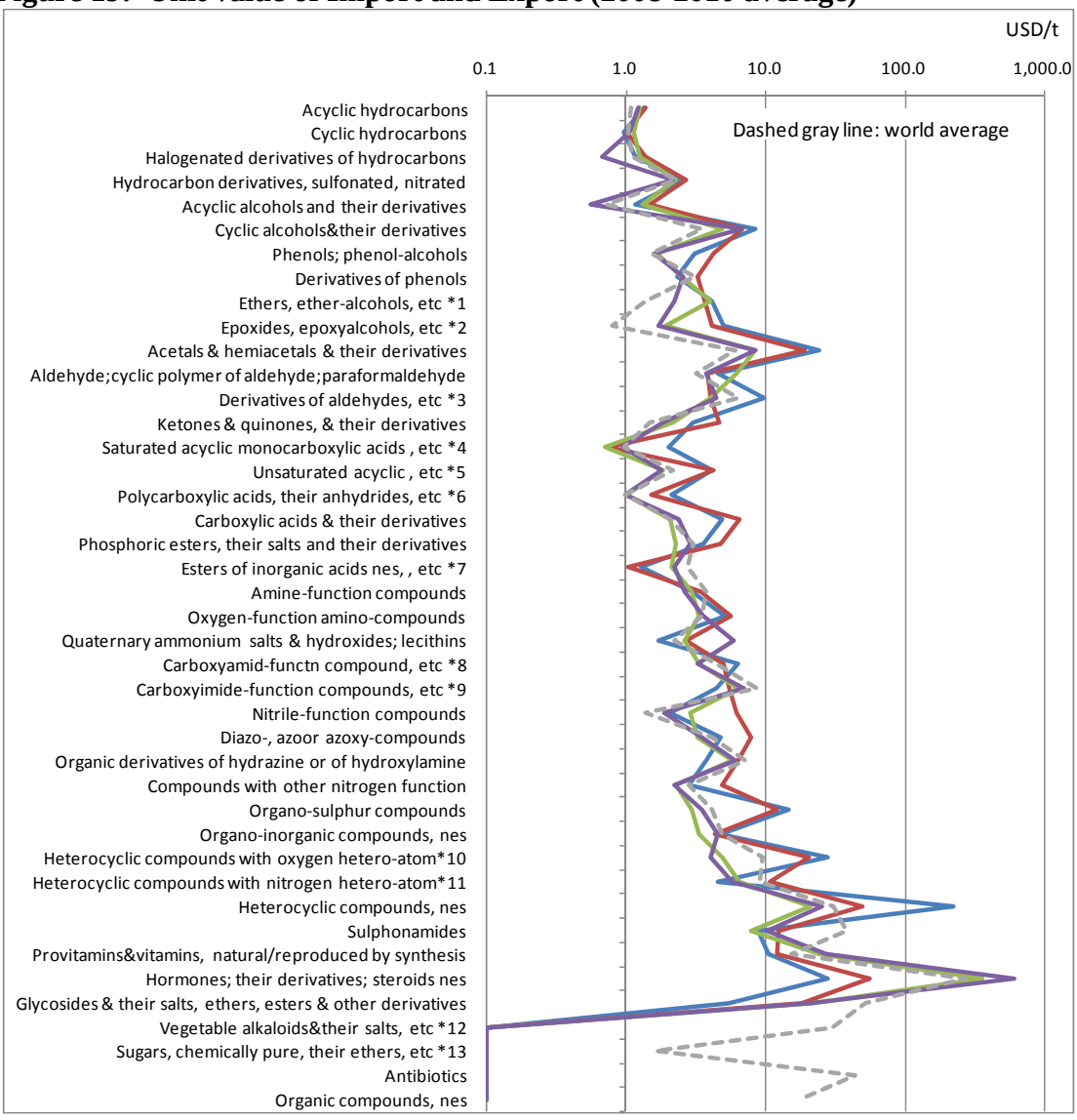
Figure 18: Value of import (negative) and export (positive) to ASEAN+6 and world (2008-2010 av.)



Source: UN comtrade

The difference of unit costs for importing and exporting with respect to the goods criteria is shown in Figure 19. Although some items show large differences (e.g., "Hydrocyclic compounds"), these differences are mainly because the exported volume of these items is quite small. Therefore, these differences do not necessarily reflect differences in the industrial structure.

Figure 19: Unit value of Import and Export (2008-2010 average)



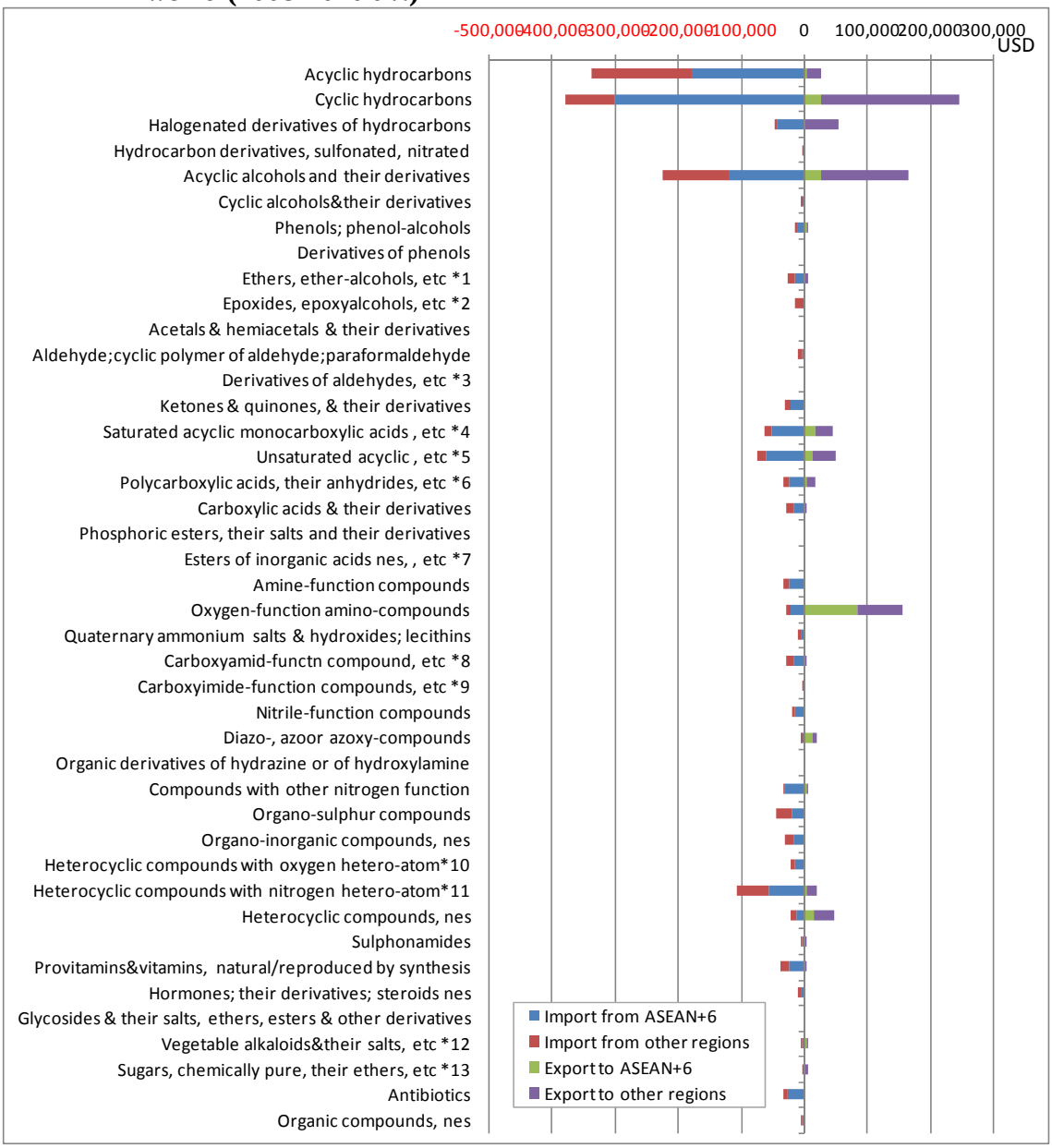
Source: UN comtrade

2.6. Chemical Substance Trading in Indonesia

Trading of Chemical Goods

In Indonesia, the imported value is generally higher than the exported value in the field of organic chemical goods, although there are some chemicals with a higher exported value than imported value (e.g. "Oxygen-function amino-compounds").

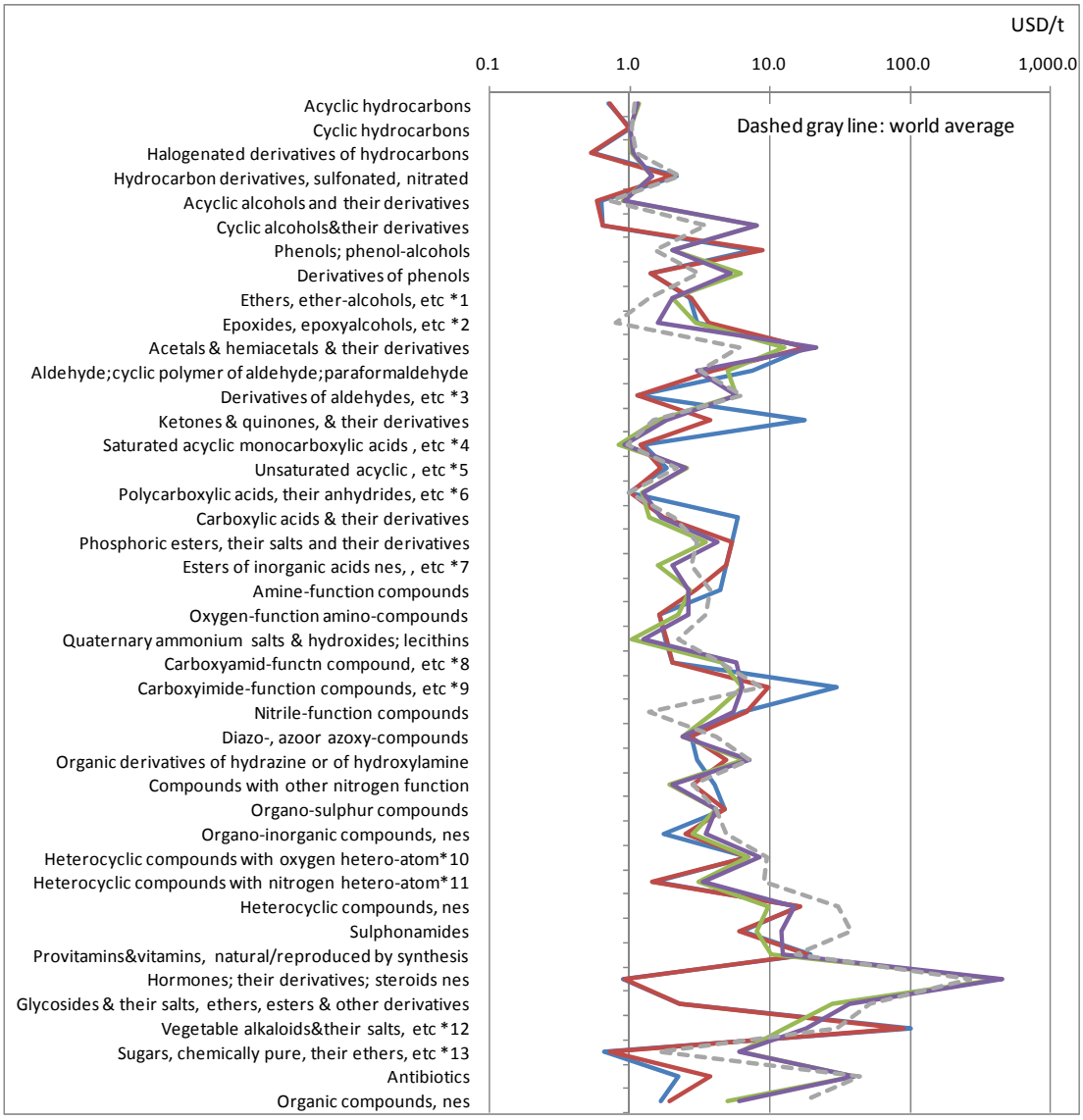
Figure 20: Value of import (negative) and export (positive) to ASEAN+6 and world (2008-2010 av.)



Source: UN comtrade

The difference of unit costs for importing and exporting with respect to the goods criteria is as shown in Figure 21. Although some items show large differences (e.g., "Hormones; their derivatives; steroids nes"), these differences are mainly because the exported volume of these items is quite small. Therefore, these differences do not necessarily reflect differences in the industrial structure.

Figure 21: Unit value of Import and Export (2008-2010 average)



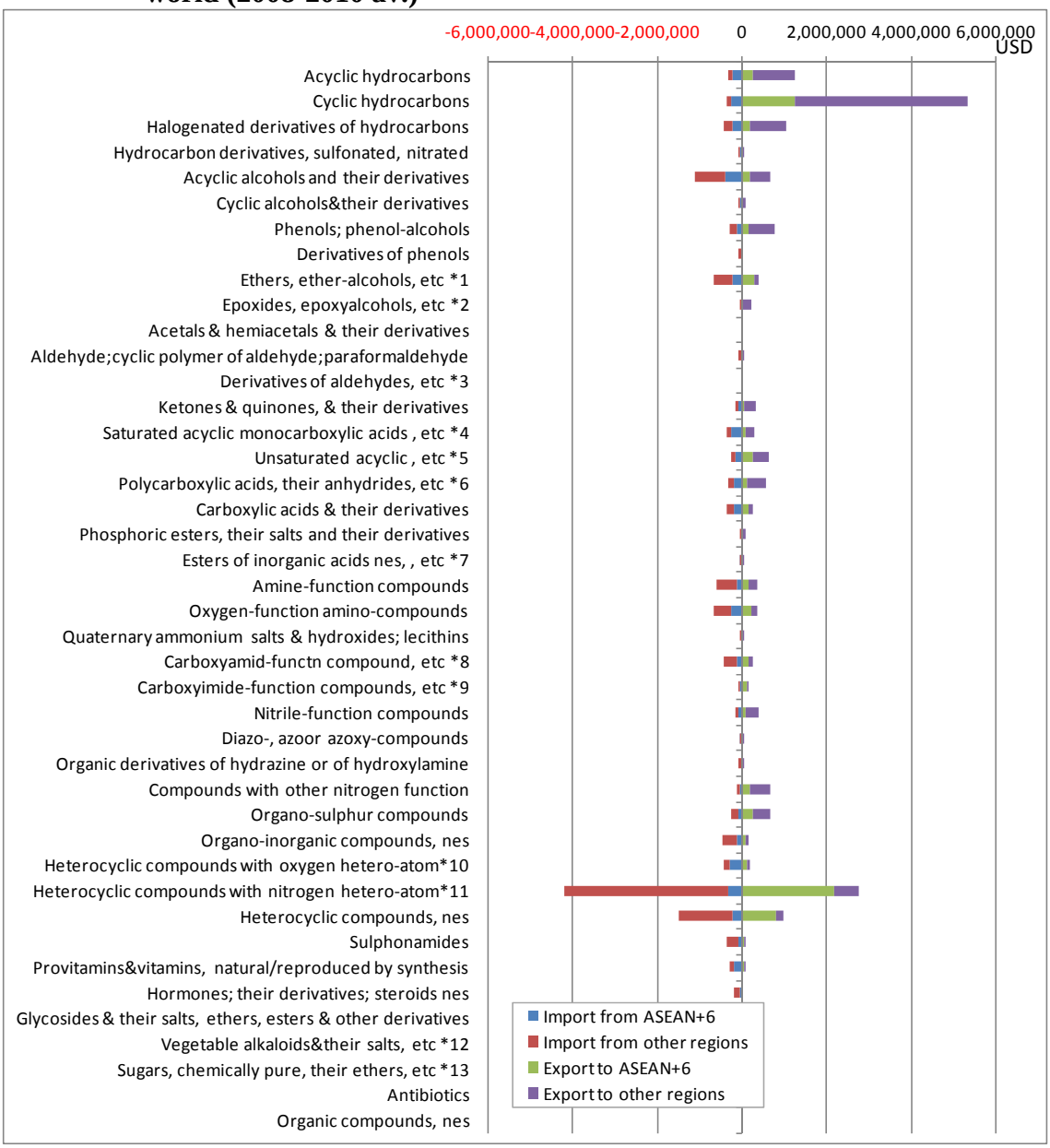
Source: UN comtrade

2.7. Chemical Substance Trading in Japan

Trading of Chemical Goods

In Japan, the exported value is much higher than imported value in the field of organic chemical goods, and particularly the export of cyclic hydrocarbons is of the highest value.

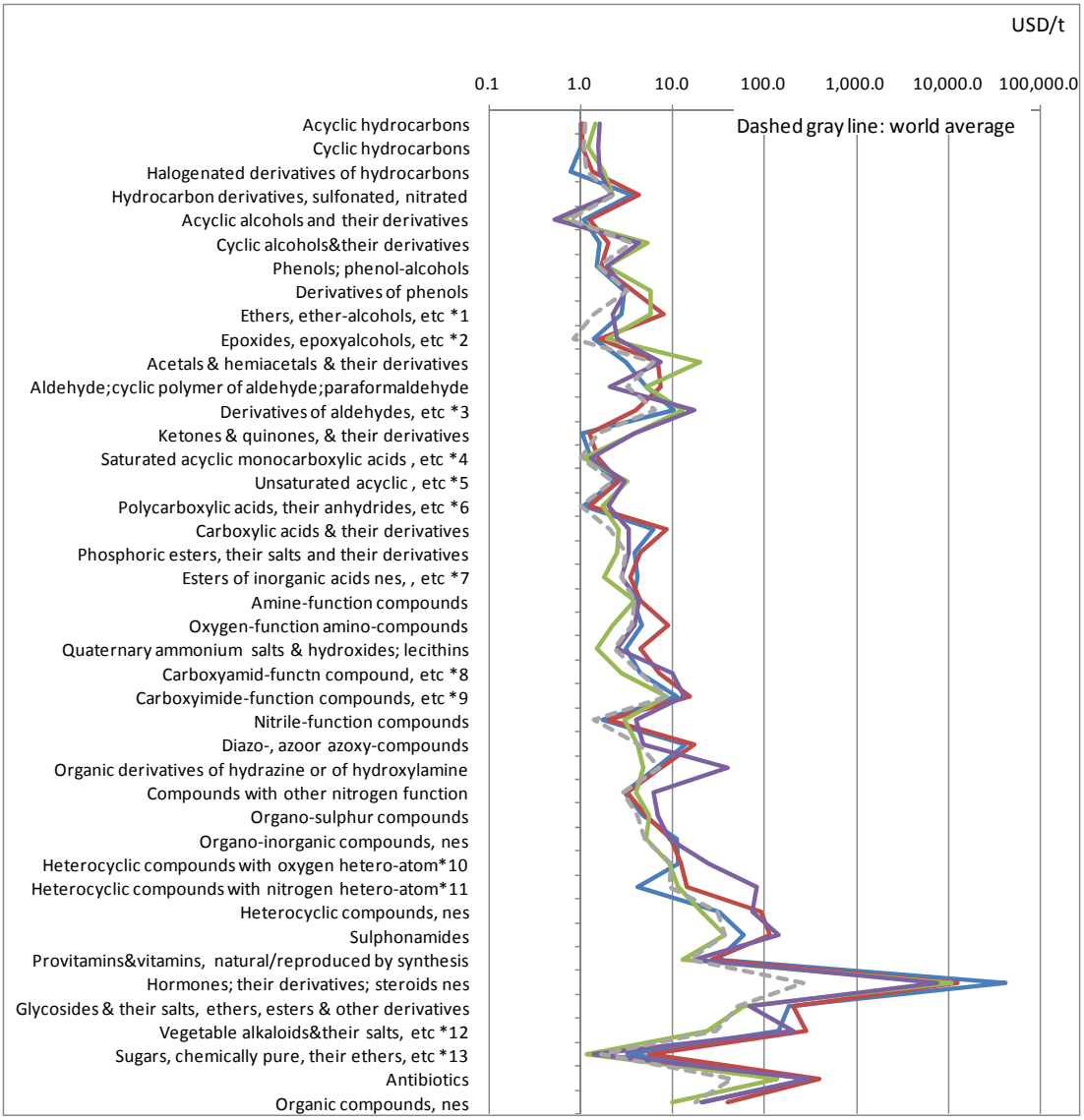
Figure 22: Value of import (negative) and export (positive) to ASEAN+6 and world (2008-2010 av.)



Source: UN comtrade

The difference of unit costs for importing and exporting with respect to the goods criteria is as shown in Figure 23. Although most of the items do not record large differences from the world average,the unit costs of import items as well as export items are generally higher.

