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The Acta Group
K-REACH Webinar
Questions and Answers
December 4, 2014

1. **Q:** Can you provide a little more detail in the types of guidance documents that are to be developed and expected time frame for completion?

   A: In November 2014, the National Institute of Environmental Research (NIER) announced seven draft directives:

   - Directive on Classification & Labeling, etc. of chemical substances.
   - Directive on preparation of registration dossier & Hazard Assessment.
   - Directive on Testing method of Chemical Substances.
   - Directive on Detail method for Risk Assessment of Chemical Substances.
   - Directive on Preparation method of Chemical substance Information.
   - Directive on Object & Method of Risk Assessment for Risk concerned Product.
   - Directive on Data sharing & cost of Hazard test performed by MoE.

   As discussed during the webinar, when these will be issued remains unclear.

2. **Q:** Since new chemical registration activities are to begin under K-REACH in January 2015 and much of the guidance is yet to be developed, do you have any advice regarding the need to conduct new chemical registrations?

   A: We have several clients that appear to be in a similar quandary. These entities were unable to make the early cut-off date for registrations under the Toxic Chemicals Control Act (TCCA), so several clients have completed the necessary testing or obtained the data to support their registration applications for a January submission. Since guidance is not yet available, we are relying heavily upon representations from the Competent Authority to gauge expectations until guidance documents are available. Based on initial feedback, we intend to provide the necessary information, even when forms and IT platforms are not available, to support the registration. Although IULCID export files are not being accepted, we will create data sets that are similar to IUCLID in robust study content and satisfy other pertinent criteria for submission in Word. Of course, any robust study summaries or any documentation will need to be translated into Korean, so sufficient time should be allowed to complete translation activities.

We anticipate working closely with the Competent Authority to ensure that it has the documentation it needs to evaluate our submissions. Everyone should be prepared for potential delays resulting from the almost certain administrative disarray that can be expected to prevail as the South Korean government ramps up for a new program.

3. **Q:** Do you know if K-REACH has a time frame in which data from the proposed test plans is required to be submitted?

   A: Timing will derive from the specific elements in any test plan submitted as the date test data are expected to be submitted should be included in the test plan.

4. **Q:** Can you elaborate on the exact categories of information manufacturers and importers much provide to downstream users upon their request and what the penalties are for failing to provide requested information?

   A: K-REACH does not contain the same provisions for downstream user communication as does EU REACH. There are, however, basic provisions to allow for the sharing of certain types of information to support gathering the information needed as part of the supply chain for reporting and registration activities while aiding in hazard communication activities. Specifically, manufacturers and importers can request from downstream users:

   - Volume of use and sales.
   - Detailed uses.
   - Exposure information.
   - Information on safe handling.

   Downstream users, however, can consider volume and sales details as confidential but may not exclude the communication of detailed uses that will need to be present in the risk assessment.

   Penalties for non-compliance allow for imprisonment up to one year and a fine of 30,000,000 Korean Won (around $25,000 USD).

5. **Q:** What protections are available under K-REACH for trade secret or other proprietary data?

A: As most people are probably aware, the ability to claim certain information as confidential business information (CBI) is becoming more restricted under chemical regulatory programs. This is true for provisions under K-REACH. CBI claims are allowed but have certain criteria that must be met to assert a claim is possible.

- The substance cannot be classified.
- Restricted to formula (composition) and content.
- Must meet the requirements to be considered as "Trade Secret."
- Is not publicly available.
- Economic value.
- Substantial effort has been made to maintain confidentiality.

6. **Q:** Are registrants under K-REACH required to submit all available data for each endpoint (as required under EU REACH) or can a registrant submit just the most reliable/relevant data (as mentioned in your example for the HPV Challenge program)?

A: All data necessary to support the notification, and facilitate the conduct of a risk assessment, will be required under K-REACH. In the case of existing substances (Priority Evaluation Chemicals (PEC)), regulators have access to data that were submitted and thus published for the same substances under similar regulatory programs, *i.e.,* EU REACH. For consistency, it is advisable to ensure that the hazard and risk characterization approaches are aligned. Any inconsistencies in the data presented may invite regulatory scrutiny.

7. **Q:** What types of data are considered not available for confidential protection—common name or brand name, for example, data already in the public domain—is there a list anywhere?

A: Data that are already available to the public are not available for CBI protection. A disclosure in one country and made publicly available can eliminate the ability to claim CBI elsewhere. In addition, the following information is excluded from applying for CBI:

- Common name/brand name.
- Use data on the substance and end-use product.
- Data relevant to the safe use of the product.

- Data relevant to accident response.
- Data relevant to physical-chemical, toxicity, and risks of the substance.
- Other data that MoE believes is relevant.

8. **Q:** Do polymers need registration or, like in the EU, only its monomers?

A: New polymers are subject to registration. If manufacturing or importing of a polymer falls under one of the following items, however, the chemical substance is subject to potential exemption following the confirmation of registration exemption in accordance with Article 10.

a. Polymer with number average molecular weight over 10,000 whose content includes less than 5% of molecules with molecular weight of less than 1,000 and molecules of molecular weight less than 500 are less than 2%.

b. Polymer with number average molecular weight between 1,000 and 10,000 whose content includes less than 25% of molecules with molecular weight less than 1,000, and molecules of molecular weight less than 500 are less than 10%.

