New Landscape of Chemical Regulations in Korea
implications to industry with reform of K-REACH, introduction of Biocidal Regulation and
upcoming regulatory changes
18 May 2018, Yokohama | Gayoung Lee
knoell Companies/ Locations
Knoell Korea Ltd. Service Scope

- **K-REACH Registration**
  - Preparation and support for all stages of relevant registration dossiers incl. chemical risk assessment

- **Consortium Management**
  - Support for all stages of SIEF/consortium for joint registration and data/cost sharing

- **Representative Service**
  - K-REACH Only Representative service for foreign manufacturer
  - Third party representative service to support compliance under Korean chemical regulations (e.g. K-REACH Act, Chemical Control Act, Occupational Safety and Health Act, upcoming K-BPR, etc.)

- **GHS/Product Safety**
  - Classification /re-classification and labelling according to local laws and legislations
  - Compliance check of existing SDS
  - Preparation and translations into national languages (>46 languages)

- **Biocidal Regulation**
  - Support for compliance with current biocidal regulation under K-REACH
  - Support for preparation of upcoming Biocidal Regulation legislation (a.k.a. K-BPR)

- **Coordinate the global project**
  - Efficient interface between Korean clients and knoell subsidiaries worldwide

- **Liaising with Korean authorities**

- **Translation**
Background

From humidifier disinfectant incident

To chemiphobia
Korean Regulations on Chemicals

### K-REACH
- Registration of substances: ≥1 t/a PEC and new substance
- Annual reporting (to be abolished)
- Product notification containing hazardous substances
- Product safety and labelling standard (to be covered by K-BPR)
- Amendment to be effective from 1st January 2019

### Chemical Control Act (CCA)
- Verification of chemicals (LoC requirement)
- Management of hazardous chemicals
- Statistical survey on chemicals
- Expected to be amended

### Occupational Safety and Health Act (OSHA)
- Classification
- Labelling
- GHS-MSDS
- Hazardous data submission for new substance ≥ 0.1 t/a
- Expected to be amended

### Biocide Regulation (a.k.a. K-BPR)
- To be effective from 1st January 2019
- Approval of biocidal substances
- Authorisation of biocidal products
- Labelling of treated articles
- Safety and labelling standard of consumer products
Obligations under K-REACH

- Enforcement of the Act (1st Jan)
- Announcement of 510 phase-in substance subject to registration (Jul)

- Regulation of new chemicals regardless of tonnage
- Annual reporting (by 30 June)

- Registration of existing substances ≥ 1,000 t/a
- (Existing substance ≥ 10 t/a)

- Product Notification of consumer products containing hazardous chemicals*
- Pre-registration of existing substances
- No more annual report

- Product Notification of ‘Priority Control Substances’ contained products**
- Safety and Labelling standard on products of concern over risk

K-BPR

* Consumer products containing hazardous substance(s) over 0.1 % weight ratio per product and the total amount of the substance is more than 1 t/a.
** Consumer products containing Priority Control Substances (CMR, vPvB, etc. set by MoE; similar concept with SVHCs) over 0.1 % weight ratio per product and the total amount of the substance is more than 1 t/a.
K-REACH PEC Registration

PEC Registration status (as of 3 May 2018)

- Consortia exist for 343 PECs.
- 43 Lead Dossiers are registered.
- 175 Lead Dossiers are under review.
- Most of consortia are active to finalise data sharing agreement and payment.

Extension of grace period

- Substances can be manufactured or imported until end of September, if registration dossier is submitted until end of June.
- K-REACH originally stipulated PEC registration shall be done until end of June 2018. Otherwise, manufacture or import of PECs will not be allowed without valid registration.
K-REACH Experience in Practice

Our experience shows that...

- Many Korean consortia are contacting EU consortia to request for LoA purchase
  - Understanding of both EU-REACH and K-REACH regulatory framework is essential to go forth with discussions
- Liaising directly with the Korean authorities is the key to clarify any questions
- Close communication with importers is necessary to acquire relevant information for dossier preparation
  - Foreign manufacturers often face language-barriers
  - In-country support (e.g. OR / local consultant) is inevitable
K-BPR Legislation (from 1 January 2019)

Consumer chemical products safety and labelling standard
- Manufacturer/importer of consumer products subject to safety test shall have test result from designated test institute (result valid 3 years), report to MoE and comply with labelling standard.
- Transferred from safety and labelling standard of product over risk concern under current K-REACH.

Approval of biocidal active substance
- Manufacturer/importer of active substance(s) shall get an approval from MoE before manufacture/import.
- Existing active substance(s) (place on Korean market before 31 December 2018) can be manufactured/imported within given grace period.

Approval of biocidal product
- Manufacturer/importer of biocidal product(s) shall get an approval from MoE before manufacture/import.
- Approved biocidal product shall meet labelling standard.