Figure 23: Unit value of Import and Export (2008-2010 average)



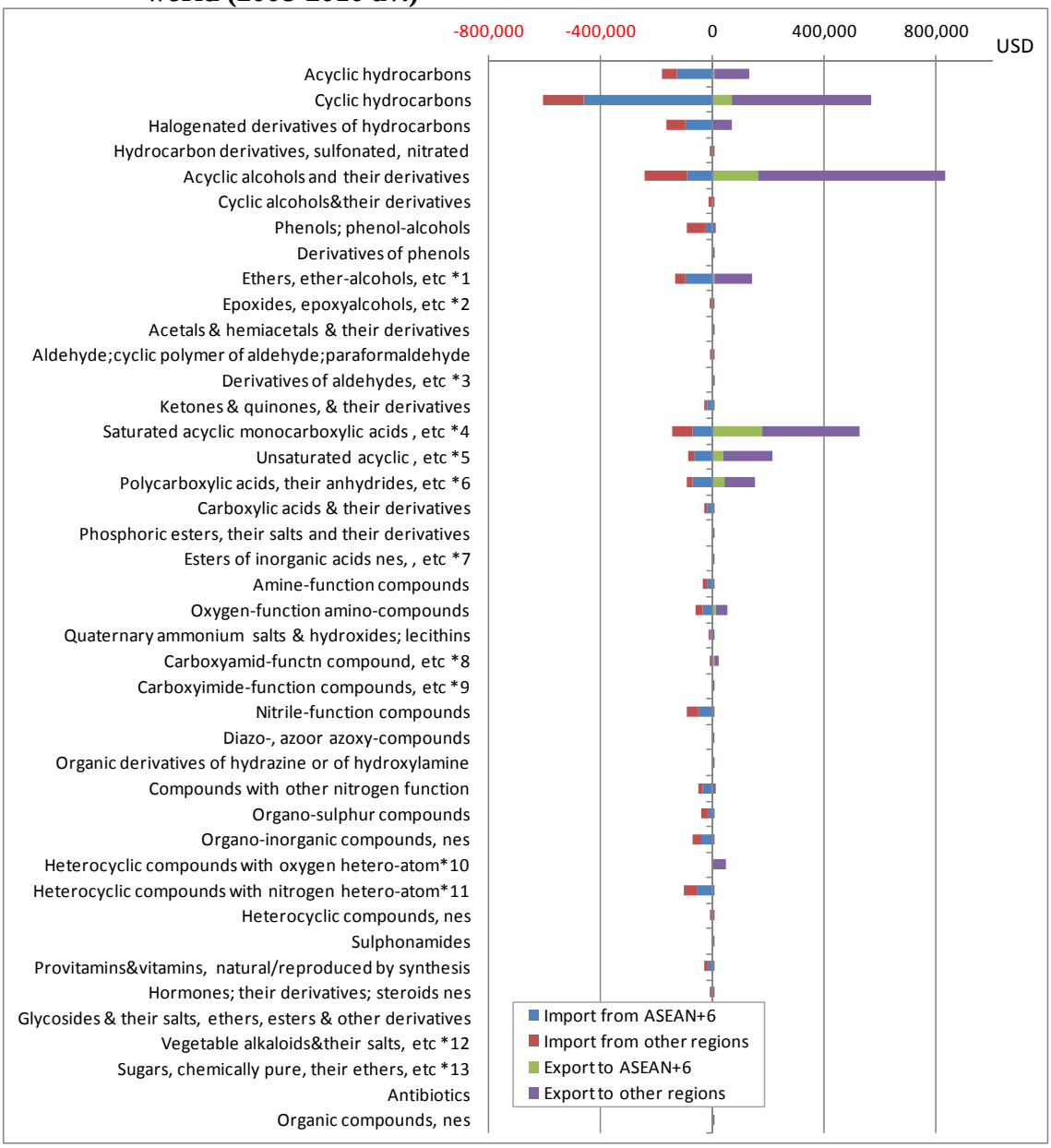
Source: UN comtrade

2.8. Chemical Substance Trading in Malaysia

Trading of Chemical Goods

In Malaysia, the imported and exported value depends on the kind of chemical goods. While some organic chemicals such as "Cyclic hydrocarbons" record higher imported and exported value, there are many other chemicals with low imported and exported values.

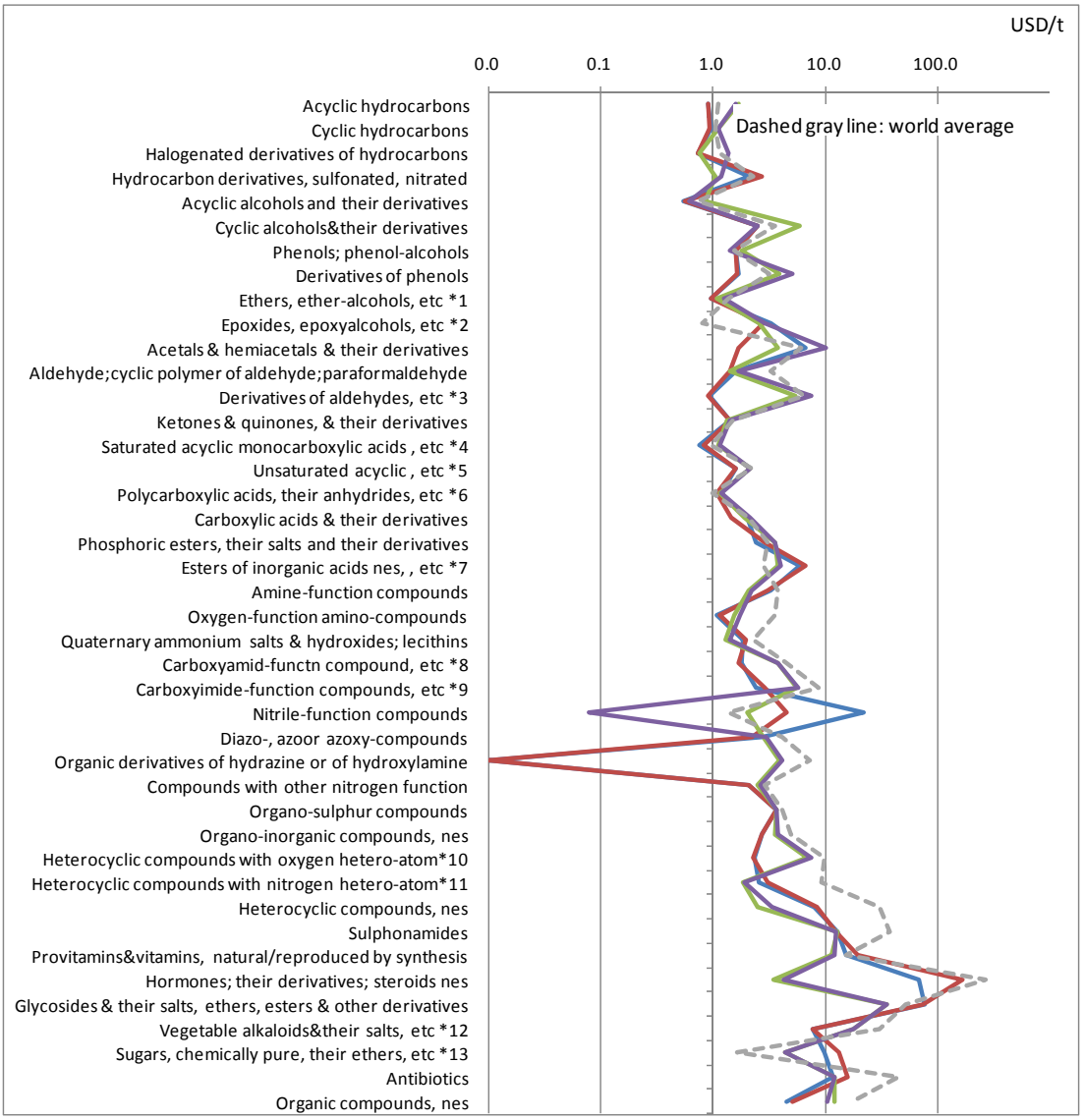
Figure 24: Value of import (negative) and export (positive) to ASEAN+6 and world (2008-2010 av.)



Source: UN comtrade

The difference of unit costs for importing and exporting with respect to the goods criteria is shown in Figure 25. Although some items show large differences (e.g., "Nitrile-function compounds" or "Organic derivatives of hydrazine or of hidroxylamine"), these differences are mainly because the exported volume of these items is quite small. Therefore, these differences do not necessarily reflect a difference in industrial structure.

Figure 25: Unit value of Import and Export (2008-2010 average)



Source: UN comtrade

2.9. Chemical Substance Trading in New Zealand

Trading of Chemical Goods

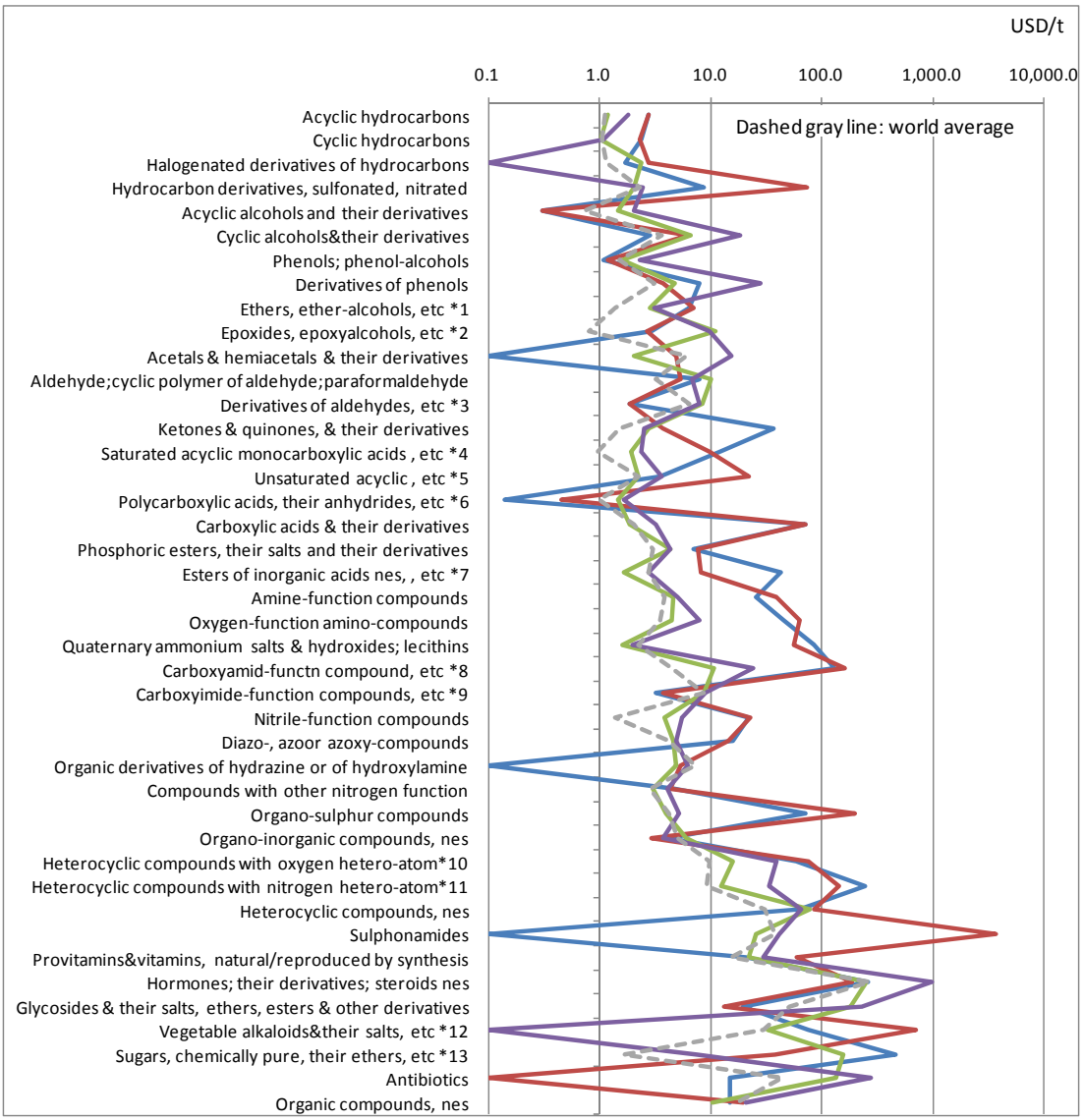
In New Zealand, the imported value is generally higher than the exported value in the field of organic chemical goods, in spite of some exceptions such as "Acyclic alcohols and their derivatives."

Figure 26: Value of import (negative) and export (positive) to ASEAN+6 and world (2008-2010 av.)

Source: UN comtrade

The difference of unit costs for importing and exporting with respect to the goods criteria is as shown in Figure 27. There are generally large differences in most of the chemical goods due to their small exported and imported volume, and unit costs of imported items are generally higher than the world average.

Figure 27: Unit value of Import and Export (2008-2010 average)



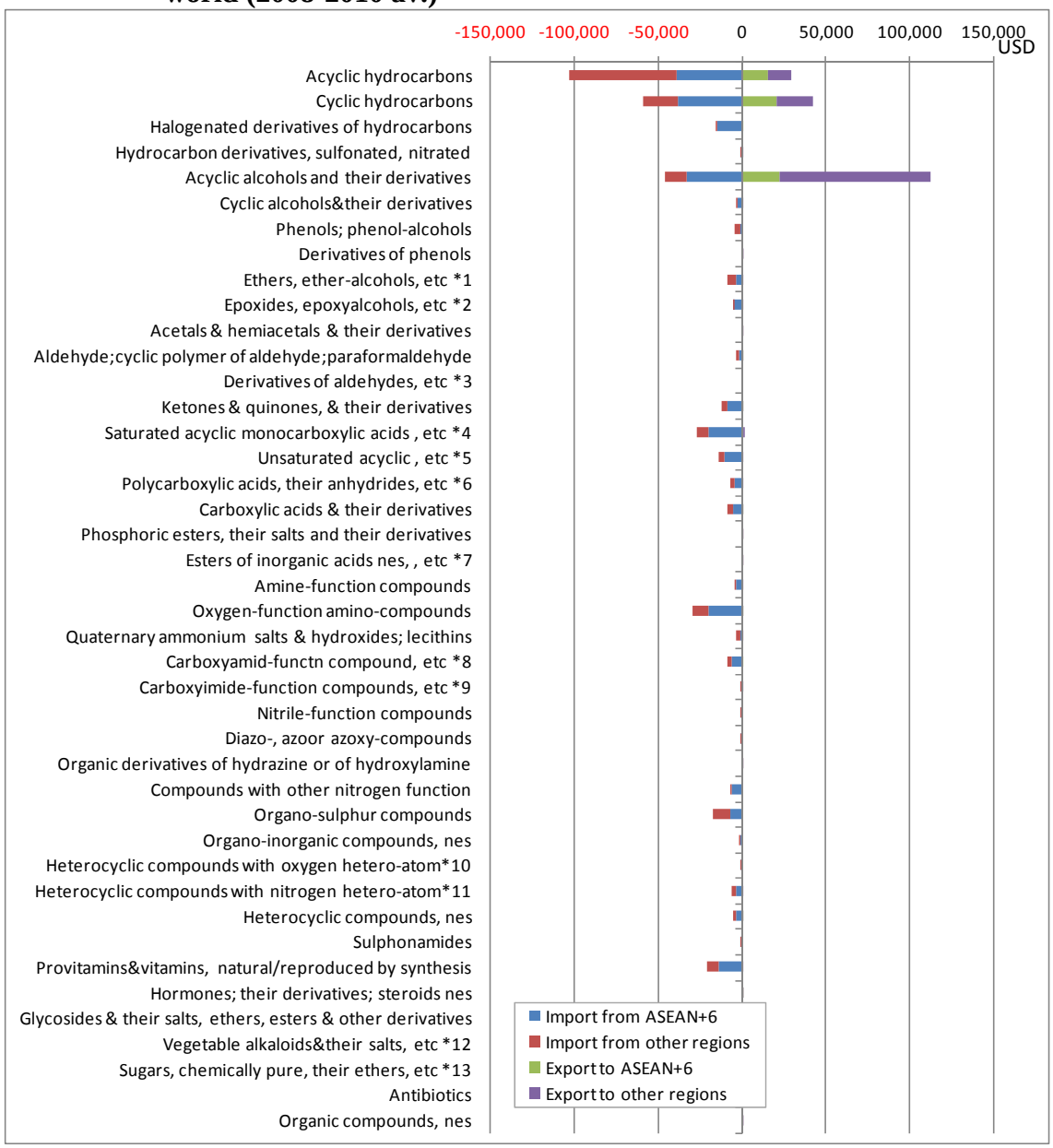
Source: UN comtrade

2.10. Chemical Substance Trading in the Philippines

Trading of Chemical Goods

In the Philippines, the imported value is much higher than that of exported value in the field of organic chemical goods,although there are some exceptions (e.g.,"Acyclic alcohols and their derivatives").

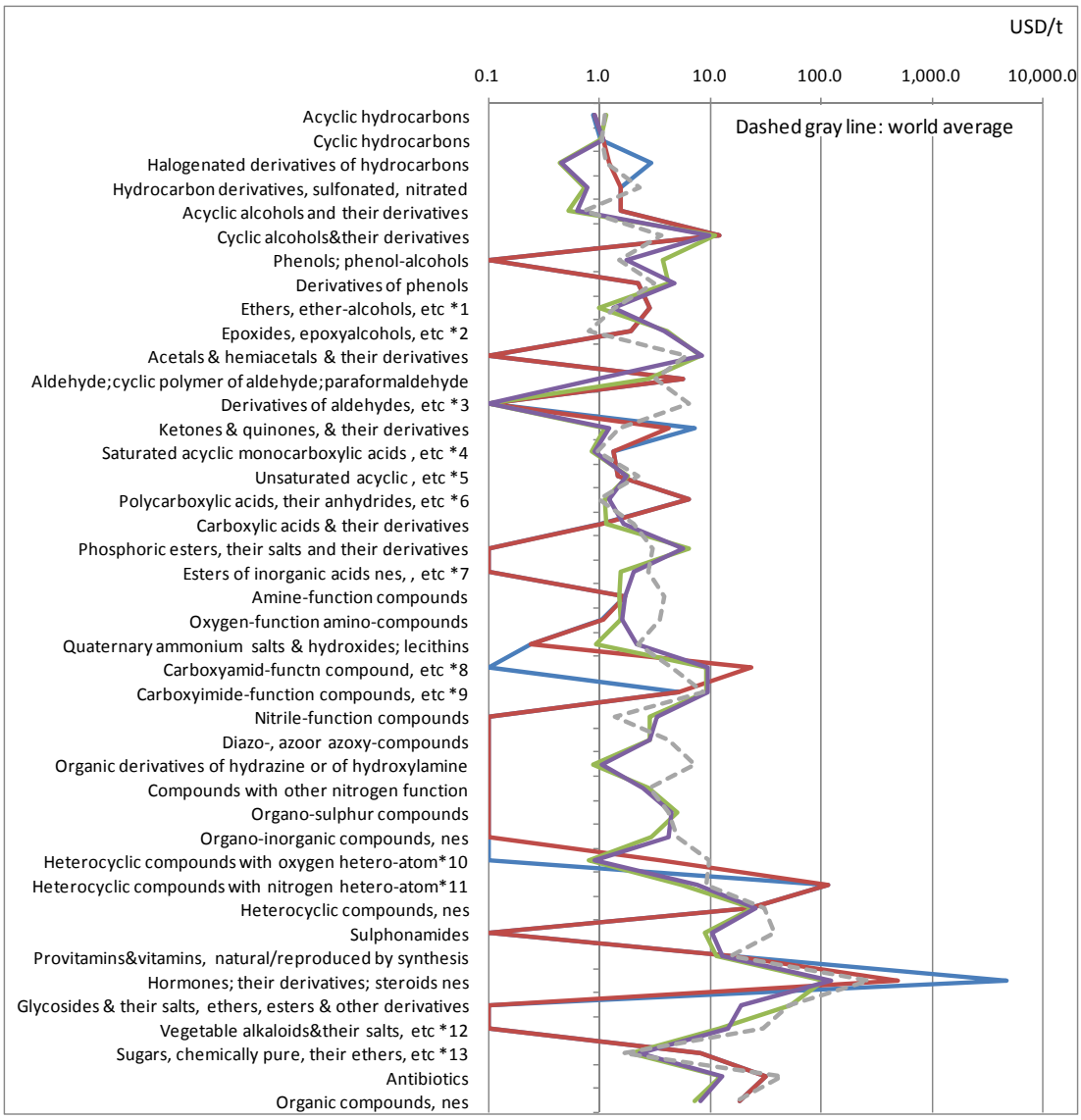
Figure 28: Value of import (negative) and export (positive) to ASEAN+6 and world (2008-2010 av.)



Source: UN comtrade

The difference of unit costs for importing and exporting with respect to the goods criteria is shown in Figure 29. Although some items show large differences (e.g., "Phenol; phenol-alcohols" or "Acetals and hemiacetals and their derivatives"), these differences are mainly because the imported and exported volume of these items is quite small. Therefore, these differences do not necessarily reflect differences in the industrial structure.

Figure 29: Unit value of Import and Export (2008-2010 average)



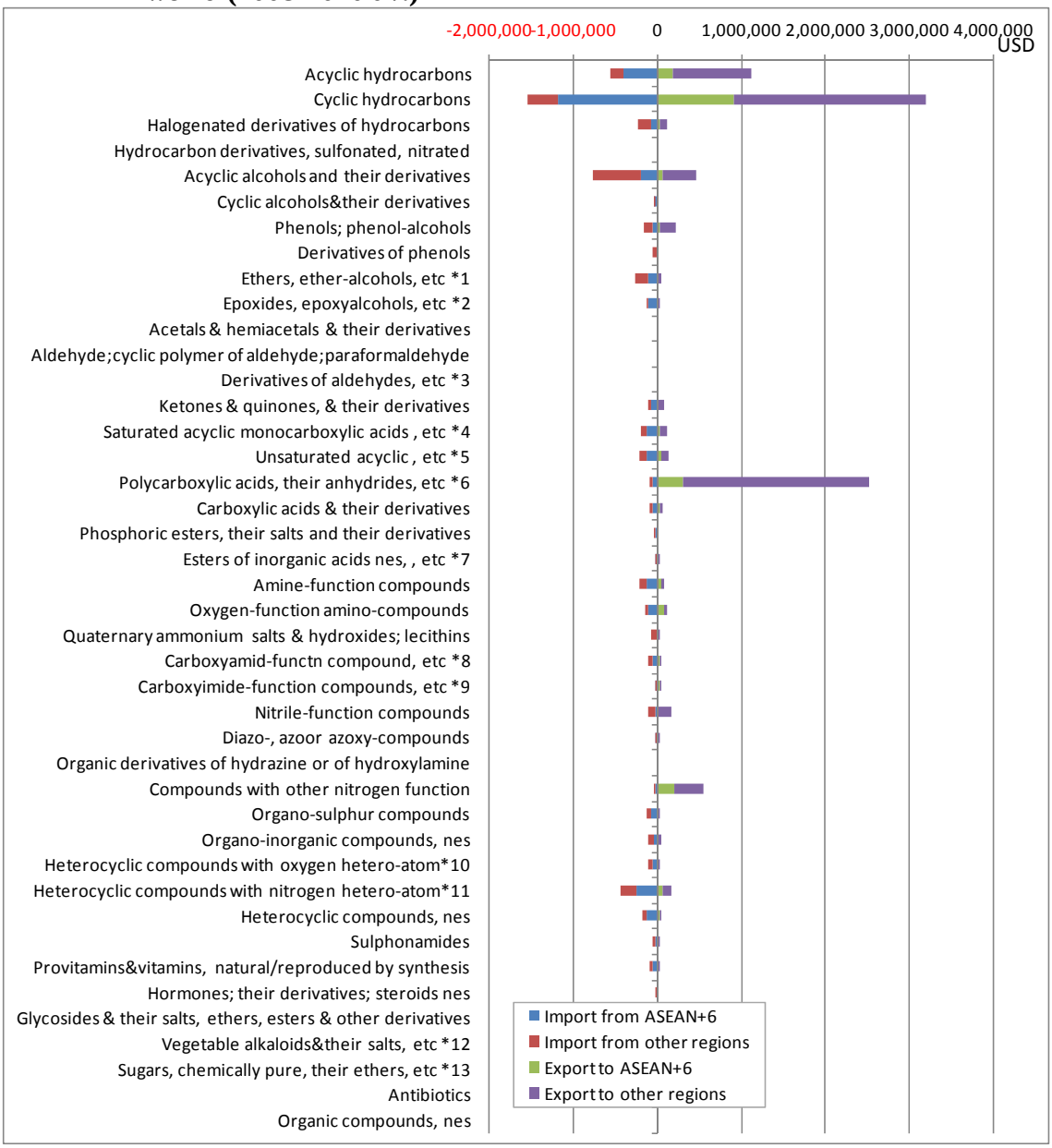
Source: UN comtrade

2.11. Chemical Substance Trading in the Republic of Korea

Trading of Chemical Goods

In the Republic of Korea, the exported value is generally higher than the imported value in the field of organic chemical goods, and in particular, the export of the "Cyclic hydrocarbons" and "Polycarboxylic acids, their anhydrides, etc." are of high value.

