EUROPEAN COMMISSION

ENTERPRISE DIRECTORATE-GENERAL
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REACH REGULATION
PUBLIC INTERNET CONSULTATION

A - Contact details
(Please enter your contact details)

Name:
Organisation : General Administration of Quality Supervision, Inspection and Quarantine of P. R. China (AQSIQ) Ministry of Commerce, P. R. China

B - Confidentiality

☐ **I would like my identity to be kept confidential**
(please leave this box blank if you agree that your name and organisation will be identified on the Commission's website for public access)

C - SME

☐ **Are you a small or medium sized enterprise?** (EC legal definition)
please specify the number of members:

D - Description of your primary activities
(please select only one of the following)

Industry

☐ **Manufacturer**
☐ **Importer**
☐ **Downstream user**
☐ **Distributor**
☐ **Trade association**
☐ **Other**

NGO

☐ **Environmental group**
☐ **Animal welfare group**
☐ **Trade union**
☐ **Consumer organisation**
☐ **Other**

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Public authorities

- ☐ **EU Member State government**
- ☒ **Other national government**
- ☐ **International organisation**
- ☐ **National or regional authority**

Other

- ☐ **Academic or technical institute**
- ☐ **Worker in chemicals or downstream industry**
- ☐ **EU citizen**
- ☐ **Other**

Please structure your response according to the following topic areas and provide comments or proposals for amendments to the legislation. Please comment on those topics that are relevant to you.

When finished, please send your document to the following address:
entr-env-ec-reach@cec.eu.int**.**

Thank you in advance for your contribution.

Chinese Comments on the EU REACH System

General Comments

Chinese government and the associations of relevant industry in China have noticed that the European Commission is developing a new chemical policy, and appreciates the practice of offering an opportunity for public comments. We understand that EU aims to regulate the production and utilization of chemicals to protect environment and human health through REACH system. Chinese government also attaches great importance to coordinating the relationship between economic development and the protection of environment and human health for realizing sustainable development.

However, it is our opinion that a balance should be kept between environmental and human protection and economic and social benefits. We realize that:

1. The Consultation Document is unworkable and lacks transparency.
2. The Consultation Document creates unnecessary paper works to the industry.
3. More concerns should be given to the interests of exporting countries, especially developing countries.
4. There is no clear mechanism in REACH to protect business secrets.
5. The adverse impacts made by REACH on SMEs should be given more concern.
6. The scope of REACH is too wide.
7. The duplicity of legislation exists in REACH.
8. The Consultation Document should be brought into full consistence with relevant WTO rules.

I. Duty of Care

II. Chemical Safety Assessment

Comments: For some of the existing substances, the industry and downstream users have already had a full knowledge about their toxicity and risk. It will be very expensive and resource-consuming to go through all the registration/evaluation/authorization procedures for all these chemicals, especially those whose properties have been known to us.

Suggestions: A classification is made according to our existing knowledge of harm and risk of chemicals placed on market. For example, chemicals may be divided into the following:

I). Chemicals whose harmfulness to environment and human health has been acknowledged and whose production and use have been restricted by international conventions;

II). Chemicals having been used for a long time and whose harmfulness to environment and human has not been found, or could be ignored;

III). Chemicals having been used for a long time and whose harmfulness to environment and human health needs a thorough research;

IV). Chemicals being used only recently, whose harmfulness to environment and human health is still uncertain.

REACH system should provide different management procedure on chemicals according to their classification, and less registration information and registration time should be required for the above 2nd category, for instance .

III. **Information flow**

Comments: REACH system does not specify the recognition of testing results generated outside EU.

Suggestions: In the implementation of REACH system, the testing data and risk assessment results obtained by the laboratory of a third country operating under GLP and making use of (in accordance with) the globally-accepted testing methods should be recognized.

IV. Registration procedure

1. Complex and burdensome registration procedure

Comments: Registration procedures are complex, expensive and burdensome in documentation. Although under the proposed REACH system, it is the responsibility of importers to fulfill the requirements, most of the fee for registration, however, will be passed to the exporting manufacturers in practice (trade). This will certainly weaken the comparative advantage of imported chemicals, especially those from developing countries. In addition, expensive registration cost will place the small and medium sized enterprises at an unfavorable position when competing with large ones. Moreover, enterprises of developing countries, SMEs and downstream users, are unable to submit the required information for registration timely.

Expensive registration and testing cost will also have an adverse impact on innovative ability of chemical enterprises. Under the proposed REACH system, chemical manufacturers will, in fact, have to pay a large amount of registration and testing cost as well as evaluation cost if developing new products. This will seriously restrict R&D input for new products and weaken the innovative ability of chemical enterprises, especially SMEs and chemical enterprises in developing countries.

Suggestions: Provide special and differential treatment to developing countries and SMEs.

