

Update on REACH and GHS – The Asian Outlook



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Preface

Asia, and indeed all regions of the global economy, is facing one of the most daunting potential challenges to trade in recent times: Registration, Evaluation and Authorisation of Chemicals (REACH), the controversial new legislation of chemical regulation promulgated by the European Union affects every company that manufactures and exports products containing chemicals to the European Union.

REACH is also now affecting other markets by influencing legislation in both other Western countries such as the USA, and countries within Asia itself, including South Korea.

The requirements of REACH are such that companies wishing to preserve their business in an increasingly globalised economy must work with their customers and suppliers to ensure that chemicals present in all products, even finished goods such as apparel and electrical consumer goods, are safe.

With three of the ten largest economies in the world (i.e., China, India and Japan), Asia has become a key player and promoter of growth in the global economy. Asia supplies everything, from raw materials to finished goods, to the European Union at markedly competitive prices. In fact, the European Union is China's largest chemicals trading partner, accounting for about 36% of all chemical exports. The situation is similar for India, where about 15% of all chemical exports are sent to the European Union.

With the first registration deadline in 2010, there is still much to resolve to ensure the completion of dossiers containing confidential information on product chemistry, quantity and use. For companies

outside the European Union exporting substances or articles into Europe, the 'Only Representative' provides a mechanism for achieving REACH compliance. Questions over the rules of cost sharing, the appropriate use of Only Representatives and the implications of 'no data, no market', are topics which require serious consideration. Even once registered, a substance can be subject to regulatory review under Evaluation or Restriction, as well as other legislative frameworks.

Such a related legislative framework is that of globally harmonised system (GHS) of classification and labelling of chemicals, which provides for an integrated classification and hazard communication system for chemical substances and mixtures to ensure their safe use, transport and disposal. Countries must create local or national legislation to implement the GHS. In Europe, this will affect many products before REACH is fully implemented. GHS has been in force around the world for some years in countries such as New Zealand, Singapore and South Korea.

REACH, and legislation like it, will not go away. The costs, and importantly, the opportunities associated with REACH regulation are wide ranging, but if done correctly REACH offers continued access to the European market. It is critical that companies wishing to continue, and to expand, their European markets have available the right information from the right people first time, so that time and resources are not unnecessarily expended, and commercial edge is maintained over competitors.

This book contains a series of papers and case studies on the subject of REACH and GHS, from an Asian perspective, written by experts in the field of REACH and GHS legislation and by chemical industry executives intimately involved in implementing said legislation within the manufacturing and export business sectors of their companies.

It is hoped that the information provided here will both demystify REACH and GHS, and provide guidelines for its successful implementation.

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1 Impacts of REACH and Industries' Action of REACH Compliance in China

Zhou Chan

1.1 The Impacts of REACH on China

As the biggest green trade barrier on chemical industries by now, Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) involves a great deal of products. As a result, Chinese industries incur very high expenses to cope with the regulations, and enterprises that export substances, preparations and articles to the European Union (EU) will be impacted by REACH. This paper is composed of two parts: the first part focuses on analysing the impacts of REACH on China from various angles; and the second part focuses on how industries in China cope with REACH. The main aims of this paper are to analyse the impacts of REACH on China and introduce Chinese industry actions to REACH compliance.

1.1.1 Analysis of the Requirements of Different Enterprises under REACH

1.1.1.1 Impacts on Chinese Manufacturers of Substances and Preparations

If a manufacturer of substances or preparations has to perform the obligations of registration or applying for authorisation under REACH, according to Article 8 in REACH, it should appoint an only representative (OR) to fulfill its obligations under REACH.

It is just more than one year to the first deadline of REACH registrations. However, due to the limit in geographical conditions, human resources, and modern office conditions, many manufacturers of substances or preparations in China lack the latest information. They cannot know REACH immediately or exactly. As a result, they do not attach great importance to it. Although, with the government's support, we have publicised REACH broadly since 2006, some manufacturers of substances consulted us about pre-registration after the deadline, thereby they can't benefit from the transition period.