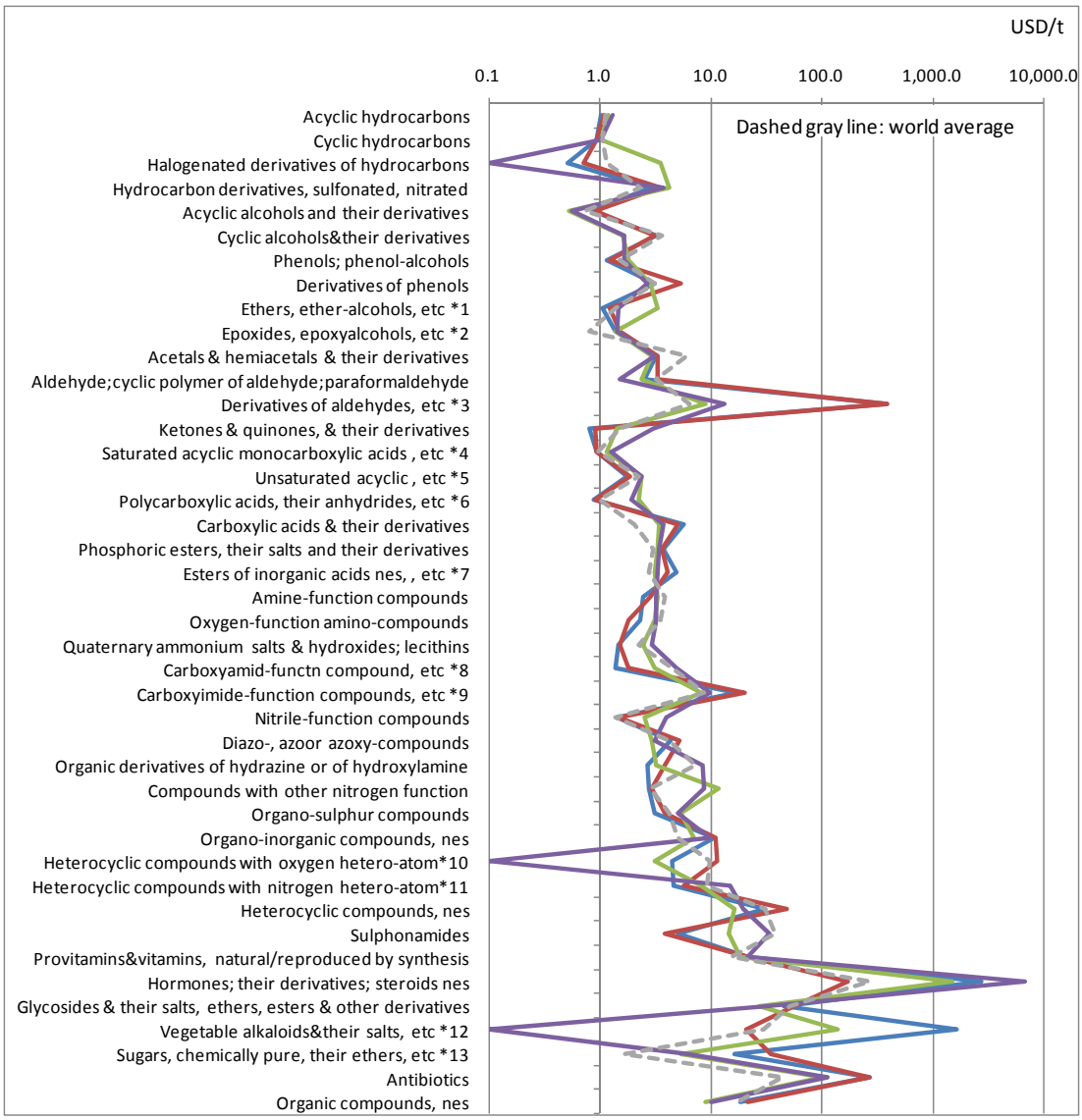
Figure 30: Value of import (negative) and export (positive) to ASEAN+6 and world (2008-2010 av.)



Source: UN comtrade

The difference of unit costs for importing and exporting with respect to the goods criteria is shown in Figure 31. Although some items show large differences (e.g., "Halogenated derivatives of hydrocarbons" or "Derivatives of aldehydes, etc"), these differences are mainly because the exported volume of these items is quite small. Therefore, these differences do not necessarily reflect differences in the industrial structure.

Figure 31: Unit value of Import and Export (2008-2010 average)



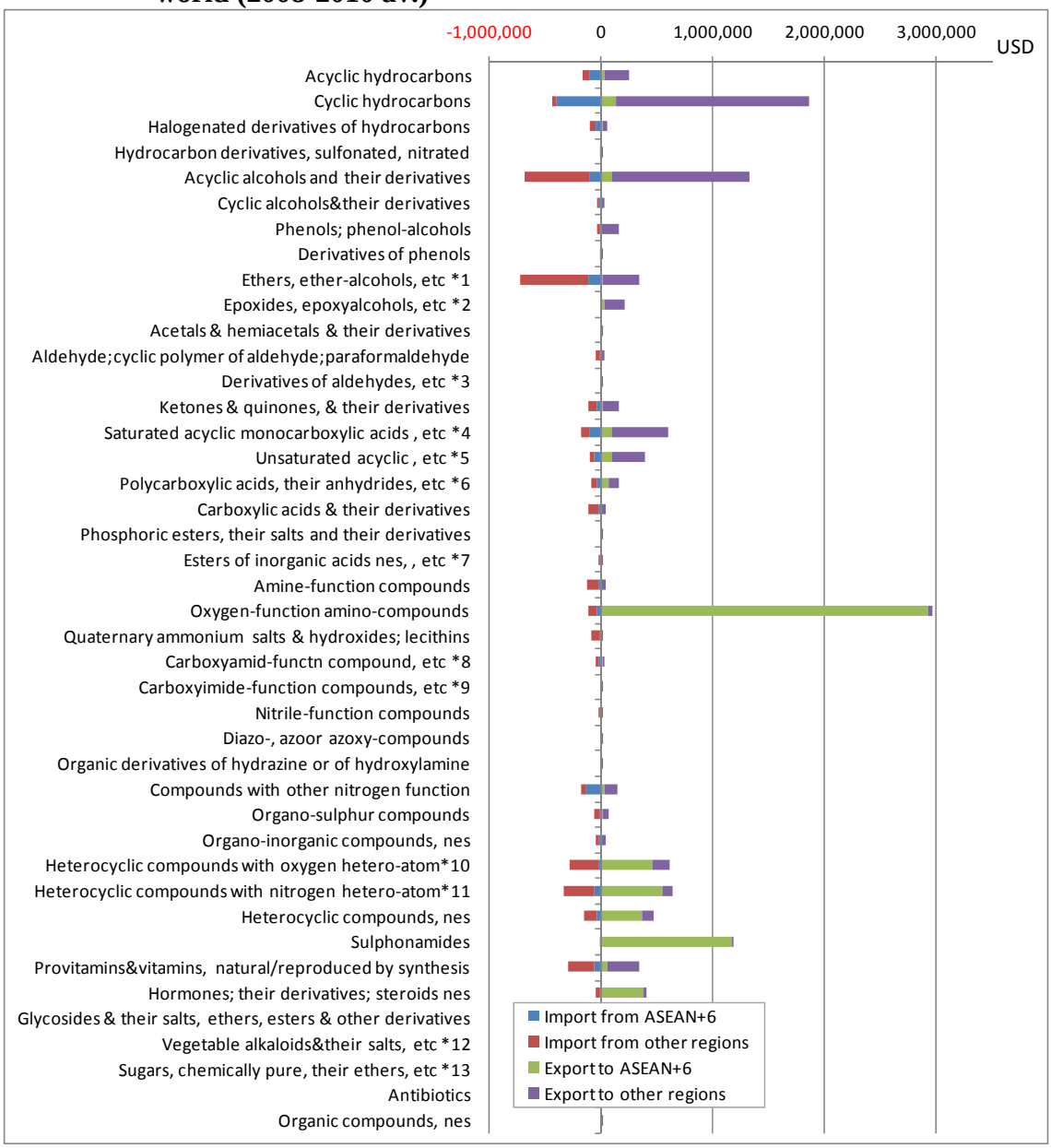
Source: UN comtrade

2.12. Chemical Substance Trading in Singapore

Trading of Chemical Goods

In Singapore, the exported value is much higher than of the imported value in the field of organic chemical goods (e.g., "Oxgen-function amino-compounds" and "Cyclic hydrocarbons").

Figure 32: Value of import (negative) and export (positive) to ASEAN+6 and world (2008-2010 av.)

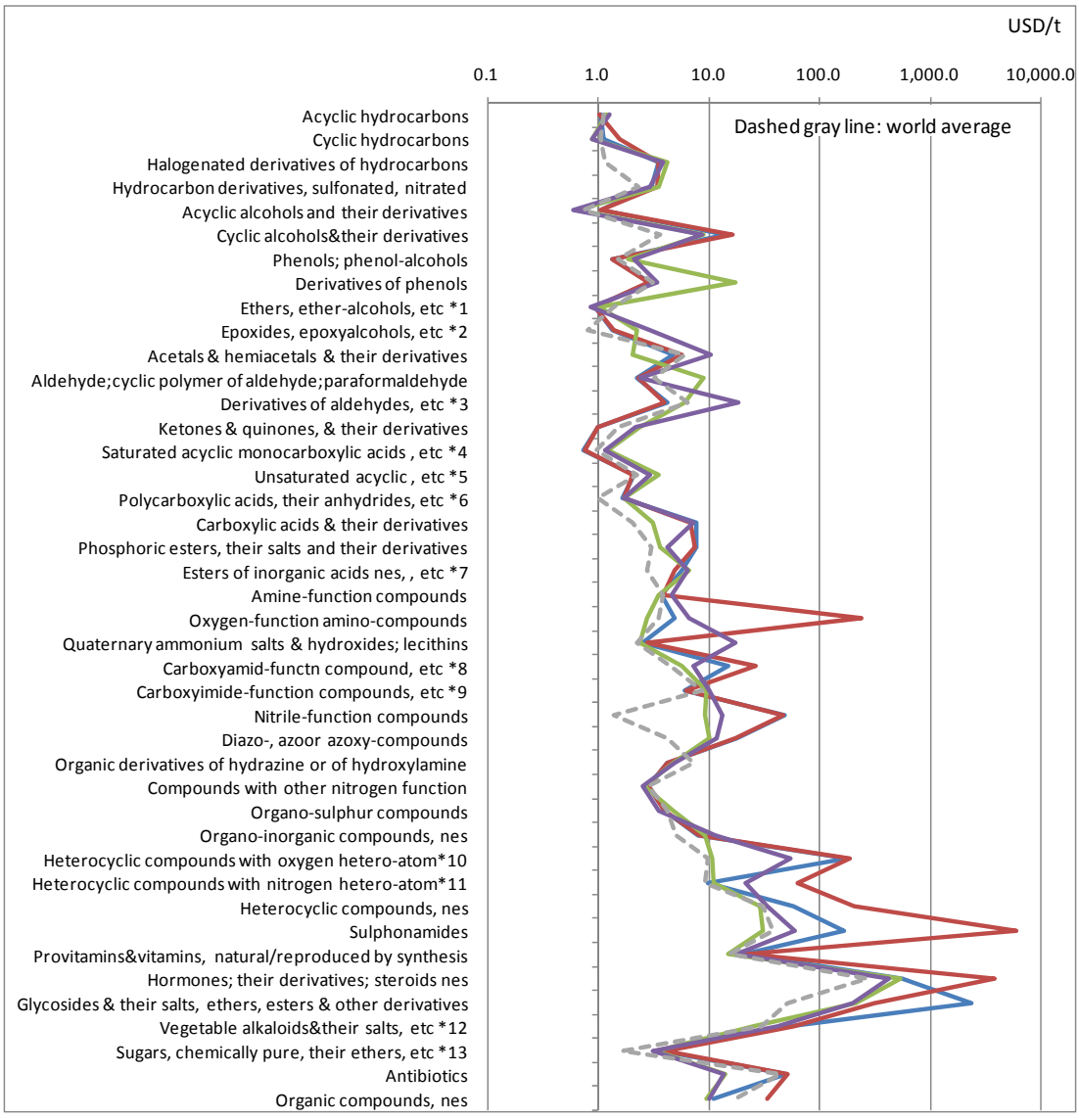


Source: UN comtrade

The difference of unit costs for importing and exporting with respect to the goods criteria is shown in

Figure 33. Although some items show large differences (e.g., "Sulphonamides" or "Hormones; their derivatives; steroids nes"), these differences are mainly because the exported volume of these items is quite small. Therefore, these differences do not necessarily reflect differences in the industrial structure.

Figure 33: Unit value of Import and Export (2008-2010 average)



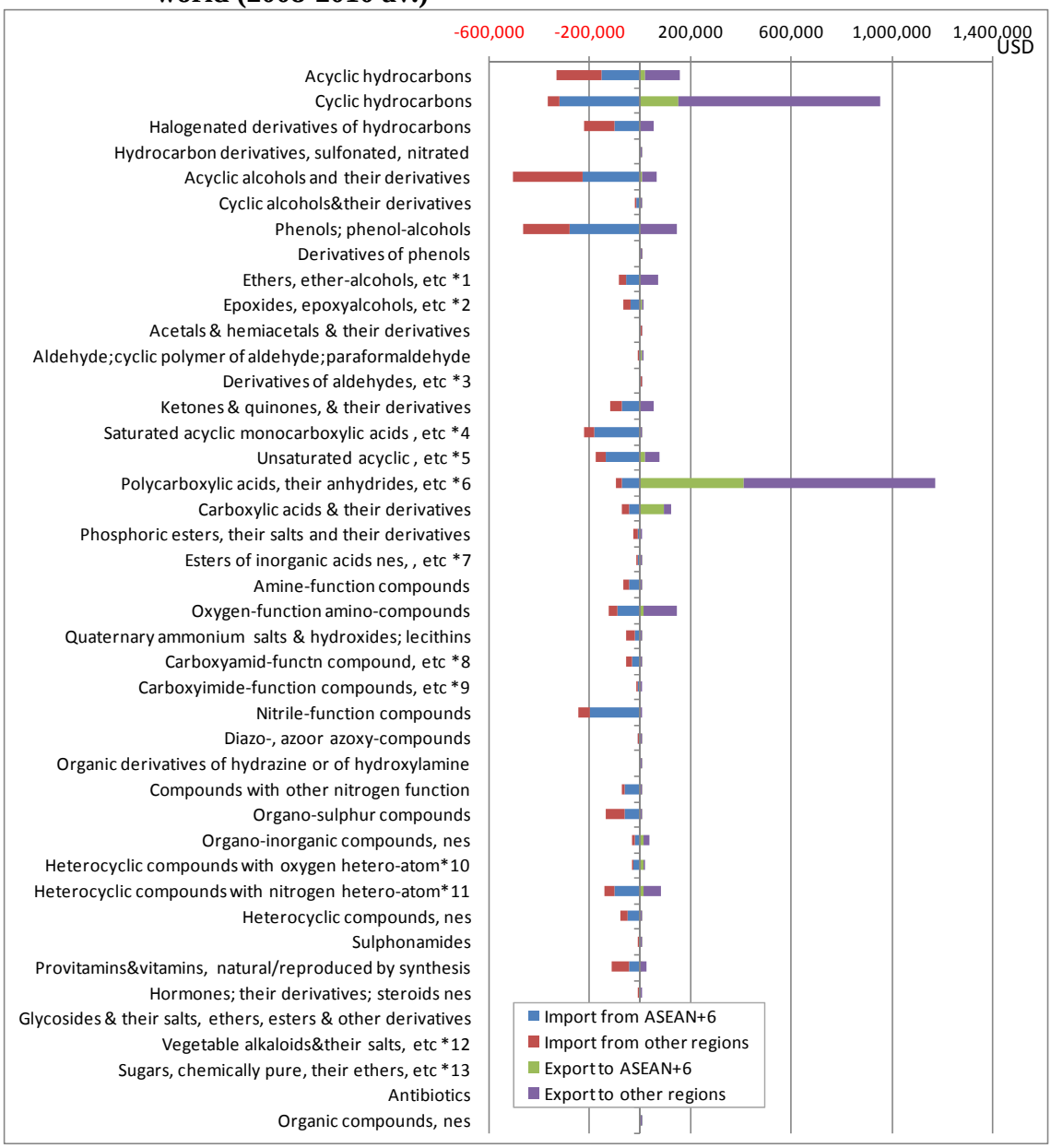
Source: UN comtrade

2.13. Chemical Substance Trading in Thailand

Trading of Chemical Goods

The imported value is generally higher than the exported value in the field of organic chemical goods in Thailand, in spite of some exceptions such as "Polycarboxylic acids, their anhydrides, etc" and "Cyclic hydrocarbons."

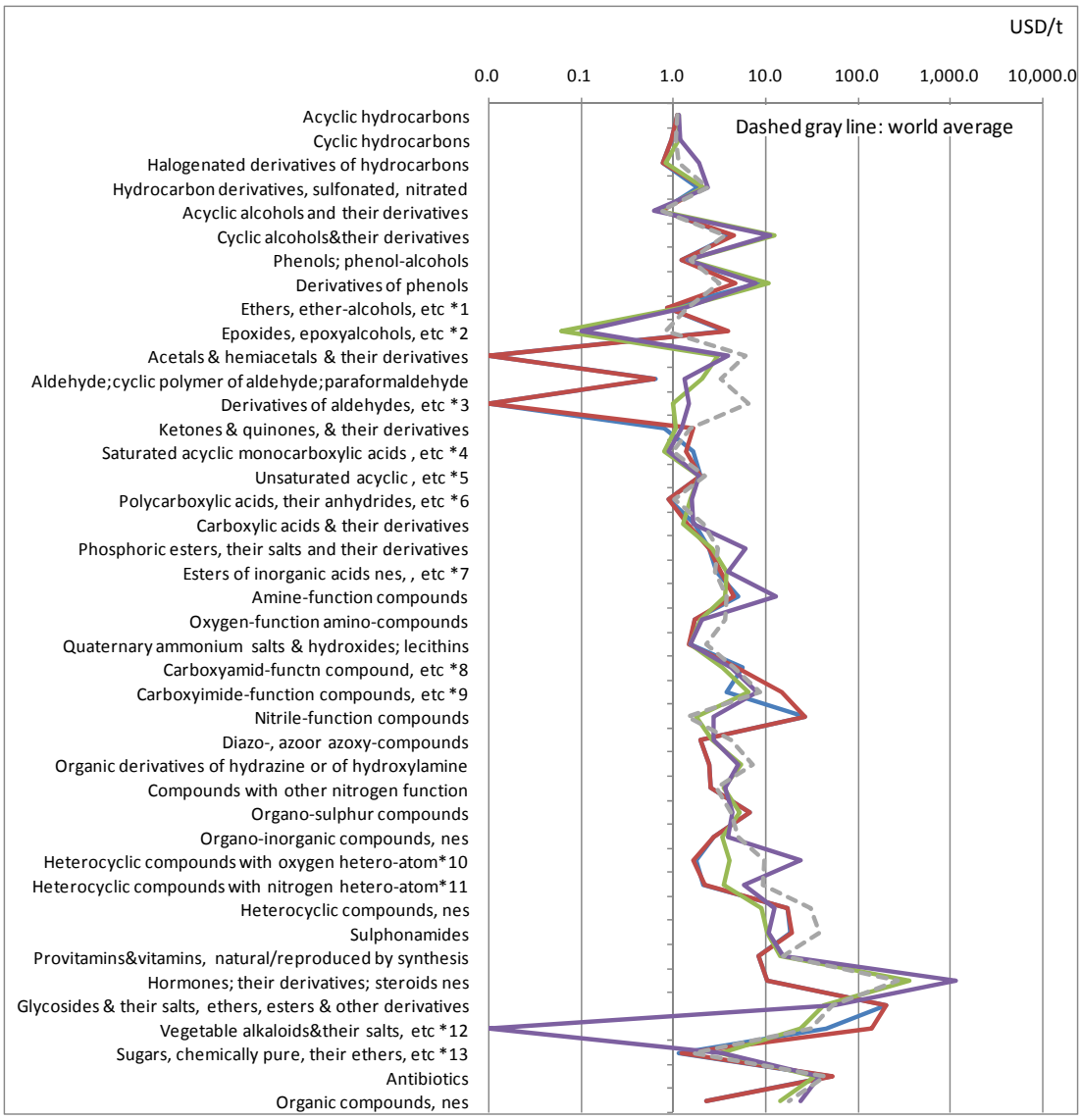
Figure 34: Value of import (negative) and export (positive) to ASEAN+6 and world (2008-2010 av.)



