USCIB
UNITED STATES COUNCIL FOR INTERNATIONAL BUSINESS

By email: imovong@korea.kr

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Minister of the Environment
Chemical Substances Section
Government Complex-Sejong
11, Doum 6-Ro, Sejong-si
339-012 Republic of Korea

Re: Comments on the Draft Ministerial Decrees to the Act concerning the Registration, Evaluation, etc. of Chemical Substances

Dear Minister:

The United States Council for International Business (USCIB) welcomes the opportunity to comment on the Draft Presidential and Ministerial Decrees to the Act concerning the Registration, Evaluation, etc of Chemical Substances. USCIB and its members, which include both chemical manufacturers and downstream users, support efforts to protect human health and the environment. We are actively engaged in the Strategic Approach to International Chemicals Management (SAICM), chemicals and green economy discussions at the United Nations Environment Programme (UNEP), chemicals deliberations at the Organization for Economic Cooperation and Development (OECD) and at the Asia-Pacific Economic Cooperation (APEC) chemical dialogue.

We support submissions that other business organizations, such as the American Chemistry Council and the Society of Chemical Manufacturers and Affiliates, have made with respect to the Draft Ministerial Decrees to the Act concerning the Registration, Evaluation, etc. of Chemical Substances and rather than duplicate those comments, we would like to share with you some additional thoughts.

USCIB members are global companies which must comply with a variety of national regulations including those specific to chemicals. USCIB downstream users and product manufacturers, including those in sophisticated, high-tech industries, rely on small volumes of highly specialized chemicals. Therefore, we are concerned about how Korea's new chemical management system may impact or disrupt the supply of these critical substances and others. If the chemical management is extremely burdensome it could have a significant impact on the ability of USCIB members to manufacture innovative products in Korea and /or import them into the country. Therefore, we hope that you read our following comments within this context so that we may contribute to the workability of the draft Ministerial Decrees and the related draft Presidential Decrees.

Prior to highlighting specific items for clarification, USCIB believes that the following issues must be resolved before adoption of the Ministerial Decrees that would be mutually beneficial to all parties. These issues include:

1) Need for additional harmonization and/or consistency with other existing regimes like EU REACH, including standardizing definitions, exemptions, adaptations to testing requirements, and establishment of criteria for determining risk.

2) An opportunity for non-Korean stakeholders to be consulted throughout the entire process including the development of guidance, prioritization of chemicals, and the chemical evaluation and authorization process.

3) Criteria for designating priority existing chemicals. Would you please clarify for us what are the criteria for hazardous lists? What is the intent for the use of the lists? Which international lists are under the Ministry of the Environment's (MoE) review?

4) Increased protection of trade secrets. For example, USCIB is interested in learning about whether MoE will be sharing the information that companies provide with other Korean agencies, and if so, under what circumstances? We are concerned about CBI being released.

5) Consideration of opportunities to streamline the overall process in order to reduce paperwork burdens on industry and the MoE.

6) Unlike EU REACH, certain polymers will need to be registered. USCIB members are concerned about the misalignment with EU REACH.

7) Clarification about what labeling forms would be needed. How does the Globally Harmonized System of Classification and Labelling of Chemicals fit into the requirements? Would there be additional forms needed beyond a material safety data sheet?

Specific Items for Clarification:

Chapter 2: Registration of Chemical substance (Ministerial Decree Article 6- Report Method of Manufacturing)

In general, a product is manufactured at the top tier, and then sent to the distributor (middle tier) who sends it along to the retailers before it finally reaches the consumer. Hence, it would be helpful if the decrees could provide clear guidance if the distributor is subjected to the reporting obligation or not; if so, what must be reported. In extending the reporting obligation to include middle tier distributor who is basically acting as a middle-man between the importer and the wholesale, there is a tendency for duplicate reporting. The same chemical which has been transferred from the importer to the distributor (this could be multiple tiers for some companies), and then to a wholesaler before selling it to the retailers will be reported multiple times. This may falsely inflate the volume of the chemical being reported. To avoid duplicate reporting, USCIB would recommend that MoE consider exempting the distributor and wholesaler from the reporting obligation.