1.1.1.2 Impacts on Chinese Manufacturers of Articles

According to REACH, it is dependent on whether products contain substances intended to be released and substances of very high concern that whether chinese manufacturers of articles should appoint an OR to perform the obligations as follows:

a. Obligation of registration

According to Article 7 in REACH, 'any producer or importer of articles shall submit a registration to the agency for any substance contained in those articles, if both the following conditions are met: the substance is present in those articles in quantities totaling over 1 tonne per producer or importer per year; and the substance is intended to be released under normal or reasonably foreseeable conditions of use.' In other words, if the articles produced by Chinese manufacturers contain substances intended to be released and the annual volume of the substances exported to the EU is over 1 tonne, the manufacturers should appoint an OR to register for the substances intended to be released and bear corresponding expenses.

b. Obligation of transferring information and notification

As stipulated in Article 7 of REACH, provided that articles contain substances of very high concern that are listed in the '*List of Substances Subject to Authorisation*' of Annex XIV; if the

substances account for more than 0.1% of the whole products, and the annual export volume of the substances is over 1 tonne, such substances should be notified six months after being listed in the '*List of Substances Subject to Authorisation*' since 1st June 2011.

On 28th October 2008, the initial 15 candidates of substances of very high concern were fixed on, among which 7 substances were submitted to the EU Committee to apply for being listed in the '*List of Substances Subject to Authorisation*' on 1st June 2009. Once the EU Committee approves the application, enterprises should perform the notification obligation from 1st December 2011, as long as their products contain any of these 7 substances. Although there is still a time period to perform the above obligation, at present, many enterprises have been required to issue a notice of substances of very high concern by downstream customers of the EU and some have consulted relevant organisations to inspect whether their products contain substances of very high concern or not. For the reason articles are composed of various materials, it will be quite a financial burden for manufacturers of articles to have these materials inspected respectively. And if the products contain substances of very high concern and need notification, the manufacturers should bear high expenses, too.

1.1.1.3 Impacts on Chinese Trade Enterprises

According to REACH, non-EU manufacturers can appoint OR to fulfill their REACH registration work, thus Chinese trade enterprises with export to the EU are at risk of losing trade initiative and downstream customers. In addition, due to the small size of most trade enterprises and various types of products covered in their business scope, even if they have offices in the European Community, trade enterprises cannot afford relevant expenses on the action of REACH compliance and thereby are not competitive.

1.1.2 Analysis of the Features of REACH

Comparing with previous management system on chemical products, REACH is featured by the following:

- Enterprises are expected to cope with REACH

One key feature of REACH is that enterprises but not management departments are responsible for controlling the risks arising from their chemical products. Enterprises that produce, trade, and use chemical products should be aware of the safe features of chemicals and whether they are harmful to human or environment. The awareness is based on experimental data. No data, no market! Furthermore, enterprises should take effective measures to control risks and ensure the communication of information. Likewise, no effective measures, no market access! Therefore, now enterprises are confronted with challenges in operation philosophy and management level.

- There are large numbers of products involved in REACH

According to REACH, substances needed registering or authorising may exist in preparations, or articles. Therefore, there are a large number (more than 30 thousand kinds) of products involved in REACH, involving most chemical products (including chemical raw materials and articles) and their downstream products. And in China at least 500 products exporting to the EU are being covered.

- Experimental data are strictly required

As required in REACH, some data should come from good laboratory practice (GLP). Although hardware of some labs in China at present has met the requirements of GLP, data cannot be accepted by the EU, for China has not joined in Organisation for Economic Co-operation and Development (OECD). In addition, as far as we know, virtually no Chinese manufacturers possess the experimental data as required by REACH.

- Expenses are great

Many kinds of expenses are incurred through enterprises performing the REACH obligations, involving administration expenses to European Chemicals Agency (ECHA) and expenses of preparing technical dossier and Chemical Safety Reports, and if you are non-EU manufacturer, you need to pay for the work done by your OR. To complete the registration for one substance, the enterprise may pay at least Ringitt RMB300,000.