Source: UN comtrade

The difference of unit costs for importing and exporting with respect to the goods criteria is as shown in Figure 35. Although some items show large differences (e.g. "Acetals and himiacetals and their derivatives" or "Derivatives of aldehydes, etc"), these differences are mainly because the exported volume of these items is quite small. Therefore, these differences do not necessarily reflect differences in the industrial structure.

Figure 35: Unit value of Import and Export (2008-2010 average)



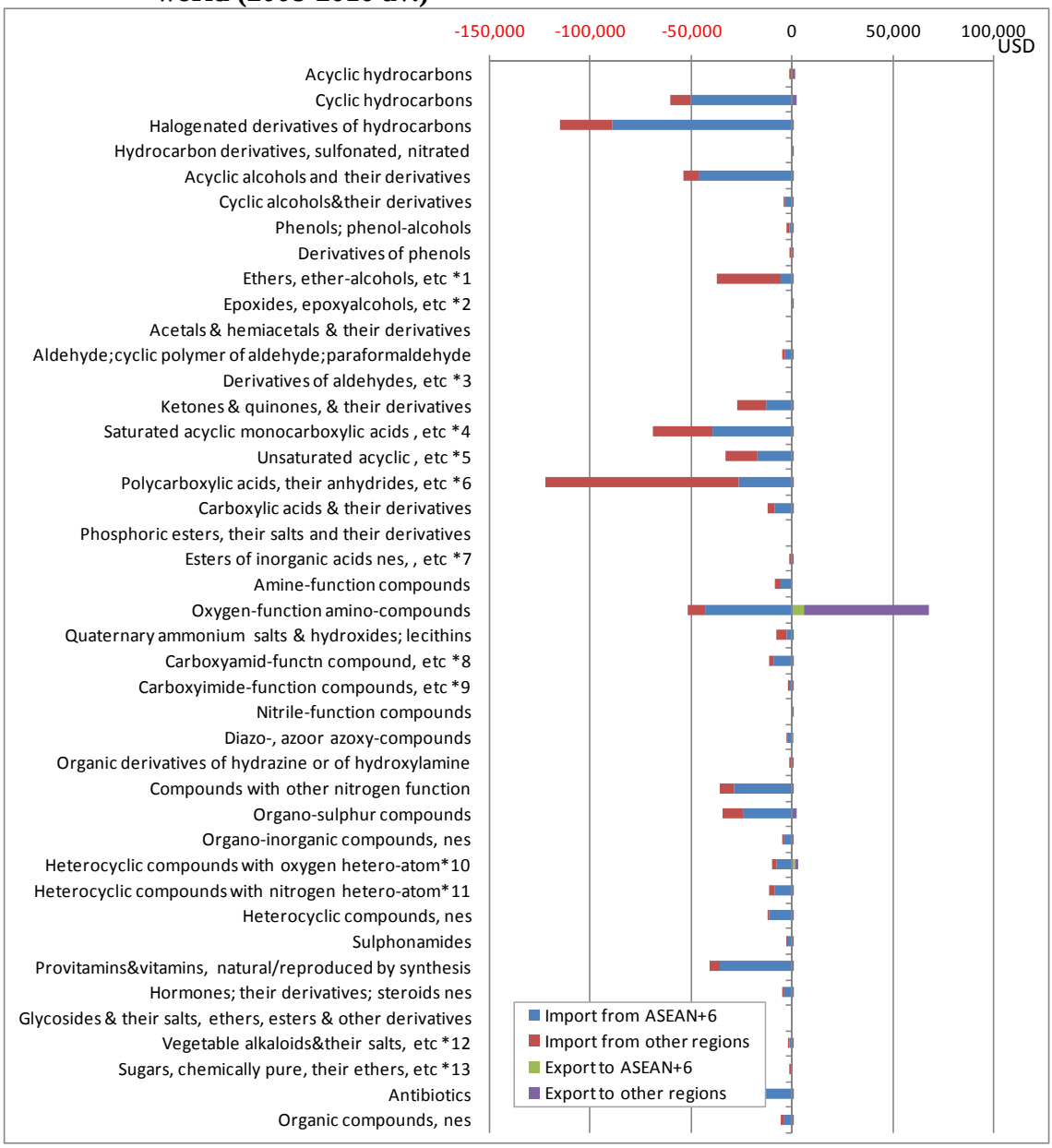
Source: UN comtrade

2.14. Chemical Substance Trading in Vietnam

Trading of Chemical Goods

The imported value is much higher than that of exported value in the field of organic chemical goods in Vietnam, and especially the import of the "Polycarboxylic acids, their anhydrides, etc" and "Halogenated derivatives of hydrocarbons" are of high value.

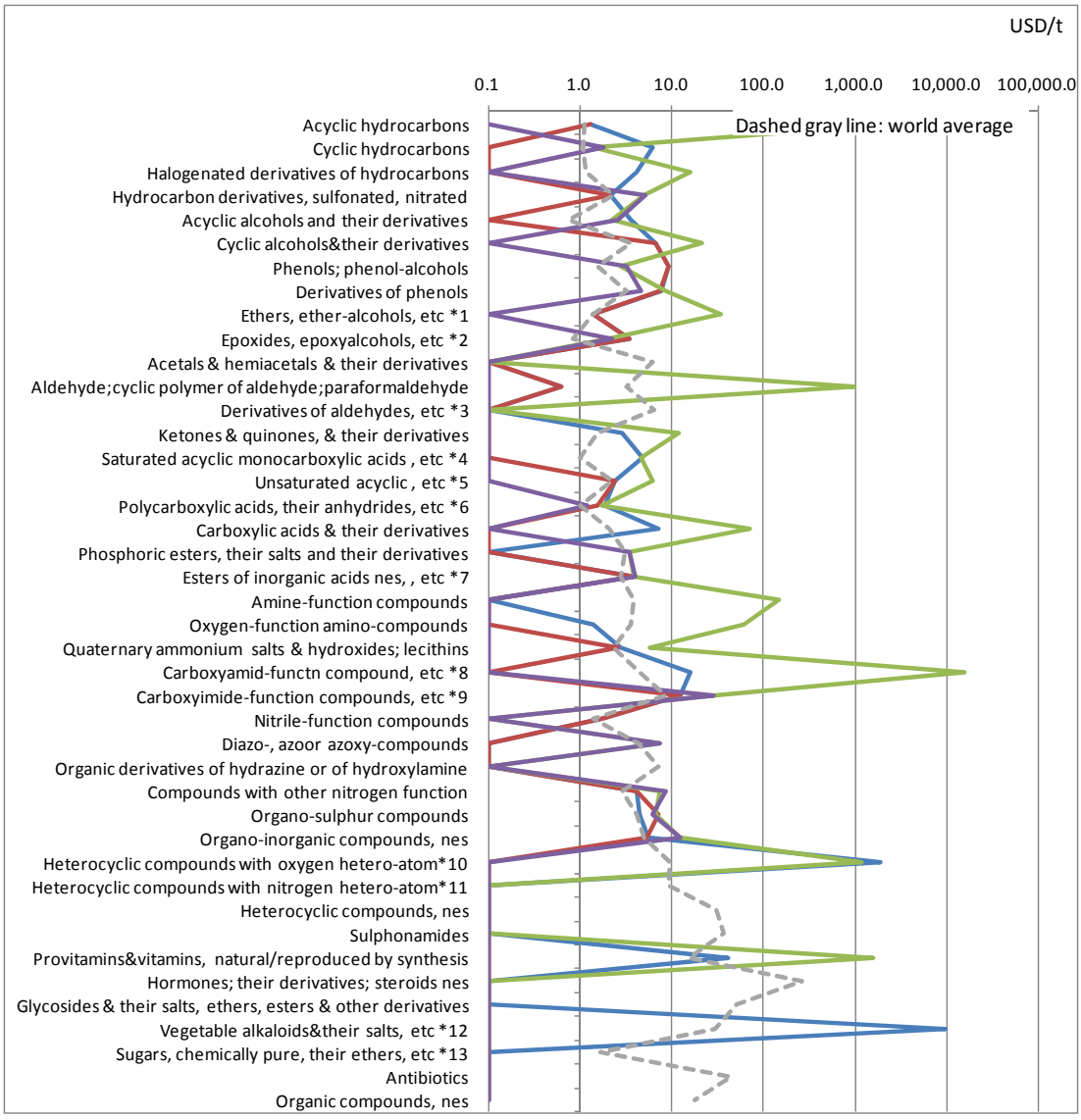
Figure 36: Value of import (negative) and export (positive) to ASEAN+6 and world (2008-2010 av.)



Source: UN comtrade

The difference of unit costs for importing and exporting with respect to the goods criteria is shown in Figure 37. Although most of the items show large differences, these differences are mainly because the exported volume of these items is quite small. Therefore, these differences do not necessarily reflect differences in the industrial structure.

Figure 37: Unit value of Import and Export (2008-2010 average)



Source: UN comtrade

CHAPTER 3

Outline of the Information Infrastructure in ASEAN and ASEAN and East Asia

In this chapter, the basic concept and outline of the proposed information infrastructure is described. Regarding the name of the infrastructure, basically there would be two options taken in to consideration: whether to describe the (legal) entity by itself only, or to describe it as one function. In the following chapter, a more comprehensive entity shall be proposed, and the infrastructure described below could be one function of that entity. Therefore, in this chapter, the infrastructure is described as a named function of that entity, and is hereafter referred to as the "ASEAN Chemical Safety Database."

1. Basic Concept of the ASEAN Chemical Safety Database

1.1. Mission of the ASEAN Chemical Safety Database

1) Target Setting

The ASEAN Chemical Safety Database pursues the achievement of the following targets, with the aim of establishing smooth distribution of chemical substances with assured safety.

1. *To share information on risks and hazards*
2. *To enhance transparency and reduce compliance risk through providing information regarding local regulations*
3. *To facilitate regulatory convergence among ASEAN and East Asian Countries*
4. *To reduce costs of duplicative testing and the burden of assessment*

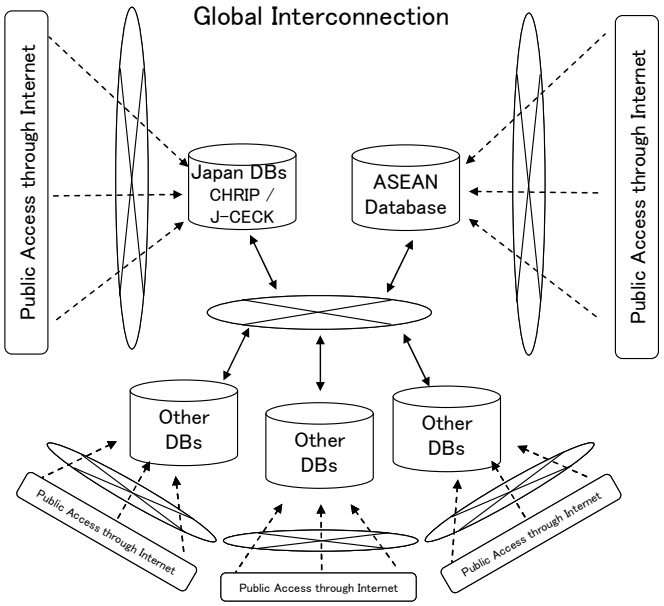
2) Previous Concept

Figure 1 illustrates the general schema of the ASEAN Chemical Safety Database examined until the last year. The ASEAN Chemical Safety Database is briefly summarized as follows:

- ✓ The ASEAN Chemical Safety Database shall be made accessible through the internet, so that it can be utilized by the public at large.
- ✓ The ASEAN Chemical Safety Database shall design mutual links with databases constructed by ASEAN, and databases in other countries, so the data can be used to best effect.

- ✓ The ASEAN Chemical Safety Database shall exchange data with information on risks and hazards with databases constructed by ASEAN and CHRIP in Japan in order to make use of information on risk and hazard data.

Figure 1: Thought starter



1.2. Possible Use of the ASEAN Chemical Safety Database

1) Investigation and Analysis of the Current Conditions

In order to understand the current conditions, we analyzed the need in each ASEAN Member States based on the questionnaire survey on the ERIA workgroup members. Moreover, in order to understand the conditions of databases in the world, we organized databases according to the way they manage their information on chemical substances.

A) Results of Questionnaire Survey on ERIA WG Members

The results of the questionnaire for the ERIA WG members are shown in Figures 2 to Figure 5.

Figure 2 displays the questionnaire on what chemical substance management information is needed. In the questionnaire, what chemical substance management information is needed is evaluated in 5-point scale, where 1 is the highest priority information, and 5 is the lowest priority information. We assigned 5 points for a response of 1, 4 points for 2, 3 points for 3, 2 points for 4, 1 point for 5, and 0 points for no response, and plotted the total number of points earned for each item. Since we obtained responses from 11 members, the maximum number of points is 55.

Figure 3 shows the results of the questionnaire on operations that use information of the Database, Figure 4 shows the answers to questions regarding the expectations of the Database, and Figure 5 shows the answers to questions on functions considered necessary for the Database. For the questionnaire, the number of responses obtained is plotted for each item.

Figure 2: What information does your country need for the ASEAN Chemical Safety Database?

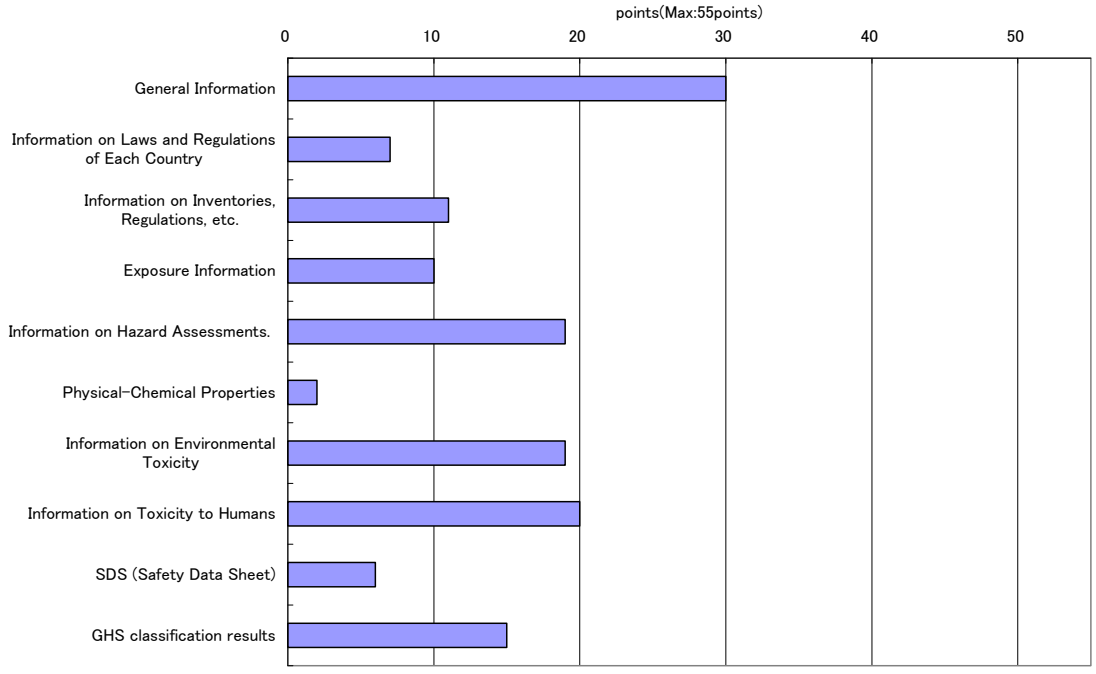


Figure 3: Please describe the possible usage of the output from ASEAN Chemical Safety Database.

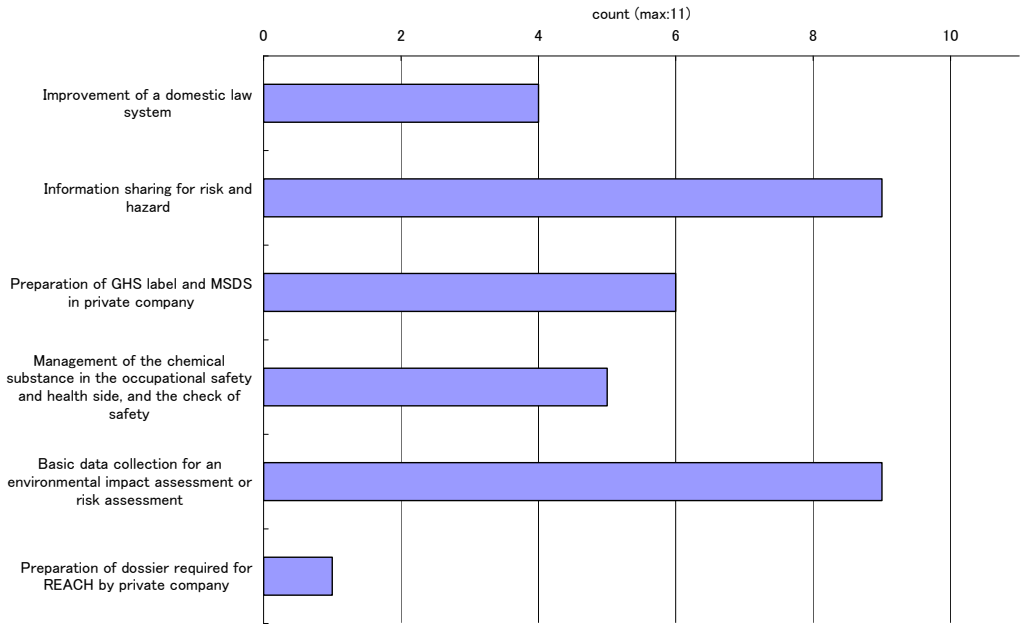


Figure 4: What does your country expect from the ASEAN Chemical Safety Database?

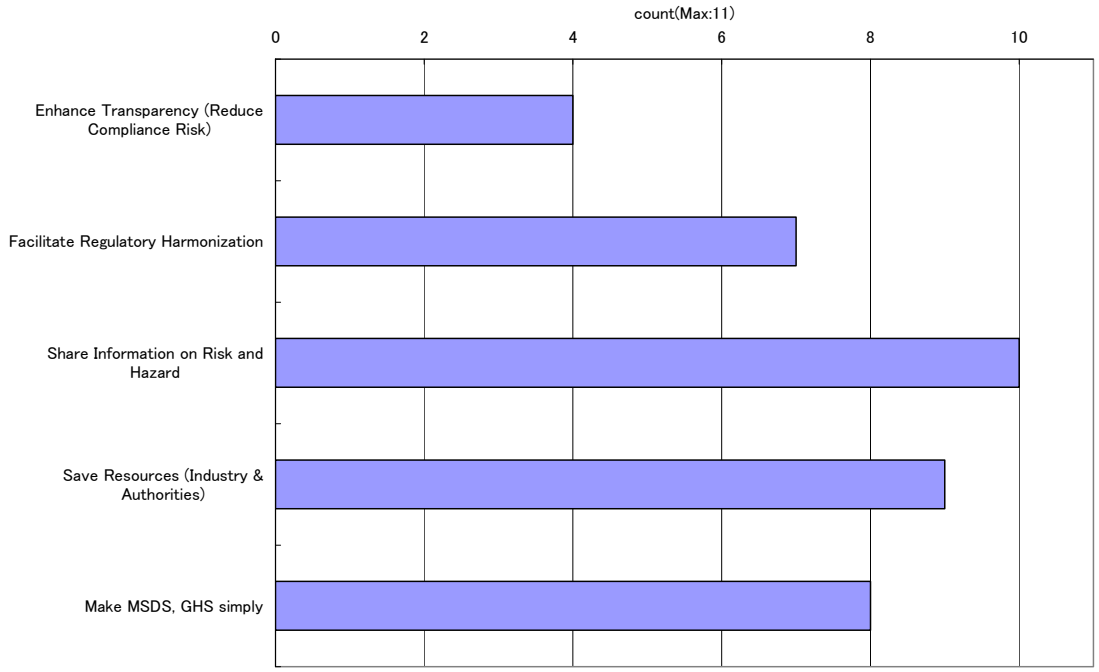
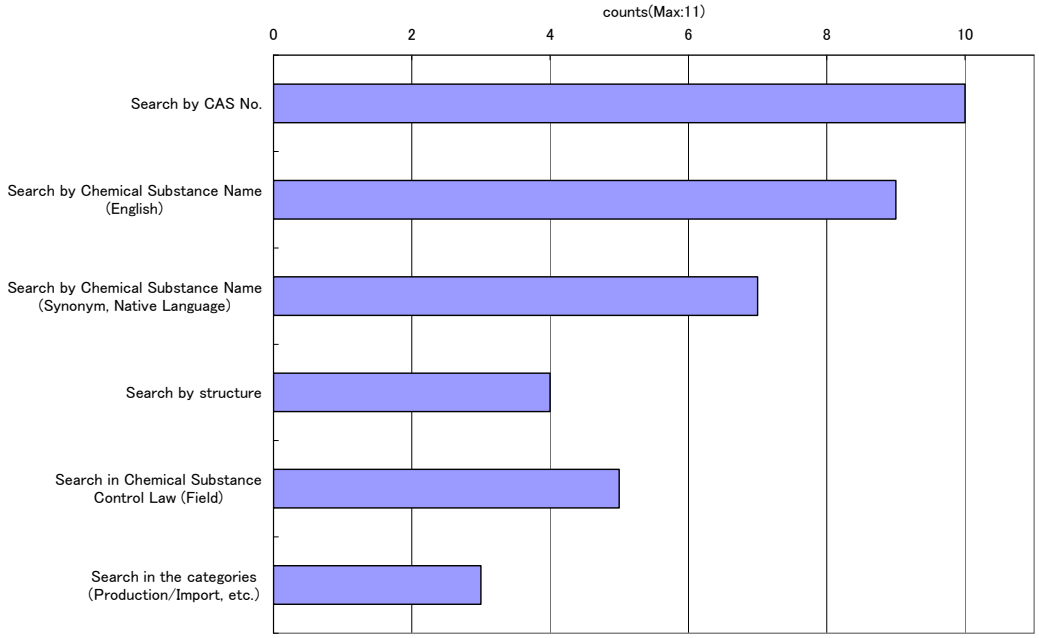


Figure 5: What functions should the ASEAN Chemical Safety Database have?