Treated article safety and labelling standard
- Manufacturer/importer of treated article(s) shall use approved biocidal product(s) only.
- If manufacturer/importer intends to promote efficacy of biocidal function of the product, risk and handling precaution shall be provided on product label.
K-BPR: Approval of Active Substance

**Applicant**
- Submission of Application
  - Before manufacture or import (except for existing substances grace period granted by MoE)
  - One year before expiration date

**MoE**
- Assessment/Draft Assessment Report
- Review of Draft Assessment Report
  - At least 30 days

**K-BPR Committee**
- Review of Assessment Report
  - Up to 30 days

**Applicant**
- Comments on Draft Assessment Report
  - Up to 30 days

With conditions of:
- Purity and impurity
- Product type
- Users
- Valid period

Before manufacture or import (except for existing substances grace period granted by MoE)
One year before expiration date
K-BPR: Approval of Existing Active Substances

Existing Active Substance

- Active substances contained in biocidal products which were placed in Korea until 31 December 2018.
- Existing active substances can be granted grace period for approval up to 10 years.

If grace period is not granted, no more manufacture or import will be allowed.

!important NO TRANSITION PERIOD!
K-BPR: Authorisation of Biocidal Product

**Applicant**
- Submission of Application
- Before manufacture or import
  - One year before expiration date
  - (Only approved ASs shall be used)

**MoE**
- Assessment/Draft Assessment Report
- At least 30 days

**K-BPR Committee**
- Review of Assessment Report
- Up to 30 days

**MoE**
- Final Decision on Approval/non-Approval
- With conditions of
  - Product name and type
  - Valid period
  - User and uses
  - All ingredients and contents
  - Treated articles and uses

**Applicant**
- Review of Draft Assessment Report
- Up to 30 days
- Comments on Draft Assessment Report
- Up to 30 days
Chemical Control Act (CCA) Obligations

Verification of Chemicals
- Domestic importers and manufacturers are obliged to declare whether the products contain any PEC, new substances and hazardous substances prior to import.

Chemicals Authorization/Declaration
- Prohibited substance / Substance subject to authorization / Restricted substance / Toxic substance

Statistical Survey on Chemicals
- Obligation to carry out a statistical survey for all chemical use, including manufacture, import, sales, storage, and transport in every 2 years.

[N.B.] Leniency Scheme for violations of CCA/TCCA*
- Self-declaration of following items will be accepted by MoE until 21 May 2018 and previous violations will be pardoned.
  - Verification of chemicals
  - Chemicals authorisation/declaration

* Toxic Chemical Control Act: previous chemical regulations before K-REACH Act and CCA have been introduced.
Expected Changes of CCA

Ministry of Environment (MOE) announced the draft of CCA Amendment on 3 May 2018.

**Notification and Tracking of Chemical Ingredients**
- Stricter enforcement: report → notification
- Periodic notification: one-off at the time of first import → every 5 years
- Chemical identification number will be assigned by the authority.

**Introduction of OR Concept**
- To avoid false notification or failure of data collection from suppliers
- Appointed OR by foreign suppliers can fulfil importer’s obligations

**Provision of chemical information**
- Chemical identification number, hazardous substances, hazard/risk information, etc.
- Can be included and provided in safety data sheet

**Implementation of the change**
- 2 years after the enforcement announcement (end of 2020 at the earliest)
- Public consultation is open until 13 June 2018
OSHA Amendment (Changes of MSDS rules)

Ministry of Employment and Labor (MOEL) announced the draft of OSHA Amendment on 9 February 2018.

**Preparation/submission/provision of MSDS**
- Manufacturer/importer of chemical substance defined by MOEL (hazard/risk classification standard) or mixture containing such chemical substance shall prepare MSDS including following information:
  - Chemical composition information (chemical name and contents) shall be submitted to MOEL.
  - MSDS shall be provided to downstream users if subject to preparation of MSDS under OSHA.

**Confidential Information of MSDS**
- If manufacturer/importer wants not to disclose chemical name and contents in the MSDS due to confidentiality matters, it shall have approval from MOEL (3 year validity, renewal available).
- Upon the approval from MOEL, alternative name and contents shall be provided in the MSDS.

**Data submission via Only Representative (OR) of foreign manufacturer**
- Foreign manufacturer can appoint OR for following tasks to cover importer’s obligation:
  - Submission of chemical name and contents to MOEL
  - Application for CBI approval on chemical name and contents from MOEL
- The fact of OR appointment/dismissal shall be notified to MOEL.

**Implementation of the change**
- 2 years after the enforcement announcement (Effective date is not fixed yet)
Conflicts in Supply Chain
Take Home Messages

Keep in mind to be compliant:

- Deadline for registration application submission of the first PECs is June 2018
- Annual report will still be required by June 2018 on the substances imported and/or manufactured in 2017
- Detailed information will follow

Get ready for impact:

- Evaluate your products sold to Korea and identify the inventory status of chemicals (substance identity profile!)
- Communicate with importers/downstream users
- Improve quality of SDS
- Track the volume per chemical
- Keep yourself informed of the official announcement
- Check your needs for external help
ANY QUESTIONS?