1.1.3 Conclusions

- REACH will cause an increase in the trade cost of chemical products between China and the EU

For performing the obligations stipulated in REACH, both Chinese manufacturers and EU manufacturers or importers should bear tremendous expenses, and it will definitely incur an increase in the cost of chemical products on both sides. As Chinese biggest trade partner of chemical products, EU exports mostly non-substitutable products with high tech, high added value, and high dependence to China, as a result, the import cost of articles from the EU will increase in China.

- REACH will cause a decrease in the export volume of Chinese chemical products to EU

Owing to high registration fee required in REACH, great workload in actual operation and high requirements to human resources of enterprises, many middle and small sized enterprises may give up the EU market and shift to other markets. Additionally, trade companies, particularly middle and small sized ones, will be in a dilemma due to the implementation of REACH, thus they may shift their focus on other markets for better results. For these reasons, export volume of chemical products to the EU will decrease in China.

- REACH will cause an adjustment in industrial structure of Chinese chemical products

REACH will probably evoke chain-reactions on improving the standards of chemical products all over the world. For instance, at present in the US, many people have called for an update the management of chemical products. Activities about updating the 'Toxic Substances Control Act' have been the focus of all sides. The improvement of chemical products' management standards in all areas will lead Chinese enterprises of chemical products with low tech and high pollution to be sifted out, promote environmental protection in chemical industry, and improve industrial structures. However, on the other side, it is also likely that some foreign enterprises will come to China to produce goods that cannot meet their countries' requirements and as a result have adverse impact on Chinese people and environment.

1.2 Chinese Industries' Actions of REACH Compliance

1.2.1 Problems Existing in Coping with REACH

- Substance information exchange forums (SIEF) cannot operate effectively

In the phase of pre-registration, 65,000 enterprises have pre-registered for 146,000 substances, and for approximately 2,750,000 times. These figures are actually far beyond the expectation of European Chemicals Agency (ECHA). According to REACH, registrants should communicate and share their data in SIEF. However, as indicated in **Figure 1.1**, there are so many registrants pre-registering for the same substance (the number of potential participants in pre-SIEF for some substances even exceeds 5,000) that it is very difficult to communicate and discuss in SIEF and SIEF cannot function effectively at all.

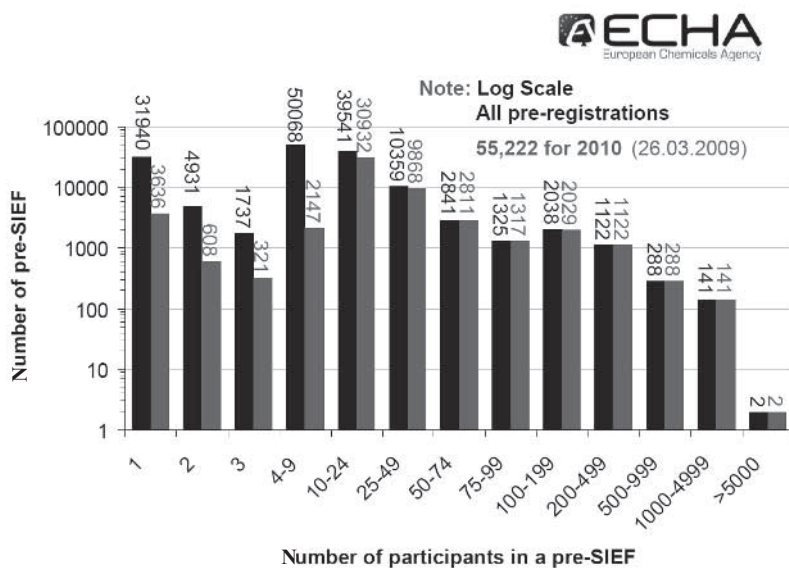


Figure 1.1 State-of-play pre-SIEF

In addition, according to REACH, the lead registrant, who is elected in the industry, should submit a joint dossier. However, SIEF is in a mess now, so election is impossible. What's more, there seems no restriction when lead registrants quit their lead-registration job. As a result, there are more uncertainties for participants.