Looking at the results of the questionnaire survey, the chemical substance management information most highly needed by the WG members includes general information and information on toxicity to humans. Operations that use the information of the database most often are information sharing for risk and hazard assessment and basic data collection for an environmental impact assessment or risk assessment. The ASEAN Chemical Safety Database is highly expected to facilitate the sharing of information on risks and hazards and the centralization of information management.

Functions considered necessary for the Database to have included: Search by CAS No., and Chemical Substance Name (English).

The details of the items shown in Figure 2 are revealed in the following Table 1. A notation is included on the information provision of the SDS. As SDS is provided from many companies and the Database collects SDS information as a repository and discloses it with the notation of “not final.”

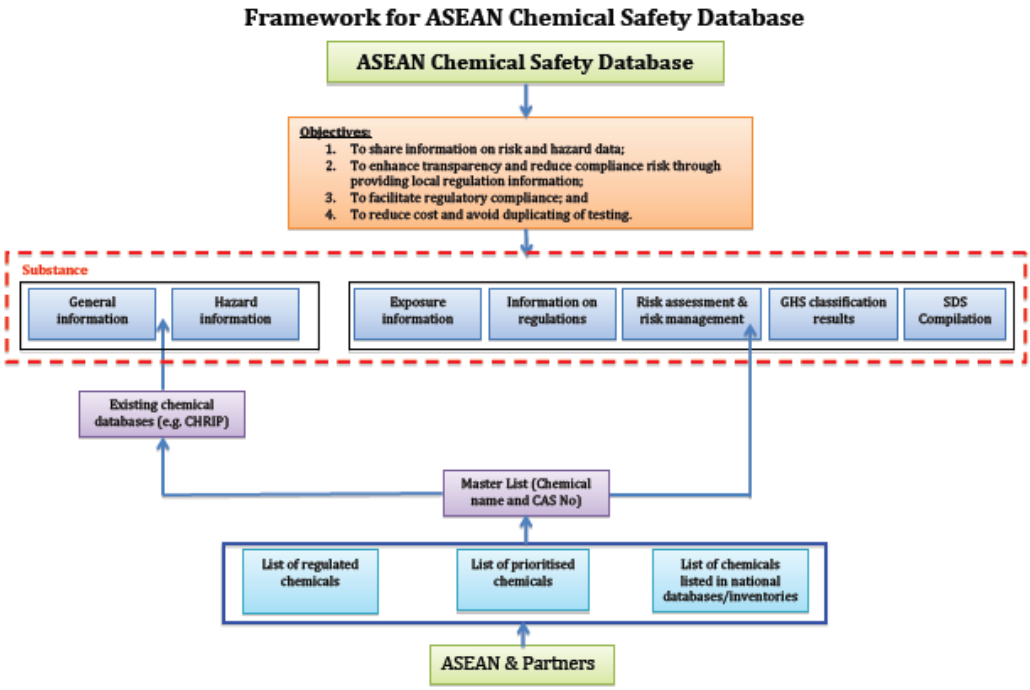
Table 1: Data Items

No.	Field	Specification
1	General Information	CAS No., Chemical Substance Name, Synonym, Structure, Total production amount
2	Information on Laws and Regulations of Each Country	Preventative information
3	Information on Inventories, Regulations, etc.	UN No. and Classification, ENICS, REACH Candidate List, etc.
4	Exposure Information	Produced and Imported amounts of chemical substances(each country), PRTR data, etc.
5	Physical-Chemical Properties	
6	Information on Hazard Assessments	
7	Information on Environmental Toxicity	
8	Information on Toxicity to Humans	American Conference of Governmental Industrial Hygienists (ACGIH), Carcinogenicity Assessment, etc.
9	GHS classification results	Pictogram, Signal word, Hazard statement, Precautionary statement
10	SDS (Safety Data Sheet)*	Examples of SDS

Note: *with note of "not final"

The framework of the ASEAN Chemical Safety Database was discussed by the WG for the purposes shown in Figure 1. The drafted framework of the ASEAN Chemical Safety Database, based on the discussion in the WG, is shown in Figure 6.

Figure 6: Framework for ASEAN Chemical Safety Database



The ASEAN Chemical Safety Database collects the lists of chemical substances from member countries in ASEAN and their partners. The possible information items to be collected are as follows:

- ✓ List of regulated chemicals
- ✓ List of prioritized chemicals
- ✓ List of chemicals listed in national databases/inventories

The ASEAN Chemical Safety Database integrates these three lists, and makes the list of a chemical substance name and CAS No. The ASEAN Chemical Safety Database indicates the data from Table 1, corresponding to the above list

B) Current Conditions of Chemical Substance Management Intelligence Infrastructure Surrounding ASEAN

We investigated several databases that provide chemical substance management information on the information stored, search keys, result display, and data location. The result of this investigation is shown in Table 2.

Table 2: Example of Other Chemical Databases

Database	Repository	Search Key	Results	Origin
eChemPortal	General/Hazardous	CAS/Property	Link Table	Other site
J-CHECK	General/Hazardous	CAS/Property	Data Table	This site
CHRIP	General/Regulation/Ha	CAS/Regulation/Pr	Data Table	Other site/
ECHA CHEM	General/Hazardous	CAS	Link Table	This site

Remark: Repository, Search Key and Results are representative values to compare databases.

Considerable differences for the database specification were seen in the method of result display and data location. As for result display method, if results are displayed as a list of links, as in eChemPortal, users must click the screen many times until the desired data is displayed. On the other hand, if data is displayed as a list, as in CHRIP, it is easier to grasp the perspective of data, and it is simpler for users to find the data they are looking for.

As for data location, if data is located on other sites, administrators need to perform operations to update/check data to be displayed in data lists, and acquire data, placing an extra burden on administrators. On the other hand, if data is placed on local sites, it can display a data list by updating data in databases, making it possible to suppress the labor

[1] Here the Search Key "Regulation" corresponds to a function that enables users to check whether the searched chemical is restricted under selected regulations or not.

of administrators in data list display, compared to cases where data is placed on other sites.

2) Examination of an Ideal Database

We deliberated how the ASEAN Chemical Safety Database should be based on the needs of the ERIA WG members, the current conditions of regulatory information in each country, and the conditions of chemical substance management databases surrounding ASEAN.

A) Viewpoints in Consideration

We considered how the Database should be organized, from the following three aspects of information: input/output to/from databases, operations of databases, and construction of databases. The result of our consideration is shown below.

- Information input/output to/from databases
  - ✓ It is possible to search through databases by CAS No. and chemical substance name.
  - ✓ Databases include inventory information of chemical substances compliant with regulations.
  - ✓ Databases include information on human toxicity of chemical substances in the inventory.
- Operations of databases
  - ✓ Databases are operated according to a schedule. This schedule determines the scope and period of gathering information registered in databases.
  - ✓ Data in databases shall be managed by the authorities in each country. Data management refers to data registration (addition of inventory information, information on human toxicity, etc.) and other tasks.

- ✓ Management of users and systems of databases shall be performed by the operator. User management refers to tasks of managing ID and passwords of users who register data etc. System management tasks include data backup, securing security, etc.

♦ Construction of databases

- ✓ It needs to be possible to construct databases within the ASEAN Chemical Safety Database in a way that means countries without existing databases can join the ASEAN Chemical Safety Database.
- ✓ It needs to be possible for countries with databases to use their own databases from the ASEAN Chemical Safety Database, so that they can easily join the ASEAN Chemical Safety Database.

B) Information Output from Databases

We deliberated over 4 display options for information output from databases. The screen images of the 4 options are shown in Table 3 to Table 6.

In all of these display options, results of searches by CAS No. or chemical substance names are shown, and the search results shall display the information on regulations and hazards in each country for each regulatory target area.

As with the regulatory information for each country, links to Web pages containing regulatory information of each country or links to regulatory pages within databases shall be displayed.

In terms of displaying information on hazards, each of these options is different from the others:

- ☐ Case 1

  Links to databases providing information on hazards are displayed. The links to be displayed shall be set manually.

☐ Case 2

Representative values in information on hazards are displayed. The representative values shall be set manually.

☐ Case 3

Displays representative values of databases providing information on hazards if data can be provided automatically. If data cannot be provided automatically, links to databases shall be displayed. The links to be displayed shall be set manually.

☐ Case 4

Representative values in information on hazards are displayed. The representative values shall be set either automatically or manually. If data cannot be provided automatically, and cannot be set manually, links to databases shall be displayed. Links to be displayed shall be set manually.

Table 3: To be system – case 1

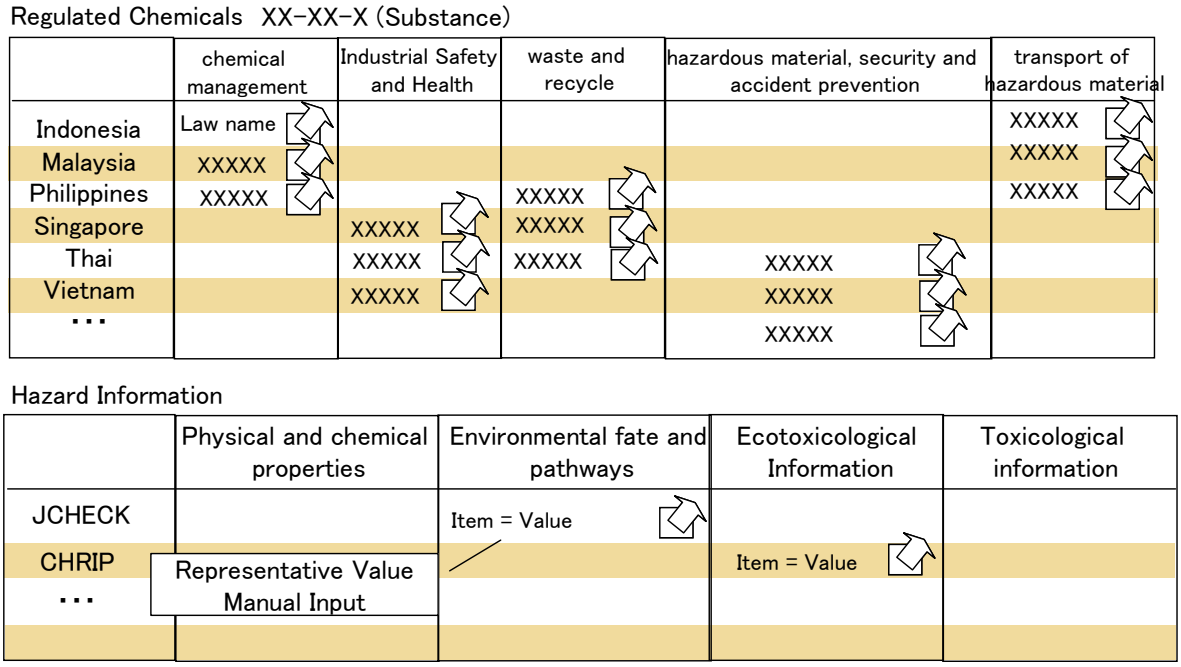


Table 4: to be system – case 2

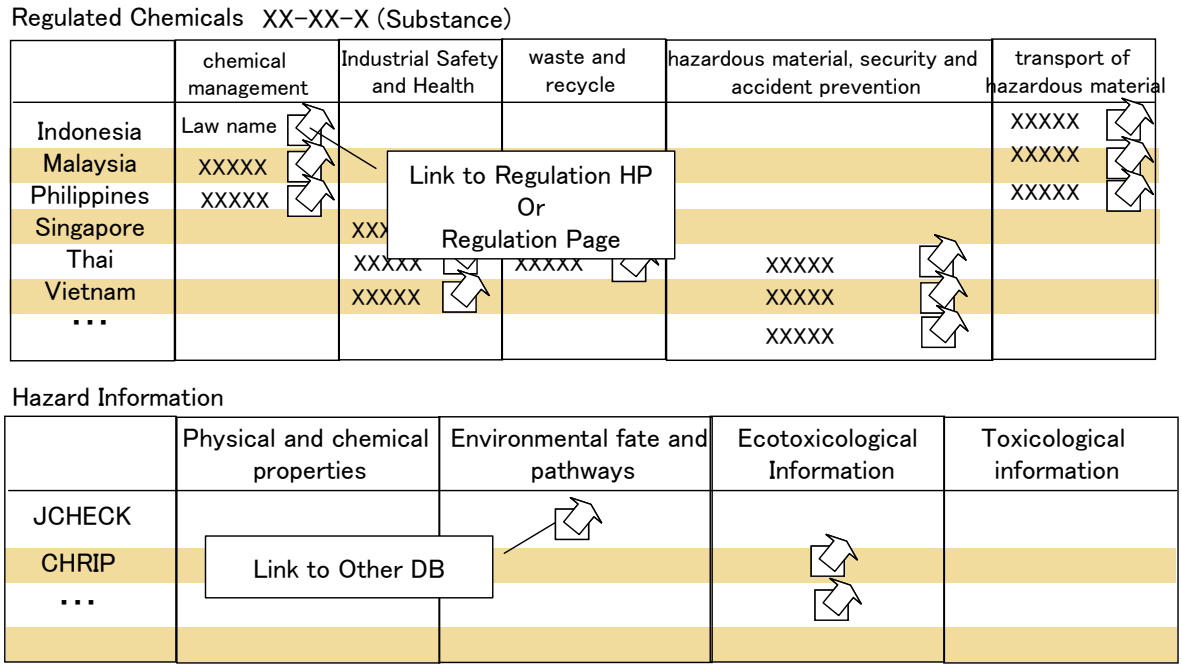


Table 5: to be system – case 3

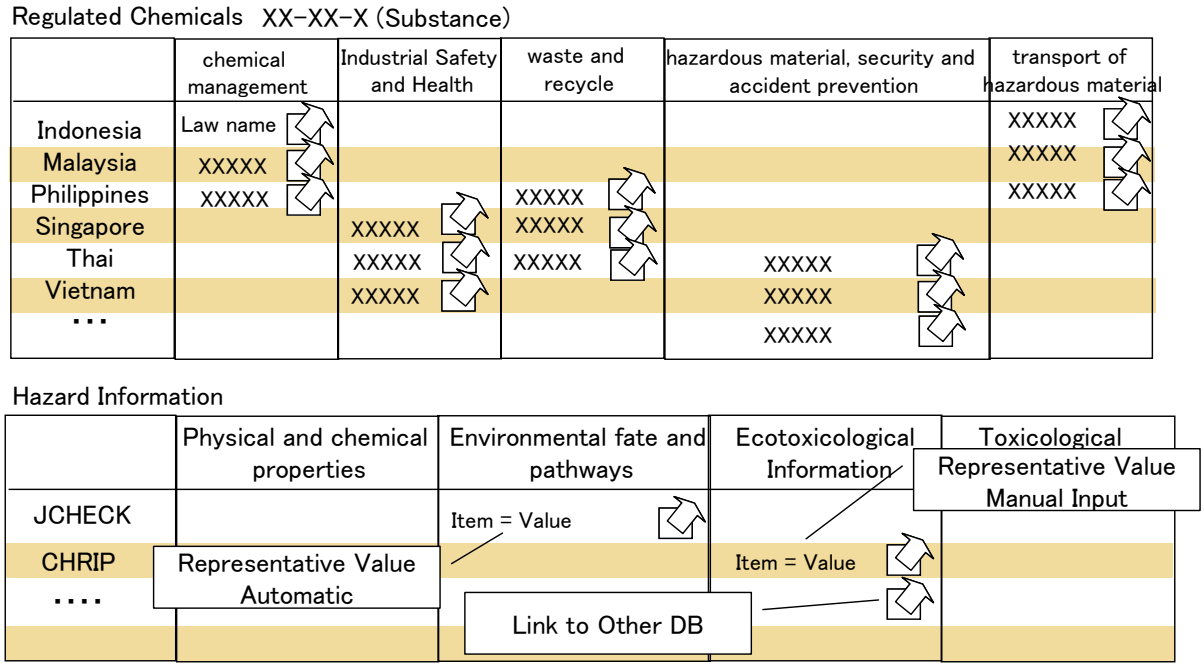


Table 6: to be system – case 4

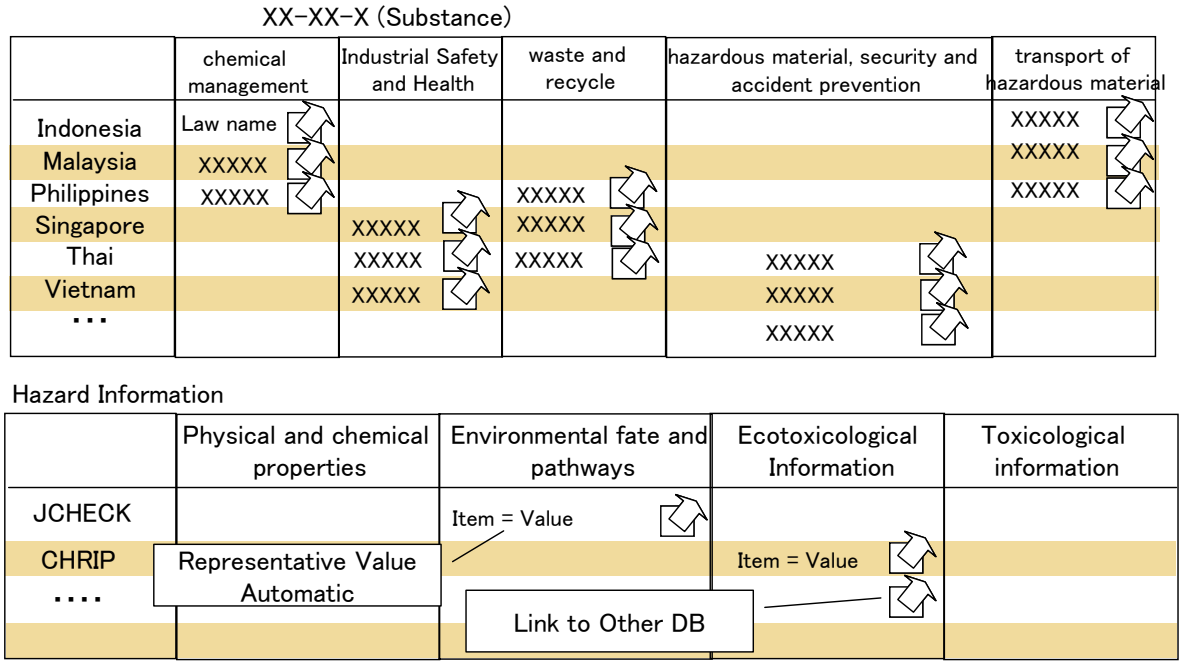


Table compares the display of cases 1 to 4, concerning information input/output to/from databases, database operations, and database construction.

The representative database of case 1 is eChemPortal. In case 1, both operation and construction are easier than in the other cases, but a list of data cannot be displayed; users must click links many times until the desired data is obtained.

CHRIP is a typical database of case 2. With case 2, users can find the desired data with ease compared to case 1. However, manual work is required to maintain data, placing more labor on administrators than in the other cases.

Case 3 combines advantages of cases 1 and 2. We were unable to find existing databases falling under case 3. In case 3, a data list displays values of databases whose data can automatically be obtained in order to reduce work required to maintain data. In this case, it is necessary to construct a function to automatically display data for databases that provide data.

In Case 3, a database which cannot perform automatic registration instead displays a link. It may be more useful to display data into these databases. With this in mind, we deliberated Case 4, which is a hybrid of Case 3 and Case 2. In Case 4, data which cannot perform the automatic registration of Case 3 is registered using the function of Case 2.

Table 7: Comparison of CASE 1 - CASE 4

	Case 1	**Case 2**	**Case 3**	**Case 4**
Representative Database	eChemPortal	CHRIP	N/A	N/A
Input / Output	Data is not shown in the results table. Cannot hold the global image of data. Should click many times until useful data is found.	Data is shown in the results table. Can hold the global image of data. Can obtain useful data by one click.	Data is shown in the results table. Can hold the global image of data. Can get useful data by one click.	Data is shown in the results table. Can hold the global image of data. Can get useful data by one click.
Operation	Not to register data.	Difficult to register data. Register data manually.	Easy to register data. Register data automatically.	Easy to register data. Register data automatically and manually.
Modification of national databases	Not required	Not required	Might be required*1	Not required*2

Note: *1 Modification of national database might be required if each country's data (not link) should be displayed and updated automatically.

*2 Modification of national database shall not be required as long as the automatically update is not required.

3) Application of the Database to Practical Operations

We examined how the Database can be utilized in chemical substance management operations, from both standpoints of regulating chemical substance and using chemical substance in industries.

- Regulatory standpoint
  - ✓ Review of chemical substance regulations of home country based on environmental impact assessment and risk assessment
    The Database allows corresponding regulatory information and environmental impact assessment and risk assessment for each chemical substance. It becomes possible to review regulations of chemicals with no regulatory information since environmental impact assessment and/or risk assessment are performed
  - ✓ Confirmation of information on risk and hazard of chemical substances
    The Database allows displaying environmental impact assessment and risk assessment of each country. The comparison of information on risk and hazard of relevant chemical substances not only at occurrence of accident but also as a precautionary purpose enables study of safer measures.

- Industrial standpoint
  - ✓ Checking regulations on chemical substance distribution in each country
    The Database allows viewing regulatory information of each country for each chemical substance. It is thus possible to check regulations of target country in distribution of chemical substances in East Asia with ease.

4) Concept

After the deliberations of 1)–3), further description of the concepts of ASEAN Chemical Safety Database is as follows.

- ✓ It is possible to search CAS No. and chemical substance name, inventory information of chemical substances compliant to regulations, and information

on toxicity to humans of chemical substances in the inventory from databases via Internet.

- ✓ Through the discussion in the WG, Case 4, which displays automatically and manually updated values of databases, were agreed as the most preferable option for mutual links.

- ✓ Exchange data of information on risk and hazard has an automatic method for suppressing operation costs.

2. Outline of the ASEAN Chemical Safety Database

2.1. Functions of the ASEAN Chemical Safety Database

The ASEAN Chemical Safety Database provides three functions for searching, registering, deleting, and editing data as well as logging change and usage histories, as listed below.