In addition to the above, cationic polymer, used only in a solid state and being insoluble or not diffused in water, is subject to registration exemption confirmation.

9. **Q:** Is a public hearing on the draft list of the 518 designated existing chemical substances foreseen? In other words, is it possible that listed substances will still be taken off the list in light of information received?

A: A candidate substance list of existing chemical substances (Draft) subject to registration was announced on October 31, 2014. MoE is planning to publish the final list in June 2015 after the review process. The list of substances (draft) may be modified before it is published in final.

10. **Q:** Can we still import chemicals under LVE after 1 Jan while preparing simplified notification?

A: If a chemical is confirmed LVE (less than 100 kg) under TCCA, a company may import the chemical until December 13, 2015. If the quantity is 100 kg ~ 1,000

kg per year, however, a company must submit a low volume new chemical registration. If the quantity exceeds 1 ton, the chemical must be registered.

11. **Q:** If the substance is considered as hazardous (SVHC) will it be available in the IT K-REACH as under REACH-IT?

A: Currently, K-REACH-IT is being developed to support registrations. Hazardous chemicals are available at ncis.nier.go.kr. The most accurate list of substances is the list of substances recently announced by NIER or MoE.

12. **Q:** Regarding tolling situation, as specified under K-REACH which party is responsible for registration?

A: Examples of tolling arrangements are not specified under K-REACH. In our experience under similar programs, however, the entity that is legally responsible under K-REACH (The Act) is considered the "manufacturer/importer." In the case of toll agreements, however, the agreement itself may specify otherwise or further clarify which entity is responsible for registration activities. We are familiar with situations where the toll manufacturer or other contracting entity registers the chemical. In either case, the entity performing the reporting or the registration activities will need to be a Korean entity. In many cases, the contracting entity will secure either a third party or Only Representative (OR) to register the chemical on behalf of the toll manufacturer, which is presumably South Korean.

13. **Q:** What are your thoughts on whether waivers/literature and read-across will be accepted under K-REACH.

A: Data waivers and read-across options will be accepted under K-REACH. Data with reliability 3 or 4 will not be accepted, however, as suitable to address an endpoint. Rules on test exemption may be similar to EU REACH, but likely will not be identical.

14. **Q:** Consider a chemical that is not existing chemical under K-REACH, but received hazard examination under TCCA: which form for confirmation under K-REACH? Any difference for <1mT/yr or >1mT/yr registration? How does it translate to production volume (tonnage bands) under K-REACH?

A: In accordance with K-REACH supplementary provision Article 3 paragraph 1, any person who has received hazard examination according to TCCA is deemed

to have finished registration of chemical substances according to Article 10 and hazard examination in accordance with Article 18.

Accordingly, any person who has received hazard examination under TCCA should submit an application form (table form No. 39) that is designated by ordinance of MoE and attach data, by June 30, 2015, and submit to NIER. In spite of supplementary provision Article 3 paragraph 1, if Article 12 paragraph 1 applies according to supplementary provision Article 3 paragraph 2, should apply for a change of registration (table form No. 8). K-REACH Article 12 paragraph 1 provides the following:

1. The registered chemical's annual manufacture or import volume changes which reach or exceed the range stipulated by Decree of the MoE.

2. Matters stipulated by decree of the MoE regarding the registered use, hazards, risk, etc., have changed.

15. **Q:** Received exempt confirmation for surface treated substance under TCCA: confirmation under K-REACH needed? Which form should be used?

A: According to supplementary provision Article 4 (transitional measure regarding application for confirmation of registration exemption of chemical substance), any person who has received confirmation of hazard examination exemption under TCCA is deemed to have received confirmation of registration exemption according to Article 11. It is required for exemption confirmation for surface-treated substance only for the first time.

16. **Q:** Simplified notification listed in >2 countries under TCCA; Confirmation under K-REACH? Which form? How does it translate to production volume under the tonnage bands?

A: It is not necessary to check separately since it is not subject to Enforcement Decree Articles 2 and 3.

If there is an examination result for simplified notification, the answer would be the same as the answer to Question 7, above. It will be considered as it has undergone hazard examination.

17. **Q:** For export only exempt notification, R&D exempt notification: which forms?

A: The same form will be used for both notifications. According to Article 11 paragraph 1 No. 2, any person who wishes to obtain registration exemption confirmation of a chemical substance should submit the application with all required contents by using table No. 6 to the Korea Chemical Management Association (KCMA).

18. **Q:** Maybe this question is a bit fast, but I am really interested in the practical implementation for our products. We currently export to Korea already, what do we need to do from a practical point of view?

A: If you have already been exporting substances or products into Korea, here are the matters to consider:

- Confirm whether the substance is new or subject to registration.
- Prepare the list of new chemicals and chemicals subject to registration (>1ton per year).
- Determine who will register, as registration must be conducted by a Korean entity, *i.e.*, manufacturer, importer, or Only Representative.