- It is difficult to meet the first registration deadline

In the case of registration obligation, REACH has stipulated that substances with a total volume of over 1,000-ton produced in or imported to the EU yearly should be registered before 1st December, 2010. And ECHA recommends that registration dossiers should be submitted not later than July 2010 for the purpose of a successful submission. SIEF is responsible for collecting current data, analysing data gaps, contacting qualified

labs for needed experiment or submit a proposal of experiment to ECHA, and preparing a registration dossier and then submitting it. However, as shown in **Figure 1.2** (the black parts represent the uncompleted work), most of the work has not been completed.

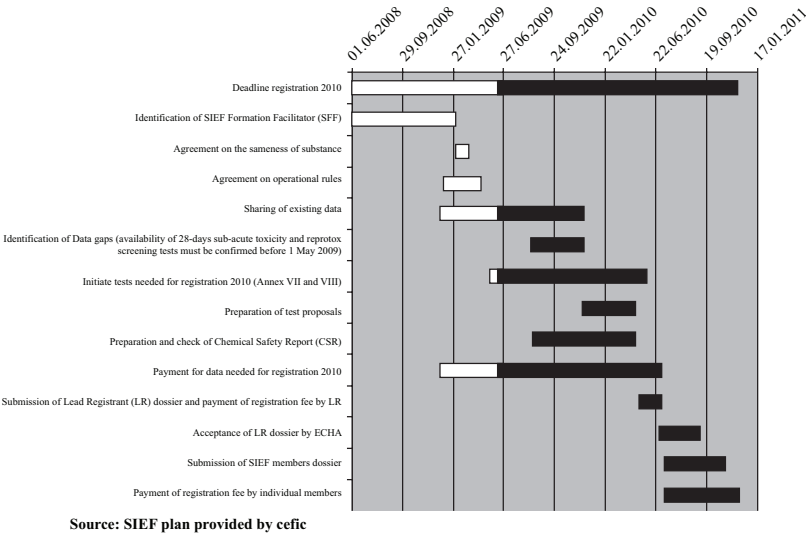


Figure 1.2 Gannt Chart on SIEF timing

Based on the information we get from ECHA, ECHA insists on finishing all registrations as planned and will not change the deadline of registration.

1.2.2 Chinese Industries' Main Actions of REACH Compliance

- Promotion and co-ordination of industrial associations

As a tie connecting government and industries in China, industrial associations play an important role of delivering government's intentions to enterprises and then feeding back enterprises' response to government. Firstly, industrial associations could help government focus on studying REACH, publish main information in newspaper, and transfer crucial indications of government to enterprises; secondly, with full knowledge of the industries, they are able to coordinate enterprises, publicise REACH, provide consultation, guide enterprises to take actions, and then feedback industries' problems and difficulties in the process to government; finally, with the help of friendly international organisations, industrial associations are able to discuss and communicate on relevant problems to help enterprises finish the work stipulated by REACH in the most timely, economical, and safest manner.

- Manufacturers of substances and preparations should coordinate with the OR to participate in SIEF and the consortium

As currently SIEF cannot function effectively and has a lot of work to do, OR need the support of enterprises when participating in the discussion of SIEF and the consortium time scales, which can actively help put forward the work to compliance. With the approaching of the first registration deadline, many enterprises have pre-registered, but they still don't know much about REACH. As a result, they become confused in the period of registration and it is hard for them to comprehend and answer the questionnaires forwarded by OR.

European Chemical Industry Council (CEFIC) has drawn a Model SIEF Agreement, which formulates that in future activities in SIEF, a team of 'lead members' will prepare registration dossier, and other 'non-lead members' should just follow lead registrant, who is also a 'lead member', to register. It is likely that substances' corresponding consortium members become 'lead members' in SIEF. There have been 136 consortiums by 16th June 2009. CEFIC has proposed four types of SIEF members, they are: 'lead', 'involved', 'passive', and 'dormant'. For substances without a