1) Can you list three key differences between REACH, K-REACH and China REACH?

<table>
<thead>
<tr>
<th></th>
<th>EU REACH</th>
<th>China-REACH</th>
<th>K-REACH</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Registration</strong></td>
<td>Non phase-in substances (new)</td>
<td>Non phase-in</td>
<td>Non phase-in (regardless of tonnage)</td>
</tr>
<tr>
<td></td>
<td>Phase-in substances (existing)</td>
<td></td>
<td>Phase-in (approx. 2,000 priority substances)</td>
</tr>
</tbody>
</table>
| **Required test endpoints (max)** | Physicochemical: 17  
Toxicity: 20  
Ecotoxicity: 25  
* Total: 62 | Physicochemical: 12  
Toxicity: 15  
Ecotoxicity: 13  
Total: 40 | Physicochemical: 12  
Toxicity: 15  
Ecotoxicity: 19  
* Total: 46 |
| **Who to register**    | -Manufacturer/Importer                       | Manufacturer/Importer        | Manufacturer/Importer                        |
|                        | Only Representative                          | Only Representative          | Only Representative                          |
| **Registration Tonnage** | 1-10t                                       | 1-10t                        | 1-10t                                        |
|                        | 10-100t                                      | 10-100t                      | 10-100t                                      |
|                        | 1001,000t                                    | 100-1,000t                   | 100-1,000t                                  |
|                        | >1,000t                                      | >1,000t                      | >1,000t                                      |
| **Type of Registration** | PPORD, intermediates, full registration | R&D, simplified, normal      | To be announced                             |
| **Polymer**            | Monomer, 2% rule applies                     | Polymer                      | Polymer                                      |
| **Annual tonnage report** | no                                          | yes                          | yes                                          |
| **Others**             | Notification of Substances of Very high Concern (SVHCs) | Some ecotoxicity data to be produced in Chinese region | Notification of products containing hazardous chemical substances  
Safety and labelling criteria for High-Risk Products of Concern (HRPCs) |
2) Will the text of K-REACH be published in the Official Gazette or on a ministry website? If so, where can we download a copy? Will the government provide an English translation?

The government usually provides an English-language version of legislation, but this doesn’t usually happen soon. There is a website [http://www.law.go.kr/main.html](http://www.law.go.kr/main.html) where you can download all the legal texts of South Korea, but it is in Korean only.

3) Are there specific requirements for polymers? Are polymers exempt from registration, notification or reporting?

Polymers are subject to K-REACH. Obligations will apply to them, rather than monomers, as under the EU REACH Regulation.

4) What is the definition of a phase-in substance?

A phase-in substance is one that became commercially available before 2 February 1991 and is listed by the Ministry of Environment (MoE) in consultation with the Ministry of Employment and Labour, or was subjected to a hazard assessment in accordance with the now defunct Toxic Chemicals Control Act on or after 2 February 1991 and is included in the list issued by the Ministry of Environment.

5) Are substances used for R&D only exempt from registration, notification or reporting?

Substances used for research purposes, and which are declared by Presidential Decree, are exempted from annual reporting. There are no other mentions of substances used for R&D in K-REACH. We expect more details will be included in the forthcoming Enforcement Decree.

6) What “safe use information” must substance manufacturers or importers provide to downstream users/sellers, and what in what form must this information be provided? Will it be the same as an extended safety data sheet (eSDS)?

There is no available information on this at the moment. The details will be included in the enforcement decree.

7) Will nanomaterials be considered as separate substances to the conventional form of that substance, or as the same substance? Will they need to be registered separately, or as part of the registration of the bulk form? What hazard and risk information must be provided for nanomaterials?

There is no mention of nanomaterials in K-REACH.

8) If a substance is classified as non-hazardous, does this mean it is exempt from registration, notification or reporting?

A list of substances subject to registration, known as “priority substances” will be published by the government. When the MoE chooses these substances they will not only consider the hazards of substances, but also the total tonnage circulating within the Korean market. Non-hazardous substances have a strong chance of being excluded from the priority substance list, but this is not guaranteed if the tonnage is very high. All phase-in substances manufactured, imported or sold in annual volumes above 1 tonne, and non-phase-in substances regardless of tonnage or whether they are hazardous, are subject to annual reporting. Think of the reporting obligation as similar to pre-registration under REACH, but with a
little bit more information required (uses), and as an annual, rather than a one-off exercise.
If a substance is non-hazardous then products containing it will probably not have to be notified to the MoE, as only products containing hazardous substances must be notified.

9) Will documents or online applications for reporting, registration and notification be accepted in English or any other non-Korean language?
Application forms will be in Korean only. But test data in English will be acceptable.

10) Will online data submission tools for registration and other requirements be provided like REACH-IT? Will they be compatible with IUCLID? Will the tools be available in English versions?
Development of electronic tools for K-REACH has been mentioned. But it is not known if the tools will be provided in English.

11) Will the system for joint submission of registration dossiers, and the role of the Lead Registrant, work in the same way as under REACH? Will substance manufacturers/importers be required to join a body similar to a SIEF?
YES, a consortium will be formed for registrations for the same substance. The Lead Registrant will submit hazard data on behalf of the consortium. Then joint registrants will submit their own dossier individually. Companies can choose to opt out, but will need permission from the MoE.

12) Are there fees for annual reporting or notification, as well as registration?
No fee will be charged for annual reporting. But Registration and Notification will incur fees.

13) What kinds of data will MoE use to conduct hazard assessment? Will it include in vivo test methods as well as in vitro? Will it include QSARs or read-across?
All forms of data will be usable.

14) Will test data from test houses outside Korea be acceptable in registration dossiers, or must all tests for registration be conducted by Korean test houses?
K-REACH does not require tests to be conducted within Korean Region.

15) Can companies provide the exposure scenario information they collected for REACH in K-REACH?
We assume that the MoE will come up with its own use categories. If so, this means the exposure scenario information will be produced using different criteria and exposure scenario information collected for REACH will not be suitable for K-REACH. However, it probably could be used as supporting data.
16) Does K-REACH include the aim of minimising animal testing?
Yes. Animal testing is to be done once only. Therefore if there is animal test data available, the potential registrant must make use of it. If the data owner does not want to share the data, registration without that data is possible with the MoE’s permission. But if the MoE decides test data is necessary, it may request registrants to produce the data.

17) When is the list of priority substances, ie substances that must be registered, expected to be published by MoE? Will that be the only list, or does MoE want all hazardous substances to be registered eventually?
We assume the list will be published by the end of this year, or early next year if late. It may not be the only list. The MoE might decide to include additional substances if it decides they need to be regulated.

18) What are the main obligations that companies will continue to have under the TCCA?
The Toxic Chemicals Control Act will only be applicable to companies manufacturing chemicals in Korea because it regulates manufacturing sites. However, the two Acts will share the same list of hazardous chemical substances. Companies’ obligations under the Act include having safety management processes for hazardous chemical substances at manufacturing sites, including emergency response measures.
For more information about K-REACH and for timely, accurate chemical regulatory news, articles and events

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