- ♦ Search
  - ✓ Display regulatory information and information on toxicity via a keyword search, in order to retrieve target information.
  - ✓ Keyword search shall allow the following search methods.
    - Search by CAS No.
    - Search by chemical substance name (English)
  - ✓ Regulatory information and information on toxicity shall be displayed in 2 steps, as is done in several other databases.
    - First step: collect and display information from each country as a list
    - Second step: display web pages published by individual countries

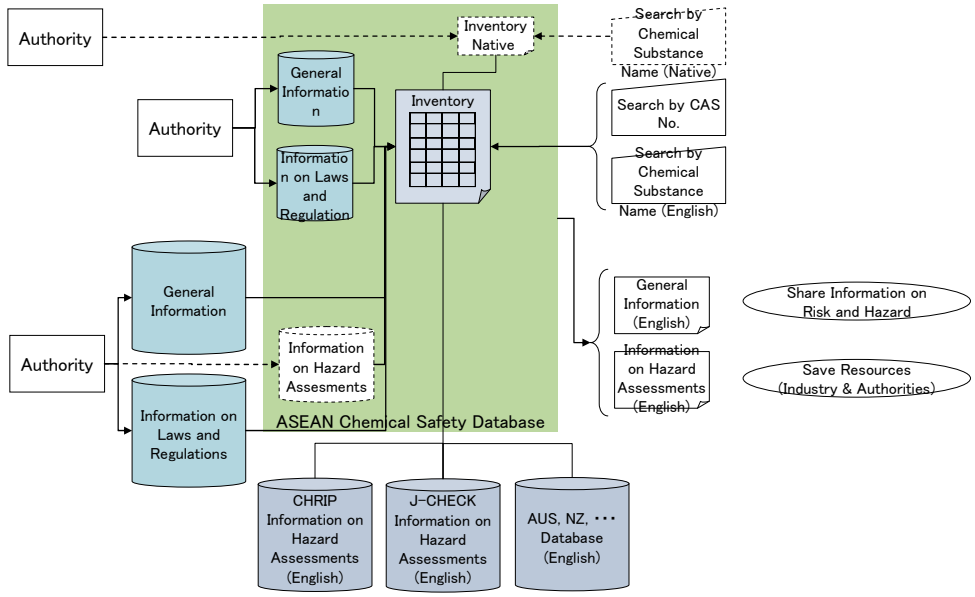
- Registration/deletion/editing
  - ✓ Register, delete, and/or edit regulatory information so that agencies in each country can maintain data
  - ✓ Provide the following functions according to the amount of information
    - Register, delete, and/or edit information directly in web pages
    - Register, delete, and/or edit data files such as CSV files (effective when there are large amounts of data)
- History
  - ✓ The following functions shall be provided in order to secure the reliability of information and allow analysis of usage conditions.
    - History of registration, deletion, and edition: which agency worked on which information
    - Usage performance: which country conducted searches using which keywords

2.2. Management of the ASEAN Chemical Safety Database

Figure 7 illustrates a general overview of the database management. The relevant authorities of each country shall manage the general information and information on laws and regulations related to the chemical substances stored in the databases.

Chemical substances and CAS No. are associated via general information management, while CAS No. and details of regulations are associated via the management of information on laws and regulations. In cases where individual ASEAN member countries have their own databases, links to these databases shall be entered in the inventory of the ASEAN Chemical Safety Database. If a country does not have its own database, the general information and information on laws and regulations shall be registered in the databases of the ASEAN Chemical Safety Database.

Figure 7: Management of ASEAN Chemical Safety Database



In the management of information on risks and hazards, agencies of each country register information on risk and hazards of chemical substances corresponding to each relevant CAS No. in the ASEAN Chemical Safety Database. In addition, the operators of the ASEAN Chemical Safety Database shall register links to data in databases on information on risk and hazard in Japan (CHRIP, J-CHECK), Australia, and New Zealand based on CAS No. in the inventory.

ASEAN member countries' authorities set up open limits of general information and information on risk and hazard to ASEAN Chemical Safety Database.

Table 8 and Table 9 show the operations and cost of administration. The operations of Authority relate to the data creation of Chemical substances, CAS No., and Regulations. The cost of each case is based on Case 1.

The operations and cost of administration differ, depending on whether the data itself is located inside or outside of the database. When data is inside the database, in every case, each administrator is required to prepare the data.

Table 8: Administration Operation (Data outside)

Operation	Case 1	Case 2	Case 3	Case 4
Chemical substances and CAS No.	Connecting	Connecting	Connecting	Connecting
Chemical substances and Regulations	Connecting	Creation	Connecting	Connecting Creation
Cost	C_A	2 C_A	C_A	C_A to 2 C_A

Note: * C_A: Authority Cost in Case 1 and Case 3

Table 9: Administration Operation (Data inside)

Operation	Case 1	Case 2	Case 3	Case 4
Chemical substances and CAS No.	Creation			
Chemical substances and Regulations	Creation			
Cost	4 C_A			

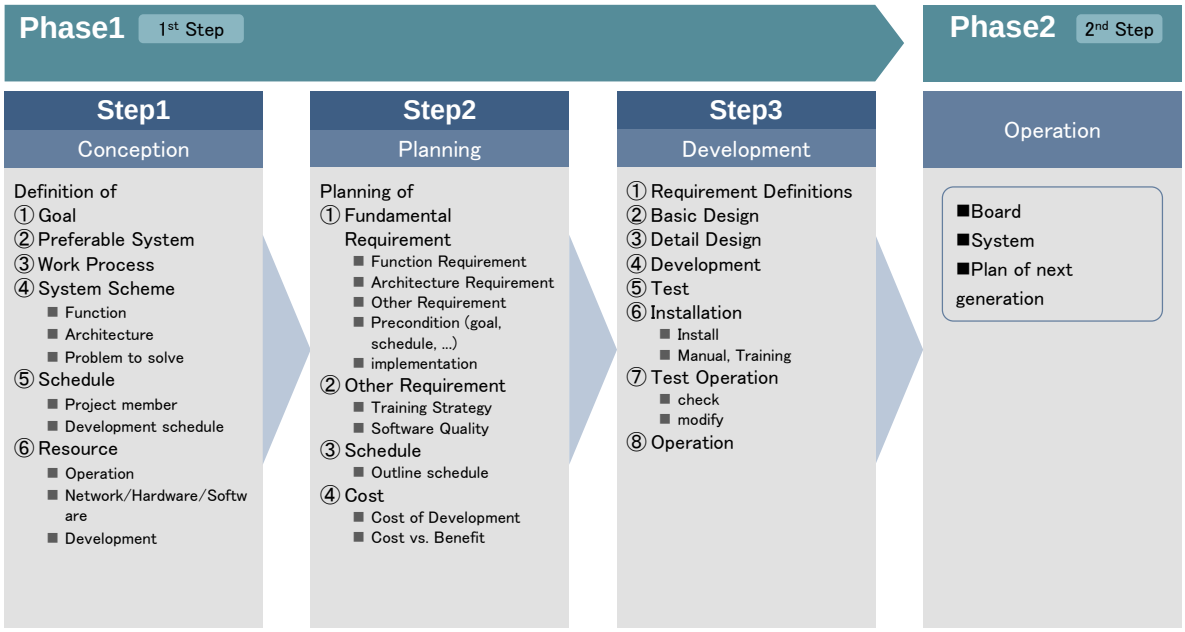
In Case 1, the administrator makes the connection between a chemical substance and regulations, connecting the CAS No. and a chemical substance. In Case 2, whenever any of the regulations are revised, the administrator prepares the data, as consistent with revised regulations. Therefore, the cost of administration in Case 2 is higher than in Case 1, and this difference is caused by the data creation. In Case 3, the administration operations are the same as in Case 1. However, in Case 3, the system could obtain data automatically when the regulation was revised. Therefore, the cost of Case 3 is basically same as that of Case 1. Lastly, the cost of Case 4 is between Cases 2 and 3, because the maximum cost Case is full manual registration (Case 2) and the minimum cost case is fully automated registration (Case 3).

3. System Architecture for the ASEAN Chemical Safety Database

3.1. Systemization Plan before the Basic Design Phase

Figure 8 shows the development schedule of the ASEAN Chemical Safety Database. The phase leading to the operation of the ASEAN Chemical Safety Database (1st Step) is divided into 3 steps: the conception of systemization, the planning of systemization, and lastly system development. This survey is part of Step 1, the conception of systemization.

Figure 8: Management of ASEAN Chemical Safety Database



In Step 2, the requirements, schedule and costs for the ASEAN Chemical Safety Database shall be planned. After the planning is completed, the requirement definitions, basic design, etc.. shall be developed in Step 3.

Formulation of Project Promotion Framework

In Step 2, it is necessary to plan requirements, schedule and costs for the ASEAN Chemical Safety Database. When developing this plan, it is necessary for members from each ASEAN member country to create a construction project in order to reflect each ASEAN country's specific requests.

The framework for the ASEAN Chemical Safety Database construction project shall be organized by the Management Board and Secretariat. The tasks of the Management Board and Secretariat are explained below.

- Management Board
  - ❖ Examination and definition of construction and operation plans
  - ❖ Examination and definition of database functions
  - ❖ Examination and definition of activities in the Management Board
  - ❖ Selection of developers
  - ❖ Investigation and definition of operational cost funding
- Secretariat
  - ❖ Drafts for construction and operation plans
  - ❖ Proposal of database functions
  - ❖ Proposal of activities in the Management Board
  - ❖ Invitation of developers
  - ❖ Calculation of operational cost

3.2. System Architecture

This section reviews the system methods of the ASEAN Chemical Safety Database considered in Section 3.1, from the aspects of network, hardware, and software.

- Network

The network architecture is comprised of a network on the management side, where regulatory bodies handle data management, and a network on the user side, which is accessed by general users. The network on the management side utilizes VPN technology for network security and to ensure the integrity of the data stored in the ASEAN Chemical Safety Database. VPN is a technology that allows the establishment of secure connections between different LANs etc., via public communication networks,

where bandwidth shared by large numbers of other subscribers, instead of fixed private communication lines (leased lines) of the communication partners.

- Hardware

For the hardware platform, at least a number of server machines, mainly comprised of CPU and HDD, are required. The specifications of CPU, HDD, and other computation resources shall be determined in Step 2. In the past, hardware was primarily procured, or leased, or rented, but currently, services providing hardware computation resources (CPU, HDD), such as data center hosting services and cloud services, are also available. In Step 2, the possibility of the utilization of such services shall also be investigated.

Data Center

- ✓ Hosting service
  Service that provides memory space and data processing functions of HDD of server machines for use
- ✓ Cloud service
- ✓ Software as a Service (SaaS)
  SaaS provides software that allows using required functions, in the required amounts, for a given job, such as services available via the Internet.
- ✓ Platform as a Service (PaaS)
  PaaS provides a platform that forms the foundation for constructing and operating software, as services available via the Internet.
- ✓ Infrastructure as a Service (Iaas)
  IaaS provides the basic components for constructing and operating computer systems (virtual machines, network and other infrastructure elements), as services available via the Internet.

- Software

The software consists of an OS for controlling hardware, and basic software (database software), and various application software for implementing the functions examined in Section 3.1.

Basic software refers to software that provides the foundation for the construction of the application software. The basic software includes database software and middleware. Since the ASEAN Chemical Safety Database will be operated in a sustainable manner, it is likely going to be necessary to replace hardware during the operation period. When selecting the basic software, it is thus necessary to select software that is not highly dependent on a specific choice of hardware.

4. Cost Estimation for the ASEAN Chemical Safety Database

4.1. Basis for the Cost Estimation

The costs of operating and constructing the ASEAN Chemical Safety Database will be estimated for different assumptions according to the economic level of the ASEAN member country in which the ASEAN Chemical Safety Database will be physically located. More specifically, when estimating the costs, it shall be assumed that the ASEAN Chemical Safety Database may be placed in one of four countries representing the various economic levels of ASEAN: Singapore, Thailand, Indonesia, and Vietnam. In order to be able to provide the services of the ASEAN Chemical Safety Database for extended periods of time, estimating the costs of database operations is of vital importance.

A) Operation of database

For database operation, the costs of the following items required to operate the framework described in Sections 3.2 and 3.3 shall be estimated.

- Operation of the Management Board:
  Estimate the cost of operating the Secretariat of the Management Board and holding meetings of the Management Board (twice a year)

- Operation of the database:
  Estimate the workload and labor costs etc. for operators (system engineers) required to operate databases

- Utilization of the database:
  Estimate the cost of housing services (location, power supply, and network) for each of the four potential host countries (Singapore, Thailand, Indonesia, and Vietnam)

- Maintenance cost of hardware and software:
  Estimate the cost of maintaining the hardware and software (basic software) procured to construct databases. Hardware maintenance tasks include replacement of parts when the hardware fails, while software maintenance tasks include updating of the basic software, etc.

B) Construction of databases

In terms of constructing the database, the costs of the following items required to construct the system described in Sections 3.2 and 3.3 shall be estimated.

- Procurement costs of hardware and software
  Estimate the costs of purchasing the hardware and software to be installed in the database.

- Cost of system construction and adjustment
  Estimate the cost of developing application software and adjusting the hardware and software to be installed in the database.

4.2. Cost Estimation Results

The table below shows the results of the estimations described in Section 4.1. The cost for database development could be divided into kinds: costs which do not differ in different cases, and costs which may differ in different cases. Table 10 shows a list of costs, and an estimated amount for the costs, which does not differ in each case, and Table 11 shows a list of costs, and an estimated amount for the costs, which differs in each case. In detail, the cost which differs in each case is only the operation cost, and this is because the difference of each cost only comes from the difference in the number of workers.

Table 10: Common Costs in Each Case (Estimation)

No	Item	Cost	Remarks
A) Operation of database			
1	Management Board	300,000 US$/year	
2	Operation	-	see Table 11
3	Data center rental		1Rack 4KVA
	Singapore	34,800 US$/year	Initial 1,900 US$
	Thailand	26,400 US$/year	Initial 800 US$
	Indonesia	21,120 US$/year	Initial 1,000 US$ *Convert 3KVA
	Vietnam	18,000 US$/year	Initial 800 US$
3	Hardware/Software maintenance	20,000 US$/year	[Buying expenses]×20%
B) Construction of databases			
1	Hardware/Software Buying expenses	100,000 US$	
2	Development	1,000,000 US$	

Table 11: Operation Cost in each Cases (Estimation)

Operation	Case 1	Case 2	Case 3	Case 4
Data Operation	Link (URL) Registration	Link (URL) Registration Update Data Check (Hazard) Data Registration	Link (URL) Registration	Link (URL) Registration Update Data Check (Hazard) Data Registration
System Operation	User Registration Security Update System Backup System Restore Data Backup Data Restore Operation Check	User Registration Security Update System Backup System Restore Data Backup Data Restore Operation Check	User Registration Security Update System Backup System Restore Data Backup Data Restore Operation Check	User Registration Security Update System Backup System Restore Data Backup Data Restore Operation Check
Workers required	1	3	1	1-3
Operation Costs				
Singapore	78,000 US$/year (6,500 US$/month)	234,000 US$/year (19,500 US$/month)	78,000 US$/year (6,500 US$/month)	78,000 - 234,000 US$/year
Thailand	30,000 US$/year (2,500 US$/month)	90,000US$/year (7,500 US$/month)	30,000US$/year (2,500 US$/month)	30,000 – 90,000 US$/year
Indonesia	18,000 US$/year (1,500 US$/month)	54,000 US$/year (4,500 US$/month)	18,000US$/year (1,500 US$/month)	18,000- 54,000 US$/year
Vietnam	12,000 US$/year (1,000 US$/month)	36,000 US$/year (3,000 US$/month)	12,000 US$/year (1,000 US$/month)	12,000- 36,000 US$/year
Authority Cost	C_A	2 C_A	C_A	C_A to 2 C_A

Note: * C_A: Authority Cost in Case 1 and Case 3

5. Comparison

Table 12 summarizes the results deliberated in this chapter. The WG agrees and highly recommends Case 4 as a preferable option for the ASEAN Chemical Safety Database. However, there is a risk of costs increasing with the data volume being registered manually.

Table 12: Comparison

	Case 1	**Case 2**	**Case 3**	**Case 4**
Result Table	✘ Link	✓	✓	✓
Method of Data Input	Link	Manual	Auto	Manual/Auto
Modification of Database	✘	✘	✓	✘
Link to Regulation Pages	✓	✓	✓	✓
Authority Cost	C_A	2 C_A	C_A	C_A to 2 C_A
Operation Cost	C_O	3 C_O	C_O	C_O to 3 C_O

Note: * C_A: Authority Cost in Case 1 and Case 3
* C_O: Operation Cost in Case 1 and Case 3

CHAPTER 4

Possible Impact of the ASEAN Chemical Safety Database

1. Qualitative Impact on the Chemical Management of the Government

Reduction of the testing cost

The largest impact of constructing the Database is probably the reduction of the test costs that can be achieved by data sharing. Whenever governments conduct tests on toxicity to humans, the test results are usually published. However, many of these reports are not written in English, but in local languages, and the information may thus not be sufficiently accessible to interested parties.

For this reason, it is important to construct databases that allow the sharing of results of independently conducted tests in common formats, and displaying the search results in a batch. In order to understand the magnitude of this impact, this report conducted case study analysis for the cost reduction in Section 0.

Reduction of the cost for information gathering

Another potential impact of constructing the Database is a reduction of costs related to information gathering. Whether the toxicity of chemical substances is tested or not is normally decided according to the following procedure: first, the update/maintenance conditions of existing information on toxicity are checked, and then, if the information is found to be insufficient, appropriate tests are conducted. The labor costs required to collect information written in state-of-the-art literature cannot be ignored either.

On the other hand, if each country is able to acquire up-to-date information on toxicity from these databases in the future, much of the cost of collecting information necessary to assign priorities to materials for which detailed risk assessment has to be conducted can be eliminated.

Improve the quality of information for risk assessment

According to the drafted information items of the database described in the previous chapter, the results of risk assessments of each country should also be shared among member countries. This information and collected information on hazards itself could help to improve the basic information used to conduct the risk assessments in each country.

Increasing transparency

The impact of increasing transparency is also an important potential impact of the database. As in the case of testing data, although the regulatory information in each country is basically open to the public, some of the information is not written in English but in local languages.

Therefore, the information item of "regulatory information" could be one of the most important items for enhancing transparency with respect to information disclosure, not only to the domestic firms but also to global firms, foreign policy makers, etc..

Harmonization of regulated chemicals

The cost reduction effects related to testing and information collection described above can in principle be obtained with eChemPortal and other databases as well. However, the databases proposed here have special extra features, in that they provide information on the laws and regulations of each country, along with functions allowing searching and displaying which chemical substances are the targets of relevant regulations in a comprehensive manner. This allows each country to determine the controlled substances of the country, while observing the regulatory conditions of other countries. As a result, it may even be possible to expect that regulations on chemical substances will gradually become harmonized within the ASEAN region.

Convergence of GHS classification result

Moreover, to the possible storage and maintainance of GHS classification results of each country in this Database has also been examined. This would allow each country to compare GHS classification results with other countries. Naturally, the conditions for adopting building blocks of GHS vary from country to country, and it is considered practically impossible to harmonize the classification results completely. However, the database is expected to be of value in cases where the classification results are different from one literature source to another, for example, as it will serve to provide a better foundation for converging on a final classification when reviewing the different classification results.

Improve health outcome

As one of the end outcomes for constructing the database, we can also find a possible contribution to improve health outcomes through more efficient and effective chemical management in all ASEAN and Partner countries.

2. Qualitative Impact on the Chemical Management of the Industry

Reduction of the testing cost/cost of information gathering, Increasing transparency and Convergence of GHS classification result

The features of this impact are much the same as in the previous section on impacts on the "reduction of the testing cost" and "reduction of cost for information gathering," but it is considered separately here because some countries place the burden of test costs on businesses. Please see the previous section for further details.

The "increasing transparency" and "convergence of GHS classification result" could be other positive impacts for the industry.

Reduction of the entry barrier for the SMEs

Data sharing could be one of the most useful functions for SMEs. For example, Multinational companies can obtain information from the global supply chain. On the other hand, SMEs preparing to start exports have technical barriers to gain helpful information.

Because of this inequality, SMEs sometimes face serious entry barriers when they consider entering the market of emerging countries. In this sense, the existence of this database may help SMEs to remove this entry barrier by providing appropriate information to the public.

3. Qualitative Impact on the ASEAN as a Whole

Contribution to the AEC Goal

The ASEAN Economic Community (AEC) shall be the goal of regional economic integration by 2015. AEC envisages the following key characteristics: (a) a single market and production base, (b) a highly competitive economic region, (c) a region of equitable economic development, and (d) a region fully integrated into the global economy.[1]

In this context, this database could contribute to the AEC goal, mainly through its key characteristic (a): a single market and production base. The sequence of impacts written here will contribute to achieving this characteristic. Furthermore, in the context of the AEC area of cooperation, the followings are mentioned; the AEC will transform ASEAN into a region with free movement of goods, services, investment, skilled labor, and freer flow of capital. To achieve the transformation of ASEAN into a region with free movement of goods (especially chemical goods), the construction of this database should be considered absolutely necessary.

[1] http://www.aseansec.org/18757.htm

Harmonization of chemical regulation

Secondly, enhancing the harmonization of chemical regulation in member countries could be one of the major long-term outcomes.

Contribution to the WSSD Target

Last, but not least, the establishment of this database also could contribute to the achievement of the WSSD Target, 2020. Although there would be some discussion as to which part of the WSSD target this database would contribute to, one potential option would be action (a), aiming to promote the ratification and implementation of relevant international instruments on chemicals and hazardous waste, and encouraging and improving its coordination as well as supporting developing countries in their implementation.