2. Shorten registration period

Comments: In *Manufacturing and import of substances* (Volume I, Point 20) of the consultation document, it states the waiting period for manufacturing and import after registration is 2 months or even longer. Such a long waiting period will inevitably create unnecessary barriers to trade.

Suggestions: When importing chemicals which have already been registered by other manufacturers or importers, an efficient registration procedure should be adopted, i.e. as long as the information submitted is correct and complete, registration code should be given in accordance with the time limit set by the importers.

V. Polymers

VI. Intermediates

VII. Data requirements

Comments: REACH system requires manufacturing enterprises to provide the technological information of products which sometimes concerns commercial secrets, for example the components of products with secrete formula.

Suggestions: REACH system should establish a more effective and workable mechanism to protect commercial secrets.

VIII. Data sharing/ consortia formation

Comments: According to REACH system (Volume 1, Point28), the potential registrant shall ask the previous registrant(s) for the information/studies involving tests on vertebrate animals he requires in order to register. However, REACH system does not specify the cost of the relevant test, which will probably force the potential registrant to pay huge fee for information property rights.

Suggestions: To implement REACH system, the existing chemicals list should be publicized, test process of products should be publicized regularly, toxicological data, eco-toxicological data and chronic impact data required by REACH system should be publicized as well. In addition, REACH should take necessary measures to prevent the first registrant(s) from making unjustified profits by using the test data so as to avoid unfair competition.

IX. Procedures for downstream users

X. Evaluation procedure

Comments: Volume IV of the consultation document describes 42 test methods for evaluating the impact chemicals will have on human health and environment. 6 of these methods i.e. B. 1TRIS, B. 6-7, B. 27, B. 37-38 are analogous to OECD Test Guidelines, and 24 of these methods (B. 1BIAS, B. 2-5, B. 8-9, B. 16, B. 18-22, B. 24-25, B. 28-36) are defined by this consultation document; 11 of these methods (B. 10-14, B. 17, B. 23, B. 26, B. 39-41) take literature references; and B. 15 doesn't quote any reference. The feasibility (e.g. scientific basis, applicability, accuracy, repetitiveness, and the availability of comparative verification) of the last 36 methods takes further efforts to prove.

XI. Authorisation procedures

Comments: The scope of authorization under REACH system has gone far beyond the definitions of categories 1 &2 of CMR and POPs set in international treaties such as the Stockholm Convention, and may pose high risk to human health and the environment.

Suggestions: Provide scientific basis for placing these chemicals under authorisation.

XII. Restrictions procedure

XIII. The Agency

XIV. Other

1. Duplicative legislation on management of articles

Comments: Title X of Volume I of the REACH system Consultation Document talks about the management of substances in articles, and stipulates the *duty of care for those placing articles on the market* (Point 63) and *duty to register substances in articles* (Point 64). The European Union has developed sound technical regulations on the performance requirements of products, besides they also set limits and restrictions to the use of chemicals in these articles so as to protect human health and environment. Therefore, it is not necessary to re-regulate articles through REACH system for those meeting requirements of the existing technical regulations. Otherwise, the specific articles will be subject to dual regulation of both relevant technical regulations and REACH system, which will bring manufacturers substantive unnecessary burdens.

Besides, once the REACH system enters into force, some articles to be imported into EU market for the first time will have to wait for 2 months for registration because of the substances used. Some of these articles only have 1 to 2 weeks to go for fulfilling the procedures from placing an order, organizing production and final exportation. Therefore, too long a registration requirement may pose an unnecessary obstacle to international trade, and this goes against the principle and objective of Article 2.2 of the TBT Agreement.

Suggestions: The European Commission further modifies the existing technical regulations on specific articles, and remove the requirements for articles i.e. Title X from the Consultation Document.

2. Differences between developed and developing countries
   Comments: The Consultation Paper hasn't taken into account of the big gap between developing and developed countries in their chemical production technology and technical levels. The REACH system fails to give a sufficient evaluation on the adverse effects on the chemical industry of developing countries.
   Modification proposal: The European Commission reevaluates the possible effects on developing countries once the REACH enters into force, and adds to the REACH system provisions on special and differential treatment towards imported chemicals from developing countries, for example, providing a longer transitional period for developing countries to meet the requirements of REACH, and providing both financial and technological supportive measures.

3. Lack of transparency in REACH procedure
   Comments: It seems that the Consultation Document lacks provisions on specific procedures for the Agency and competent authorities to examine and approve substances, which may lead to deviation in procedural requirements on examining time and information to be submitted, for instance. These deviations may result in the loss of trade opportunities for some manufacturers, and may become an obstacle for imported products entering the European market.

Suggestions: Clearly define in the REACH system the working procedures and time requirements for competent authorities.