Reporting: Annual reporting is required for all new chemical substances and 1 ton or more per year of existing chemical substances subject to registration. Volume information must be tracked and documented beginning on January 1, 2015 till December 31, 2015. In the case of foreign entities, export volumes should be tracked and annual reporting will need to be conducted by a Korean entity. The information can be reported by an importer but confidential information would need to be shared. Many companies elect to appoint an Only Representative for this purpose.

Registration: Tonnage estimates for registration should be calculated as planned tonnage of year you want to register.

Notification: In the case of exporting product that the final consumer uses, companies should make a list of products that contain a hazardous chemical substance of 0.1% or more and notify a product that is exported into Korea over 1 ton.

19. **Q:** Will implementing decrees and guidance be made available in English by the Republic of Korea?

A: Currently, the national legal information center (http://www.law.go.kr) provides Acts in English. MoE is not planning to provide any information in English or any other foreign languages. In addition, some information is available via the K-REACH Help Desk at http://www.kreach.or.kr/spkreach/archives.asp?b_name=v_data&mode=read&IDX=366&Page=&Search_Type=&Search_Value=&Category=&Parent=&Cate=&Search_Cate=&menu=&top_menu_num=&Order_Name=Ref&Order_Type=Desc.

20. **Q:** Substance with restrictions will be listed as it happens in EU REACH?

A: Regulated substances under TCCA will be applied the same as in K-REACH. MoE announced the draft list of toxic substances, restricted substances, and prohibited substances on November 25, 2014.

21. **Q:** Are concentrates and ores covered by K-REACH reporting / registration obligations? I.e. are they covered by the definition of substance or if they are covered by the definition, would an exemption apply?

A: According to K-REACH, minerals, concentrates, and ores are excluded from the reporting and registration obligations. MoE announced the draft list of existing chemical substances excluded from reporting on November 25, 2014, in which minerals, concentrates, and ores are included.

22. **Q:** Is there a grace period that I can still import chemicals under LVE after 1 Jan?

A: If an LVE (less than 100 kg) was already applied for under the TCCA, a grace period will be given until December 31, 2015.

If, however, the LVE (less than 100 kg) was not applied for under TCCA, the company must submit the low volume new chemical substance registration to NIER under K-REACH when the substance is 100 kg ~ 1,000 kg.

23. **Q:** Will be substance in authorization listed as well and publicly available in the IT web site?

A: Substances listed on the authorization list will be announced, but it is unknown when the list will be published.

24. **Q:** How to define the hazardous chemical substances contained in products

A: K-REACH Article 2 defines that hazardous chemicals are toxic substances, chemicals subject to authorization, restricted substances, or prohibited substances, or other substances that either pose or raise concerns of hazard or risk.

A hazardous chemical in a product can be defined as when the hazardous chemical is present at greater than 0.1% and on the Korean market at greater than 1 ton per year.

25. **Q:** For the submission of test plan, the test MUST be conducted in Korea or could be in overseas?

The test can be conducted by Korean Good Laboratory Practice (GLP) or Foreign GLP confirmed as complying with the Organization for Economic Cooperation and Development (OECD) GLP standard.

- Domestic testing institutions under Article 22 paragraph 1.
- Foreign testing institutions confirmed to comply with the standard operating procedures of the OECD GLP.

26. **Q:** Documentation of GLP compliance: GLP statement, Quality assurance statement, GLP certificate, should all these be provided or is one of them sufficient?

A: You must submit data that are applicable to any one of the regulations (draft) in Article 20 paragraph 1 No. 1, 2.

- Certificate issued by a member of the OECD.
- Testing results produced by the foreign testing institution complied with the OECD's GLP guidelines.

In accordance with the OECD Principles of Good Laboratory Practices (ENV/MC/CHEM(98)17), a GLP-compliant study report should:

1. Be signed and dated by the Study Director to indicate acceptance of responsibility for the validity of the data and to indicate the extent to which the study complies with GLP [§1.1(1)(h)]; and

2. Include a signed Quality Assurance statement "listing the types of inspections made and their dates, including the phase(s) inspected, and the dates any inspection results were reported to management and to the Study

Director and Principal Investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data" [§2.2(1)(f) and §9.2(4)].

Additionally, the report may include a GLP certificate issued to a testing facility (laboratory) by the designated inspecting authority for select OECD Member States to document the most recent GLP inspection. This certificate documents the compliance qualifications of the laboratory at a specified point in time for a disclosed set of study types, but does not indicate whether a given study is GLP compliant (GLP labs often conduct non-GLP studies). A GLP certificate can be informative in the evaluation of a laboratory for study placement and/or the evaluation of data quality. Final reports for GLP (non-clinical) studies conducted in some OECD member countries, like the U.S. (*i.e.*, under EPA FIFRA 40 C.F.R. Part 160, EPA TSCA 40 C.F.R. Part 792, or FDA 21 C.F.R. Part 58), will not include a GLP certificate for the testing facility, as the U.S. EPA and U.S. FDA do not issue such certificates following U.S. laboratory inspections for GLP compliance.