Paragraph 23, Chapter 3 of Johannesburg Plan of Implementation, World Summit on Sustainable Development[2]
23. Renew the commitment, as advanced in Agenda 21, to sound management of chemicals throughout their life cycle and of hazardous wastes for sustainable development as well as for the protection of human health and the environment, inter alia, aiming to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment, using transparent science-based risk assessment procedures and science-based risk management procedures, taking into account the precautionary approach, as set out in principle 15 of the Rio Declaration on Environment and Development, and support developing countries in strengthening their capacity for the sound management of chemicals and hazardous wastes by providing technical and financial assistance. This would include actions at all levels to: (a) Promote the ratification and implementation of relevant international instruments on chemicals and hazardous waste, including the Rotterdam Convention on Prior Informed Consent Procedures for Certain Hazardous Chemicals and Pesticides in International Trade10 so that it can enter into force by 2003 and the Stockholm Convention on Persistent Organic Pollutants11 so that it can enter into force by 2004, and encourage and improve coordination as well as supporting developing countries in their implementation; (b) Further develop a strategic approach to international chemicals management based on the Bahia Declaration and Priorities for Action beyond 2000 of the Intergovernmental Forum on Chemical Safety12 by 2005, and urge that the United Nations Environment Programme, the Intergovernmental Forum, other international organizations dealing with

[2] http://www.un.org/esa/dsd/susdevtopics/sdt_toxichemintegovedeci.shtml#wssd

chemical management and other relevant international organizations and actors closely cooperate in this regard, as appropriate;
(c) Encourage countries to implement the new globally harmonized system for the classification and labelling of chemicals as soon as possible with a view to having the system fully operational by 2008;
(d) Encourage partnerships to promote activities aimed at enhancing environmentally sound management of chemicals and hazardous wastes, implementing multilateral environmental agreements, raising awareness of issues relating to chemicals and hazardous waste and encouraging the collection and use of additional scientific data;
(e) Promote efforts to prevent international illegal trafficking of hazardous chemicals and hazardous wastes and to prevent damage resulting from the transboundary movement and disposal of hazardous wastes in a manner consistent with obligations under relevant international instruments, such as the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal;13
(f) Encourage development of coherent and integrated information on chemicals, such as through national pollutant release and transfer registers;
(g) Promote reduction of the risks posed by heavy metals that are harmful to human health and the environment, including through a review of relevant studies, such as the United Nations Environment Programme global assessment of mercury and its compounds.

In addition to the possible impacts written above, impact of " Facilitation of trade" and "Improvement of health and environmental outcomes" shall also be expected. The former one is rather far outcome through the contribution to the achievement of AEC goal, etc., and the latter one is basically similar to the impact written in 0.

4. Difference between the Impacts of New and Existing Chemicals

Considering the impacts noted in the previous section, the feature of the current chemical management scheme could influence the impact of the database. One feature that causes a significant difference is the difference in treating "existing" and "new" chemicals in the current chemical management structures. As already mentioned in the chapter 2, several countries employ different schemes of management for "existing" and "new" chemicals. Of course, if we try to discuss "existing" and "new" chemicals in ASEAN and Partner countries, there would be practical issues, such as how to define

"existing chemicals" in ASEAN and Partner countries, etc.[3] However, it would be worthwhile to consider whether these practical issues could be overcome, and to observe the differing impact of whether a chemical is classified as "existing" and "new."

Impact on Existing Chemicals

Considering the practical applications, the impact on existing chemicals shall be significant. For example, most of the GHS classifications are conducted for existing chemicals (of cause it depends on the definition, but if we employ the definition mentioned in the footnote of this page), because the quantity of existing chemicals is much larger than that of new chemicals. Therefore, if at least the information set to conduct GHS classification becomes common, this may lead to the further harmonization of GHS classification results in each country.

Impact on New Chemicals

Consider the case that the authority of each country uses information uploaded to the database for their chemical management strategy. The simplest way is to use the information in the approval process for producing/importing the new chemicals. In general cases, the local authority requires businesses to provide necessary information on physical, human health, and environmental hazards of the newly approved chemicals. To reduce the burden of the businesses, information gathered in the database may be useful.

[3] One possible solution toward this issue is to organize a common existing chemicals inventory among member countries. To organize the common inventory, the scheme that the Vietnamese government plans to employ may be useful. The Vietnamese government now plans to organize an inventory of existing chemicals by referring to its own inventory and that of Japan and the United States.

5. Case Study to Identify the Quantitative Impact

5.1. Notice for the Assumptions to Calculate the Quantitative Impact

Before discussing the specific calculation to identify the quantitative impact, several notation on the assumption and result of this impact should be made. First of all, this sequence of analysis is based on the previous report, "Study on the Economic Impact of Chemicals Management in ASEAN and East-Asia" ("previous report" hereafter), and basically we followed all of the basis employed in that report. Therefore, the explanation on the detailed calculation written in the previous report is omitted.

Moreover, among the impacts caused by the introduction of the database discussed by the previous section, the impacts which could be described quantitatively are categorized as the following three: 1) reducing the operational burdens to gather appropriate information by information sharing, 2) reducing the cost to confirm the credibility of data to conduct risk assessment, 3) reducing the testing cost by referring to the tested results which are conducted by other governments, testing facilities.

First of all, the cost by "1) reducing the operational burdens by sharing information" corresponds to the "Registration Cost", which corresponds to the person-day cost to prepare appropriate dossier for registration by private firms, according to the previous report and "Extended Impact Assessment".[4] The Registration cost can be divided into the three categories: a) the cost of gathering data, b) the cost of exposure assessment and c) the cost of preparing dossiers. In particular, "a) the cost of gathering data" approximately accounts for 30%,[5] all of which can be cut down on the basis of the assumption that the database sharing sufficient information can be established. Therefore, in case that each country introduced Prioritization-Led Approach by its own, the rough calculation based on the previous report expects the following reduction of cost:

$$110.4\text{million€} \times 30\% = 33.1\ \text{million€}$$

[4] Extended Impact Assessment, Commission of the European Communities, 2003

[5] Exactly, in "Extended Impact Assessment" by the European Commission and its previous report "Revised Business Impact Assessment for the Consultation Document, RPA, 2003", data gathering cost within registration cost account for 25.7% in case that Full Registration on the chemical substances over 1000t/y is conducted.

Secondly, the cost by "2) reducing the cost to confirm the credibility of data employed in the risk assessment" can be categorized as Agency Fee, which corresponds to the cost to operate an agency (e.g., ECHA), and Restriction Cost, which corresponds to the cost to conduct detailed risk assessment and socio-economic analysis toward restriction, according to the previous report and "Extended Impact Assessment". On the other hand, it is not obvious to identify what percentage of these cost are spent to confirm the credibility of gathered data. Therefore, in case that each country introduces prioritization-led approach by its own, the rough calculation based on the previous report expects the reduction of the part of following cost:

17.1(Restriction Cost)+182.3(Agency Fee)=199.4 million€

Although the two calculation above can grasp the approximate cost by rough estimation, further elaboration may be difficult. Comparatively, on the other hand, the more detailed calculation about "3) reducing the testing cost" may be possible in case that the amount of duplicated testing substances can be evaluated. Thus, this section hereafter attempts to quantify the impact of "3) reducing the testing cost by referring to the testing results which are held by other individual governments".

It should be noted to interpret the results of reducing the testing cost. Specifically, it is assumed in this case that each country introduces the prioritization-led approach in the appropriate timeline based on the economic conditions and, moreover, it conducts the tests on the prioritized chemical substances evaluated individually by its own budget.[6] On the other hand, considering the current status of ASEAN countries, it should be questioned whether each country newly conducts human health/ environmental assessment by itself; therefore, the value calculated by this analysis may be overestimated.

However, it must be significant to compare the both of the ideal state (Case 1; all countries employ the prioritization-led approach in the appropriate timeline but do not share information at all, and Case 2; all countries employ the prioritization-led approach in the appropriate timeline and share information completely) and derive policy

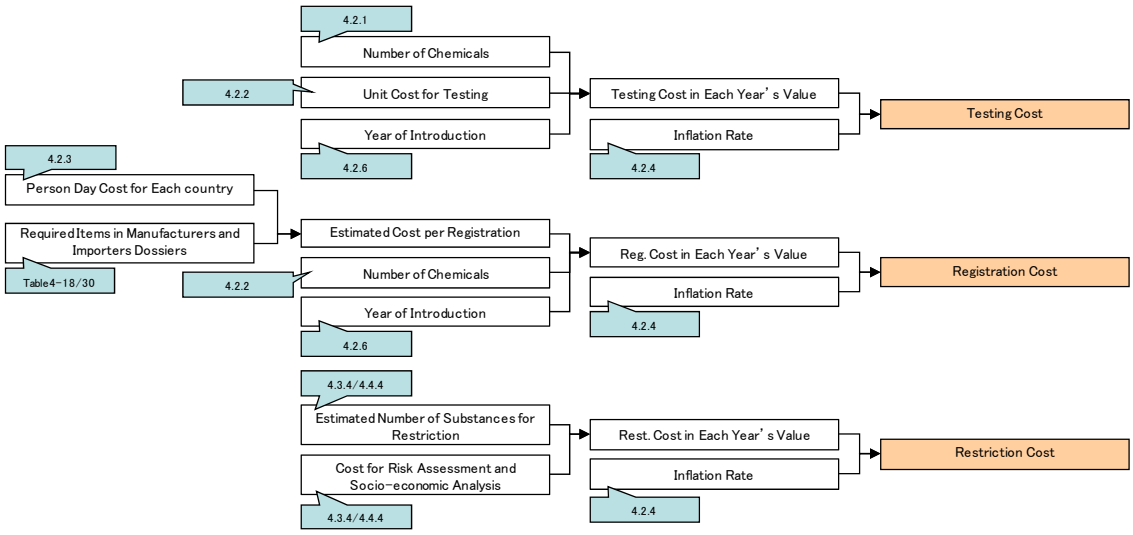
[6] Moreover, it is assumed that the tests are conducted by the laboratories in developed countries due to the lack of laboratories capable of testing in each country. Therefore, unit testing cost is the same as Europe.

implication from the comparison. Therefore, the objective of the following analysis is not to identify the exact value itself but to grasp the rough amplitude of value for comparison.

5.2. Basic Concept of the Calculation

Before estimating the expected reductions in testing costs, the basic concept of the prerequisite cost calculation is briefly explained. First, Figure shows the cost calculation flow of the previous report as a pattern diagram.

Figure 1: Basic Structure of the Calculations in the Previous Report



Source: Study on the Economic Impact of Chemicals Management in ASEAN and East-Asia, ERIA

The testing cost calculation method is described at the top of Figure , but basically, the cost is calculated by the following very simple formula[7].

(Number of chemical substances to be tested) x (unit testing cost)

If complete data sharing via the database etc., is realized, the "Number of chemical substances to be tested" in the simplified formula above is likely to change.

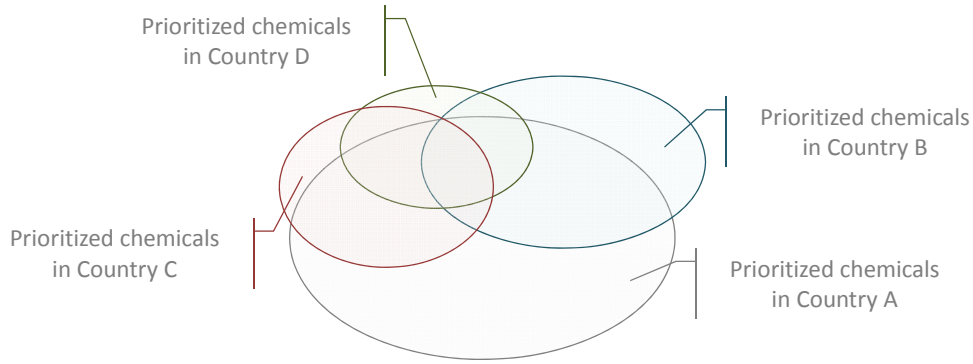
In the analysis in the previous report, a process to eliminate test results that are already available as existing information when conducting tests from the calculation

[7] Note that assumptions regarding when the tests will take to conduct must also be made in an actual calculation, in order to take inflation into account.

was described. This eliminating process draws on the eliminating process employed when the REACH regulation of EU was implemented, and it does not assume that the focus substances to be tested can be selected efficiently, because the relevant information can be shared as each country conducts toxicity tests in parallel.

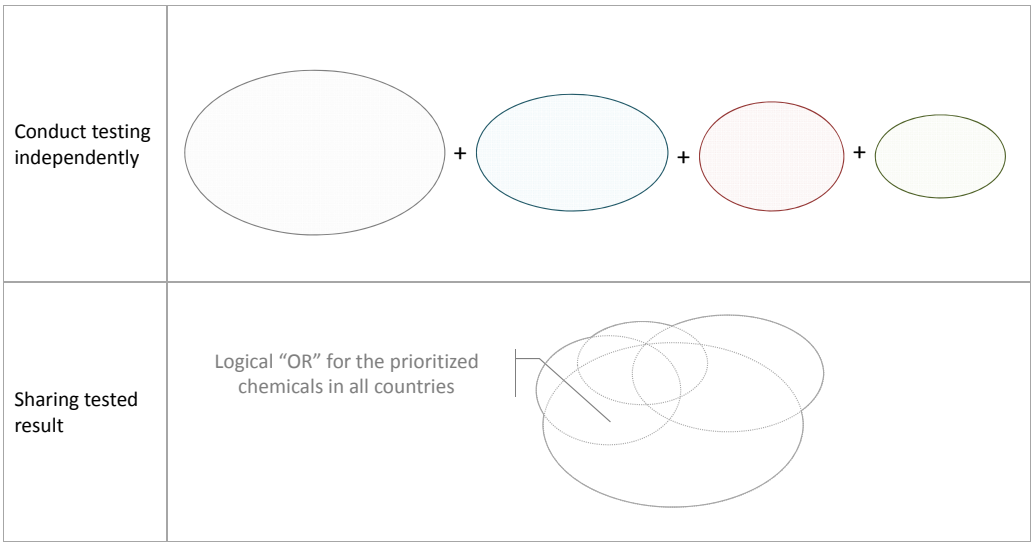
For this reason, in the analysis of this section, we decided to estimate how much the testing costs can be reduced if the relevant information is shared efficiently. Figure 1 is a conceptual drawing, showing how some chemical substances tested in different countries overlap.

Figure 1: Schematic Illustration for the Overlapping of Prioritized Chemicals



For example, when prioritized chemicals in countries A to D are expressed in a Venn diagram, it is likely that the overlapping areas will be quite large, because chemical substances that are considered to represent high risks in different countries are quite alike from the viewpoints of toxicity and/or versatility of usages. If each country conducts independent toxicity tests at a relatively fast pace toward the WSSD target year of 2020 under these conditions, it is considered practically difficult for the countries to share test results appropriately given the time pressure and language differences. Considering how much the cost can change (Figure 2), if each country conducts tests independently, and all the substances covered by circles in the Venn diagram become test focus substances. On the other hand, if each country is able to share sufficient information via the ASEAN database or similar venues, in principle only the chemical substances corresponding to the logical “OR” in the Venn diagram will have to be tested anew.

Figure 2: Basic Concept for the Cost Calculation in Two Cases



5.3. Outline of the Calculation

In order to estimate the overlap of the target chemical substances explained above, it is essentially necessary to calculate the risks of specific chemical substances from the viewpoints of both toxicity (level of hazard) and their amount of usage. Based on the result, we shall consider which chemical substances can be prioritized within each country, and the extent to which they overlap can be identified. However, at this moment, it is not possible to trace the amount of chemical substances in use in each country based on their CAS numbers and compare the toxicity of each chemical substance for all countries at the same time, as this data is simply not available.

For practical calculation purposes, the data available from all countries at the same time includes the trading statistics covered in Chapter 2. In the following chapters, we therefore use the trading statistic data to estimate overlaps of chemical substances explained above approximately, based on the data of the amount of imported chemical substances itemized in the trading statistics.

5.4. Detailed Methodology of the Calculation

As the base of estimation, we used the volume of import (excluding re-import) in the last year for each subdivision of the HS code (285 divisions) in each country under analysis. Since trading statistic data in 2010 was unavailable for some countries, we

used the trading statistic data of 2009. The specific calculation procedure is explained in A) to D) as follows.

A) Cross-Country Data Collection of the Imported Volume of Chemicals

First, we made a simple cross-country comparison of the imported volume by chemical substance group (subdivision of HS code), as of 2009. This provides a data table of 12 countries x 285 divisions. We assumed that it is possible to make a quasi-estimation of the approximate volume of production of 285 randomly picked substances in 12 countries. We further assumed that production volume and toxicity are independent (or, independent and identically distributed (IID)).

Although these assumptions are rather far-fetched, they do allow replacing the level of risk with the scale of production volume when information regarding toxicity to humans is not available. Therefore, in the subsequent analysis, we proceeded by replacing substances with high environmental risk in relevant countries as substances with high production volume for modeling purposes.

B) Assumption on the Rate of the Prioritized Chemicals among General Chemicals

Next, we considered the ratio of substances specified as Priority Assessment Chemical Substances among the 285 "virtual" substances we assumed to be randomly picked. In this analysis, we changed this ratio to make estimations in order to minimize errors. On the other hand, as explained in the report published last year, the number of Priority Assessment Chemical Substances depends on the quantity of chemical substances consumed in a country. For this reason, we used the number of Priority Assessment Chemical Substances in China, which was the greatest number encountered in the report last year, as the basis, and normalized the number of Priority Assessment Chemical Substances from the maximum figure of 285 for China to the minimum figure of 1, to express the changes of degree of overlap in as generic terms as possible.

The numbers of Priority Assessment Chemical Substances in countries other than China were then set to be proportional to the number of Priority Assessment Chemical Substances in each country reported last year. For example, in the last year's report, the number of Priority Assessment Chemical Substances in China was 5271, while the

number in Japan was 2000. Then, if 100 substances out of the 285 “virtual” substances are specified as Priority Assessment Chemical Substances in China, we calculated that 108 substances are specified as Priority Assessment Chemical Substances in Japan (285 x 2000 / 5271).

C) Calculation of the Number of Prioritized Chemicals in each Country

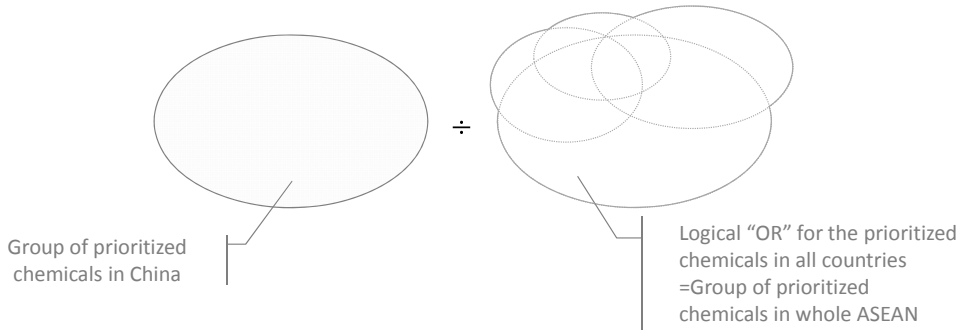
Next, we determined which substances of the 285 “virtual” substances are specified as Priority Assessment Chemical Substances for each country. Here, since the toxicity and production volume of substances are assumed to be independent, as explained earlier, it is expected that, the larger the production volume, the higher the environmental risk. Here, we took the number of Priority Assessment Chemical Substances set in the previous report, and the ratio of Priority Assessment Chemical Substances set in the previous section, into consideration to determine which substances of the 285 “virtual” substances should be specified as Priority Assessment Chemical Substances.

Specifically, we assumed that, if 5 substances are specified as Priority Assessment Chemical Substances in a certain country, the 5 substances with the greatest production volume (replacing volume of import) are specified as Priority Assessment Chemical Substances.

D) Calculation of the Rate of Overlapping in Prioritized Chemicals across Countries

Based on the table of priority assessment substances of each country we assumed in the previous section, we evaluate the ratio of overlap among prioritized chemicals when the prioritization-led approach is introduced to each country. Specifically, we calculated how many percentages the number of prioritized chemicals in China, which was estimated to be the largest, represents out of the total number of prioritized chemicals in all of the ASEAN countries.

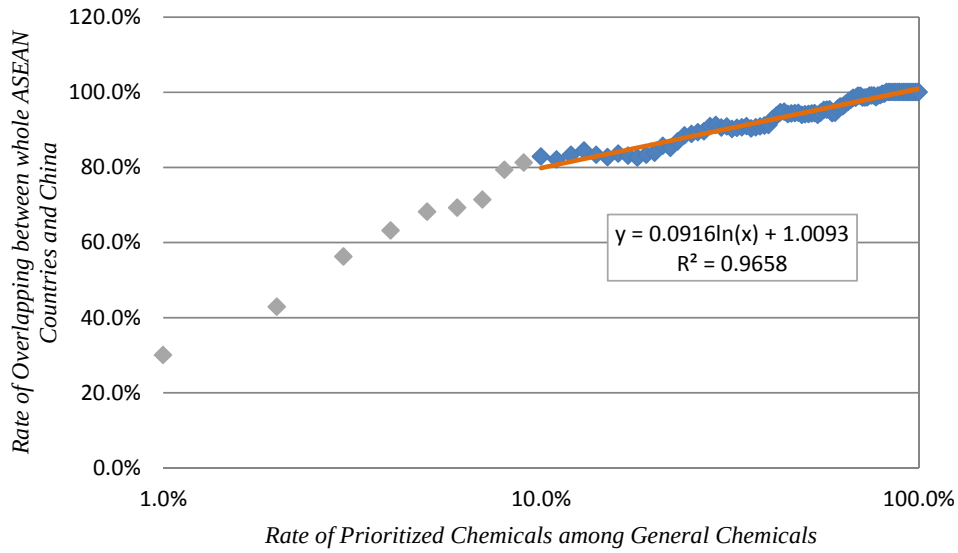
Figure 3: Concept for calculating a rate of overlap between the whole of ASEAN+6 and China



5.5. Calculation Result

The results of our calculations using the procedure above are shown below. Figure 4 shows the results by plotting the ratio of prioritized chemicals to all target substances, determined in B) above, along the X axis, and the variable determined in D) above (assuming the number of prioritized chemicals in entire ASEAN is set to 100, how great a percentage does the number of prioritized chemicals in China, which is the largest among all the countries, cover?), along the Y axis, respectively.

Figure 4: Relation between Rate of Overlap and Rate of Prioritized Chemicals



As is clear from the assumptions, if the ratio of prioritized chemicals is 100% (all chemical substances are specified as prioritized chemicals), all 285 substances under study would this time be specified as prioritized chemicals. The result of calculation of

the Chinese case only, and the result of taking the union (logical "OR") of all target countries of ASEAN+6, would represent the same set.

