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

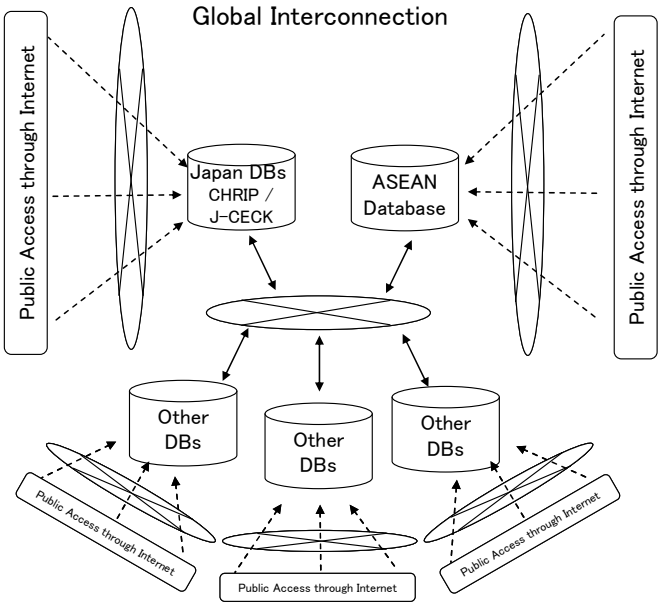
The ASEAN Chemical Safety Database pursues the achievement of the following targets, with the aim of establishing appropriate distribution of chemical substances with assured safety.

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.



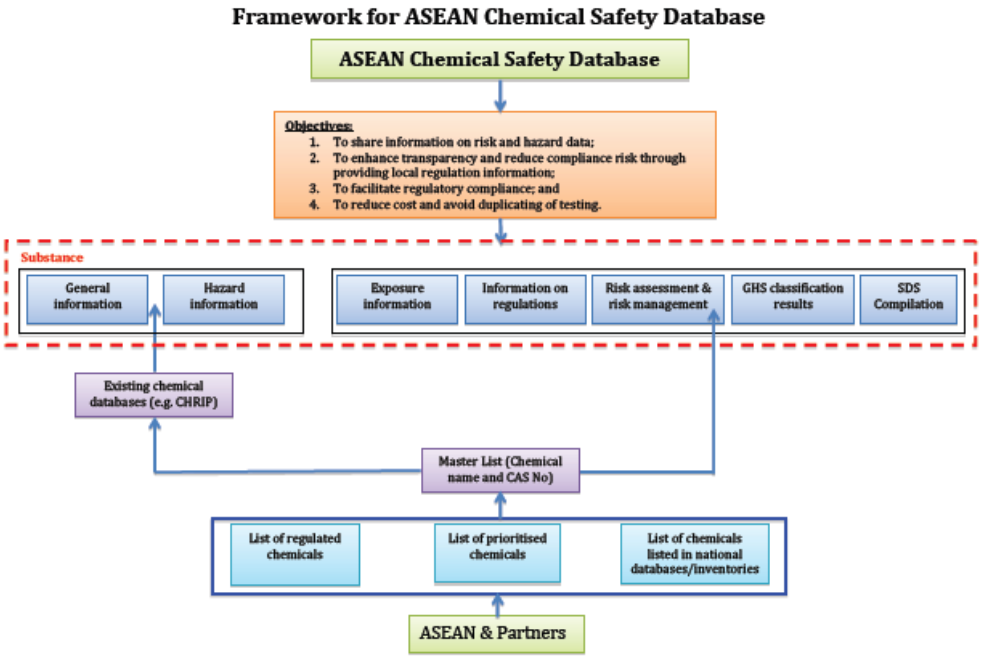
3) Information Items

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.