Currently the article requires anyone who manufactures, imports, or sells new chemicals to report. Does "sells" require that every company in a distribution chain that sells a chemical must report it? For example, if a chemical is imported, then sold to a wholesaler, then sold to a retailer, must the chemical be reported by all of these companies?

From the Ministerial Decree Article 6 it would appear that the obligation does apply to distributors (wholesalers and retailers) but that they are exempt from most of the reporting requirements (items 3 – 5). What is the value of requiring distributors to report the fact that they sell a substance? There does appear to be a confidentiality issue here. How will distributors be able to report if they do not know what substances they are selling? Will they just refer to the trade name of the preparation? USCIB would like to recommend that MOE clarify these questions above.

Chapter 2: Testing Requirements (Ministerial Decree Article 21)
We understand that foreign studies previously conducted according to good laboratory practice (GLP) will be accepted. But when the test data is not ready, some of the endpoints can be submitted by test proposal which MUST be tested by Korean GLP per Article 21. USCIB would recommend that when the testing has not yet been conducted that there is no requirement for the studies to be conducted in Korean laboratories but that testing be conducted in any laboratory using GLP.

Chapter 2: Ministerial Decree Article 24 Joint Submission Data
We would like MoE to provide more detailed procedures and instructions about how the Joint Registration Application Data should be filed and how all co-applicants can come together for joint action(s) to achieve a common objective. For example, will there be a consortium similar to the EU REACH's Substance Information Exchange Forum to facilitate data sharing between the companies? In some cases, companies would not be able to share all their information with their competitors but would still need to move forward with the registration. Could you please clarify the steps that companies would need to take to complete the registration of a chemical substance?

Chapter 4: Designation & Amendment of Authorization of Substances etc.
We appreciate that MoE has outlined how it plans to designate the criteria for authorization of substances. As stated above, high tech industries often rely on small volumes of highly specialized chemicals. Any disruption in supply of these crucial chemical substances could have a negative impact on the ability to manufacture these types of products in Korea. Therefore, we urge the MoE to work cooperatively in an open and transparent manner with companies for the purpose of authorizing critical substances.

Chapter 6: Ministerial Decree Article 50 Notification Condition of Product Containing Hazardous Substance

Would like MoE to clarify Article 50 Notification Condition of Product Containing Hazardous Substance (Ministerial Decree), although we have a translation, we are concerned about how one would interpret item Article 50 and items 1, 2 and 3. Does notification occur if a hazardous substance exceeds 1 ton per year AND exceeds 0.1% in a products? Or does notification occur if hazardous substance exceeds 1 ton per year OR exceeds 0.1% in a product." If MoE wants control over designated hazardous chemicals over a certain tonnage, even if present in a given product at a very low percent, please clarify how volume is to be calculated. Is it by company or is it aggregated to include all products made by various companies?

Chapter 7: Presidential Decree Article 34 Data Not Subject to Data Protection.
Could MoE please clarify what information can be considered as confidential business information? We seek clarification as there is some confusion on whether applicable use of restricted use is subject to data protection. There is a discrepancy on this issue between Chapter 7: Presidential Decree Article 34 Data Not Subject to Data Protection and Chapter 5: Ministerial Decree Article 55 Content of Information Provision on Substances Contained in Products.

Finally what type of guidance will industry have? Is MoE considering a tutorial or a webinar? What happens if the web-based system doesn't work? Is there a contingency plan? Will there be a pilot website that would be available to companies?

We thank the MoE for considering our comments/concerns and hope that the draft Presidential and Ministerial Decrees are revised in accordance with the above.

Submitted Respectfully,
United States Council for International Business