When the ratio of prioritized chemicals is lowered, the selection of chemical substances produced is large volume in China, but not in other countries, and vice versa, it becomes more relevant. As a result, the unions (logical "OR") of prioritized chemicals of ASEAN countries and prioritized chemicals in China start to differ. Looking at how this difference changes, a strong linear correlation can be seen between the logarithm of the ratio of overlapping, and the ratio of prioritized chemicals.

Next, before proceeding to the subsequent actual estimations, we examine the percentage of chemical substances that are specified as prioritized chemicals out of all chemical substances. Indeed, if the number of existing chemical substances is set as a population parameter, the number of chemical substances with a CAS No. assigned exceeds 100 million. However, since the scope of the target of this system is limited to industrial chemicals, it is not considered appropriate to include chemical substances that are hardly used in the industrial world when calculating the population parameters.

In the analysis in the previous report, we similarly estimated the number of chemical substances whose transaction volume in each country is 1 ton or larger, for the purpose of calculating the costs involved in No-data and No-market Approach. We have thus also decided to make use of that result in this analysis, and set chemical substances with a transaction volume of 1 ton or larger as the parent population of this analysis. In the analysis in the previous report, the percentage of chemical substances specified as prioritized chemicals among those whose transaction volume is 1 ton or larger was found to be 17.3%. For this reason, in the subsequent estimations, 17.3% of all chemical substances are assumed to be specified as Priority Assessment Chemical Substances, among which 25% are subjected to toxicity tests.[8] Thus, information regarding 4.3% of the commonly used chemical substances (17.3% x 25% = 4.3%) should be shared in the industrial circles. The degree of overlap between ASEAN as a whole and China is calculated under these assumptions by setting x in the following estimation formula to 0.043 (=4.3%) as explained in Figure 4:

$$y = 0.0916\ln(x) + 1.0093$$

[8] According to the assumptions written on page 174 of the previous report.

Using the ratio calculated here, we estimated the number of prioritized chemicals corresponding to the logical "OR" in the union of all of the ASEAN countries using the approach outlined in Figure 2, and found it to be 7306 substances. We thus distributed this number of chemical substances, according to the ratio of number of prioritized chemicals originally set for each country, and estimated the number of target substances to be tested when data is fully shared.

Table 1: Number of Prioritized Chemicals in Two Cases

	Conducting Test Independently	Sharing the Test Results
Australia	108	67
Japan	2000	1229
Singapore	296	182
New Zealand	11	7
Korea	1807	1111
Malaysia	315	194
Thailand	691	425
China	5271	3239
Indonesia	342	211
Philippines	37	23
Vietnam	71	44
India	944	580

Based on this result, we conducted exactly the same testing cost analysis as in the previous report. Table 2 shows the results. According to this analysis, the reduction of testing costs achieved by effective data sharing is €571.5 million (around 770 million US dollar), which is a very significant amount.

Table 2: Comparison of Testing Cost between the Two Cases

(€ million)

	Conducting Test Independently	Sharing the Test Results	Amount of Cost Reduction
Australia	12.5	7.8	4.8
Japan	298.6	183.5	115.1
Singapore	40.2	24.7	15.5
New Zealand	1.3	0.8	0.5
Korea	232.9	143.2	89.7
Malaysia	34.2	21.1	13.2
Thailand	75.1	46.2	28.9
China	679.3	417.4	261.9
Indonesia	25.0	15.4	9.6
Philippines	3.4	2.1	1.3
Viet Nam	6.1	3.8	2.3
India	74.7	45.9	28.8
Total	1,483.4	911.9	571.5

APPENDIX

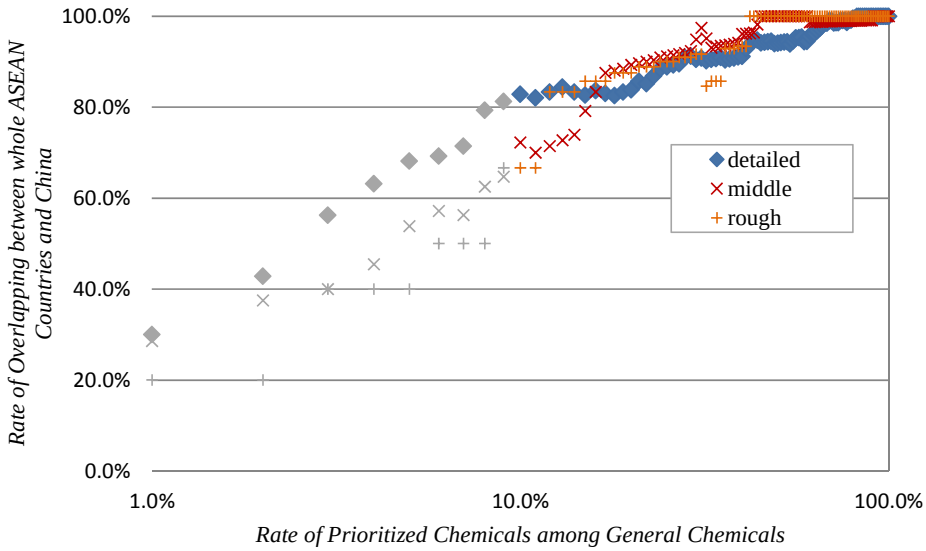
Scale Independence

At the end of this chapter, we briefly examine the scale independency of this analysis as an addendum to this study. We conducted this analysis using data of groups of 285 substances in the trading statistics as the basis. One of the issues of this information source is that the data is not about individual substances, but about groups of substances. For this reason, we consider the appropriateness of handling data of substance groups based on the estimations made above.

The basic idea for consideration here is as follows. Since it is impossible to further subdivide data of the groups of 285 substances, we conducted similar analysis on the major and medium division data, rather than the groups of 285 substances, which are of minor division data, and examined the robustness of our results.

Figure APX-1 shows the results of the analysis explained above, repeated for varying degrees of roughness for each substance group. As can be seen from the graph, the trends are generally identical, except in the low percentage range, where the statistical errors become more significant. Almost the same result was obtained by actual fitting. For this reason, it is safe to consider that this analysis method guarantees a certain level of robustness, regardless of the roughness of dividing substances into groups. Thus, it can be concluded that the result of this analysis is likely to be approximately the same as the result for the analysis of all target chemical substances.

Figure APX-1: Difference from the Segment Roughness



CHAPTER 5

Roadmap of the ASEAN Chemical Safety Database

1. Objective of the ASEAN Chemical Safety Database

The primary objectives to be fulfilled by the ASEAN Chemical Safety Database are the following 4 items, as shown in Chapter **Error! Reference source not found.**:

1. *To share information on risk and hazard*
2. *To enhance transparency and reduce compliance risk through providing information on local regulations*
3. *To facilitate regulatory convergence among ASEAN and Partner Countries*
4. *To reduce the costs of duplicative testing and the burden of assessment*

The first objective represents the original motivation for establishing the ASEAN Chemical Safety Database, and thus must receive high priority. This objective aims to promote information-sharing among member countries, in order to avoid the overlapping of testing in each country, and shared information will be used for risk assessment and risk management purposes.

The second objective prescribes that the ASEAN Chemical Safety Database will be utilized as a medium providing information to ensure the transparency of the chemical regulation in each country, and to reduce compliance risk in the industry.

Note that the intent of the first and second objectives is to ensure that the information gathered is to be utilized in an open manner to the public, rather than in a closed environment, thereby contributing to the SAICM objectives, including "knowledge and information."

The third objective covers that the database is established as a valuable tool to manage high-risk chemical substances in a consistent manner, and also to provide an opportunity to review the scope of regulations in each country, such as a rationalization of regulation and establishing new regulations. These functions will be realized by, for example, employing schemes where controlled substances and GHS classification results in each country can be displayed in a manner that allows direct comparison.

Lastly, the fourth objective has a direct impact both on government and an industry. It will be possible to avoid duplicative testing by sharing test results. Assessment results from other countries will significantly reduce the burden of conducting risk assessments, not only for governments, but also for industries.

To achieve those objectives, the following information items are being considered to be included as functions of the database. Although the timing of information collection for each item depends on the scale of tasks required for its implementation, all the items listed below are expected to be covered in the near future, and will be searchable by versatile search keys such as CAS number as a result of the preliminary information collection. The following updates, such as the revision of related regulations, are expected to be done by each country.

1. *Instruction on the usage of ASEAN Chemical Safety Database*

2. *General information*
   - ✓ *Chemical identity (general name, CAS number, chemical structure), use information, etc.)*

3. *Information on regulation*
   - ✓ *Regulatory information (preventative information)*

4. *Risk assessment information*
   - ✓ *Result of risk assessment*

5. *Exposure information*
   - ✓ *PRTR information (exposure to the environment)*
   - ✓ *Production amounts (if available)*

6. *Information on hazards*
   - ✓ *Physical hazard, human health, and environmental hazard*

7. *GHS classification results*
   - ✓ *Verification status*
   - ✓ *Pictogram, Signal word, hazard statement and precautionary information*

8. *SDS repository (with a note of "not final")*

2. Rough Roadmap for the ASEAN Chemical Safety Database

Table 1 summarizes a rough roadmap for establishing the ASEAN Chemical Safety Database.

Although detailed discussion of primary objectives, information items, etc. in terms of the database was carried out, political agreements on constructing the database have not yet been made at a high level. Therefore, the years themselves are not specified on the drafted roadmap. Instead, expressions such as Y1, Y2,… were used to describe the year range for the roadmap of the database. This means that the construction of the database will start in the year that the political agreement is made (e.g., if agreement is made in 2012, Y1=2012).

It should be noted that the following roadmaps simply summarize the rough paths and tasks to be carried out and the approximate time periods; it should not be considered either final or conclusive. For example, the following points still have room for further

considerations: 1) languages employed in the database and financial support for realization: 2) research conduction for improving the operation of database.

Table 1: Rough Roadmap for the ASEAN Chemical Safety Database

		Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10
Items to be determined	Definition of the scope of service										
	Governing structure										
	Decision-making group										
	Operator and its location (to build a new entity/use existing)										
	Funding scheme / Human resource arrangement										
	Connection to other databases										
Benchmarks for the development of ASEAN Chemical Safety Database	Setting outline of the established database system										
	Planning for systemization										
	System development										
	Data feeding										
	Trial operation										
	Operation										
Cooperation from member countries	Provision of restricted chemicals lists in CAS No. base										
	Provision of hazard data (incl. GHS classification) / SDS sample										

	Contribution to the development and maintenance of the Database										
	Providing experts for direction setting										
	Providing human resource for development and maintenance										
	Monetary support										
Listed items in database	General information										
	Regulatory information / regulated chemicals										
	Risk Assessment Information										
	Exposure information										
	Information on hazards										
	GHS classification result										
	SDS repository										

In the following, each item described in Table 1 is explained in detail.

Items to be determined

This section lists issues that must be determined before developing the ASEAN Chemical Safety Database. When examining how to realize the ASEAN Chemical Safety Database, it is necessary to determine a clear outline and the scope of services of the Database, as explained in Chapter 3 of this report.

Moreover, in order to make proper decisions, it is necessary to clearly designate decision-making bodies related to the ASEAN Chemical Safety Database, and, for this purpose, it is necessary that an agreement on the decision-making bodies is reached, and decisions by the bodies are made as part of the governing structure. Furthermore, it is necessary to bring into perspective who will actually work as operators in practical businesses when progressing with the development. It is thus necessary to coordinate who will assume the role of operators, based on the decisions made by the decision-making bodies above.

Moreover, for the operation of the Database to be sustainable, rather than temporary, it is also necessary to resolve various financial and personnel-related resource issues. For this reason, the member countries shall also reach some level of agreement regarding contributors to funding, method of contribution, method of procuring human resources etc..

Lastly, as explained in Chapter 3, the implementation of functions to connect the databases of the ASEAN Chemical Safety Database to databases owned by the member countries, so data stored in them can also be displayed, has been considered. Reviewing the feasibility of the functions from a technical perspective and specific schemes will also be required in the future.

Benchmarks for the development of ASEAN Chemical Safety Database

These rows contain points of particular importance that can become benchmarks when constructing the ASEAN Chemical Safety Database, assuming the aforementioned items to be determined beforehand have been properly determined. The first benchmark is establishing an outline of the established database system, as

explained at the beginning of the previous subsection. By establishing the outline, it becomes possible to share and clarify objectives and information items to be implemented in the ASEAN Chemical Safety Database, and the Database will also be able to disseminate such information externally.

The second benchmark concerns planning for systemization, enabling the project to progress from conceptual to specific system designs. At this phase, detailed planning will has been completed, such as what search keys are required in the ASEAN Chemical Safety Database, and how the data should be structured; this planning will then be used in the next phase of specific system designs.

The third benchmark will be at the point where the system development of the ASEAN Chemical Safety Database is completed. At this point, since the skeleton of the databases will already have been completed, only the details need to be reviewed.

The fourth benchmark will be when it is time to start feeding data to be stored into the ASEAN Chemical Safety Database. In practice, this task will be conducted in parallel with the system development above. By this point, both the underlying framework and main contents will be completed.

The fifth benchmark will be trial operation/operation. In this phase, a test operation is performed, based on the underlying framework and contents of the system completed so far, and bugs generated while rotating PDCA will be corrected. From this point onward, the ASEAN Chemical Safety Database will be made accessible by general users as well.

Cooperation from member countries

In order to realize this roadmap, participating countries should take appropriate action. The first step is a kind of commitment to the roadmap. It may cover financial or in-kind contribution to the database and its management body. A committee consisting of appropriate representatives from participating countries will be the decision-making body of both the developmental phase and the operation phase.

Feeding and updating information to the database will be a key role expected of the different countries involved. Specifically, provision of restricted chemical lists in CAS No. bases within the countries will enable the creation of a CAS number-based

inventory of controlled substances, which will contribute to enhancing the compliance of industry through easier access to regulatory information and convergence of regulations, thus contributing to economic integration. Since the data must be provided well ahead of starting the data feed to the ASEAN Chemical Safety Database, the target date is set to within Y3 for the time being. Other items, such as GHS classification results, SDS samples, exposure information and risk assessment results, will be gathered in parallel.

Human resources and/or financial support are crucial for realizing and maintaining the database. From this point of view, a high-level commitment must be made within an appropriate forum, such as a minister level meeting of ASEAN countries.

CHAPTER 6

Toward Further Harmonization

1. Vision and Strategy

The ASEAN Chemical Safety Database will significantly contribute to the economic integration of the region and strengthen chemical management in a less burdensome manner, as discussed in the previous chapters. However, it is also recognized that the database and the management body of the database will provide a great opportunity for further harmonization in the area of chemical management. Thus, further harmonization should be aimed for by revisiting the background of the idea proposed for the ASEAN Chemical Safety Datacenter and the AEC goals mentioned in the Chapter 4.

Therefore, in this chapter, a future vision for sound regional chemical management is discussed. Although this attempt may seem to be ambitious, this vision and the following strategy could contribute to promoting further harmonization in this region.

To consider the vision for sound regional chemical management, it is necessary to revisit the goal of the ASEAN Economic Community (AEC). The AEC's goal is economic integration, and concepts such as single market, equitable economic development, and integration into the global economy are mentioned as possible ways of achieving this goal. On the other hand, chemical management schemes may work against economic integration. For example, if the convergence of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) classification results is not adequately realized, this may hinder trade in the ASEAN region. In this context, the further utilization of the database and the management body should be considered as a potential way of achieving further harmonization or convergence of the chemical management scheme in this region.

Therefore, the vision for the future of regional chemical management could be stated simply, as follows:

"To achieve greater economic integration through chemical management"

To achieve this vision, the function of the database and management body should be discussed, and a deliberate strategy should be considered. Although this report does not contain a concrete strategy, several functions are discussed, and establishing an appropriate body is discussed. The strategy could include these ideas that have been discussed.

The followings are examples of functions that have been discussed, to be fulfilled by the body:

- ✓ **Technical Assistance**

This function was originally discussed as assistance in uploading or updating information added into the database. However, this area has a large potential for strengthening the capability to conduct risk assessment and management, using information gathered in the database. Moreover, policy advise for strengthening chemical management was also discussed.

- ✓ **GHS convergence**

The database will contain GHS classification results. It is widely recognized that GHS classification results differs due to various reasons, such as different building blocks, different sources of information, and different interpretation of test results. Thus, it may be useful to conduct case studies to understand the reason for the difference. Such case studies are considered to be useful to the convergence of GHS classification results.

- ✓ **One stop service**

The idea of this function is from the idea that the database will contain regulatory information. Exporters and investors to the region may need information regarding the regulation of chemicals in the region. If such inquiries are answered through the body, it will be convenient, and hence encourage trade and investment.

- ✓ **Providing chemical management tools (e.g. risk assessment tools)**

This function relates to the first function. It may be possible to conduct risk assessments using available information in the database. However, various chemical assessment tools, such as exposure models for risk assessment and QSARs, are already

available. Providing such tools with manuals, training, etc., may be useful for helping governments and industry.

Furthermore, a management body with the above functions requires an appropriate host organization. This is not in the scope of this study, but it should be carefully reviewed, because establishing a new independent organization is costly due to various reasons, including required management such as human resources, etc.. However, all the functions listed above are closely linked each other, and should be operated in a consistent manner. Thus, the management body of the database will be an appropriate body to work to achieve the vision described above. At that time in future, the body may be known as a center (i.e. "ASEAN chemical management research center" or "ASEAN chemical management promotion center") if appropriate.

2. Criteria for Moving Forward

During the discussion regarding the future utilization of the management body, it was also discussed that, no matter how attractive and deliberate the strategy and vision seem to be, it is not appropriate to follow the primary strategy or move forward as originally planned. For the achievement of the vision, it is necessary to revisit or review the strategy in order to take the progress of the database project and changes of circumstances into account. From this point of view, the discussion of criteria for moving forward, including the criteria to establish a center as discussed in 6.1, may be useful for future consideration by the body or leaders in the region.

The followings are examples of the criteria for moving forward. If the criteria are satisfied, then moving to the new phase, including establishing a center, will become a realistic agenda to discuss.

- ✓ The development of the ASEAN Chemical Safety Database goes on as roadmap planned
- ✓ The appropriate management body of the ASEAN Chemical Safety Database is assigned, etc.
- ✓ (After the development of the Database) the ASEAN Chemical Safety Database is fully used and updated
- ✓ Appropriate business plan (including securing human and finance resources) to provide new functions is developed

CHAPTER 7

Conclusion and Discussion

1. Conclusion and Policy Implication

1.1. Policy Implications from the Proposal of ASEAN Chemical Safety Database

As the first policy implication regarding the ASEAN Chemical Safety Database, when considering the qualitative advantages and quantitative cost benefits of constructing the database, it is concluded that constructing the ASEAN Chemical Safety Database is efficient from both quantitative and qualitative aspects, and it is deemed worth moving on to a detailed examination in the future.

The main information to be gathered includes two aspects: information on laws and regulations, and information of toxicity to humans, of chemical substances in each country. The information on laws and regulations is beneficial for both industrial circles considering beginning production and exports to other countries, and administrative government agencies using regulations in other countries as guidelines. Moreover, by summarizing and displaying existing toxicity information in a straight-forward list format, persons in charge of administrative government agencies can feasibly use the information when making decisions on the control of substances in the future. Moreover, easily available information can mean that autonomous management within companies is promoted.

Finally, by displaying the information in a form that allows direct comparison, it is possible to expect a secondary effect, where the rules on control substances in related countries will gradually converge toward a common understanding.

1.2. Policy Implications from the Discussion on Further Harmonization

The discussion on further harmonization indicates many potential policy implications. The ASEAN summit held in 2007 clearly set a target for establishing the ASEAN community by 2015, and the target was affirmed repeatedly. Although

chemical management is not clearly mentioned in the documents relating to economic integration of the region, it is recognized that establishing the database and further harmonization have significantly contributed to economic integration in a timely manner.

In addition, enhancing further harmonization in ASEAN and East Asian countries is highly useful from a practical aspect, as explained in Chapter 6. For example, if the option to establish a new center (i.e., the ASEAN Chemical Management Research Center) for this purpose, or for another sustainable framework, could be established, this center would be able to become an entity that provides benefits to many stakeholders. When considering the sustainable operation of the ASEAN Chemical Safety Database as well as the sophistication and the convergence of chemical substance management within the ASEAN region, the existence of a central player who can provide the opportunity for each ASEAN country to cooperate and can provide the leadership within the ASEAN region to promote chemical management is essential. Managing chemicals appropriately without hindering trade and investment poses challenges and may be costly for individual countries. On the other hand, if ASEAN and its partners countries work together through an appropriate mechanism, like the center that has been mentioned here, the future convergence of chemical management in the ASEAN and East Asian region will be more realistic, and this will ultimately lead to the activation of trading and FDI (Foreign Direct Investment) within the region.

For this reason, the discussions on further harmonization, discussed in chapter 6 of this report, will be able to play an important role in future ASEAN policies. Moreover, further elaboration of this concept may be useful in order to accelerate economic integration through chemical management.

2. The Next Steps to Be Taken

2.1. Next Step for the ASEAN Chemical Safety Database

The next step for the ASEAN Chemical Safety Database is elaborated in Chapter 5. The most important step will be the endorsement and commitment of countries to establish the ASEAN Chemical Safety Database and its management mechanism.

The commitment may include the following;

- ✓ Agreement from member countries of ASEAN and East Asian partners to proceed
- ✓ Commitment for funding and/or in-kind contribution by some countries in a position to do so
- ✓ Assigning (an) appropriate representative(s) to be a member of management and/or decision making body
- ✓ Providing information on chemical regulations, etc. (Especially CAS NO. base)

2.2. Next Step for the Utilization of the Management Body of the Database

The next steps for the further utilization of the management body of the database are discussed in Chapter 6. As discussed in the chapter, it is appropriate to conduct a study based on the following objective:

"To achieve greater economic integration through chemical management"

It is discussed that the management body of the database has a great potential to strengthen chemical management in a consistent manner in the region. From this point of view, four additional functions are discussed: 1. Technical assistance, 2. GHS convergence, 3. One-stop service, and 4. Providing chemical management tools. However, the detail and scope of each function is not yet clearly defined, and each function may have different benefits, priorities, required expertise, and so on. Thus, to make this concept concrete, and to develop an appropriate strategy to move forward, the function of the body requires further elaboration not only from the point of view of what will be gained but also in terms of feasibilities, including resource implications.