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New Landscape of Chemical Regulations in Korea

implications to industry with reform of K-REACH, introduction of Biocidal Regulation and upcoming regulatory changes

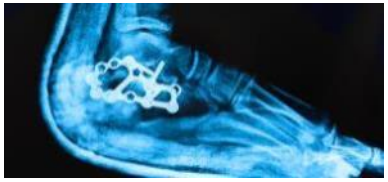
18 May 2018, Yokohama | Gayoung Lee

Knoell Business Areas

Agrochemicals

Biocides

Industrial Chemicals



Medical Devices

Food contact material

Cosmetics

Veterinary Medicine

Training

Regulatory Software Solutions

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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)

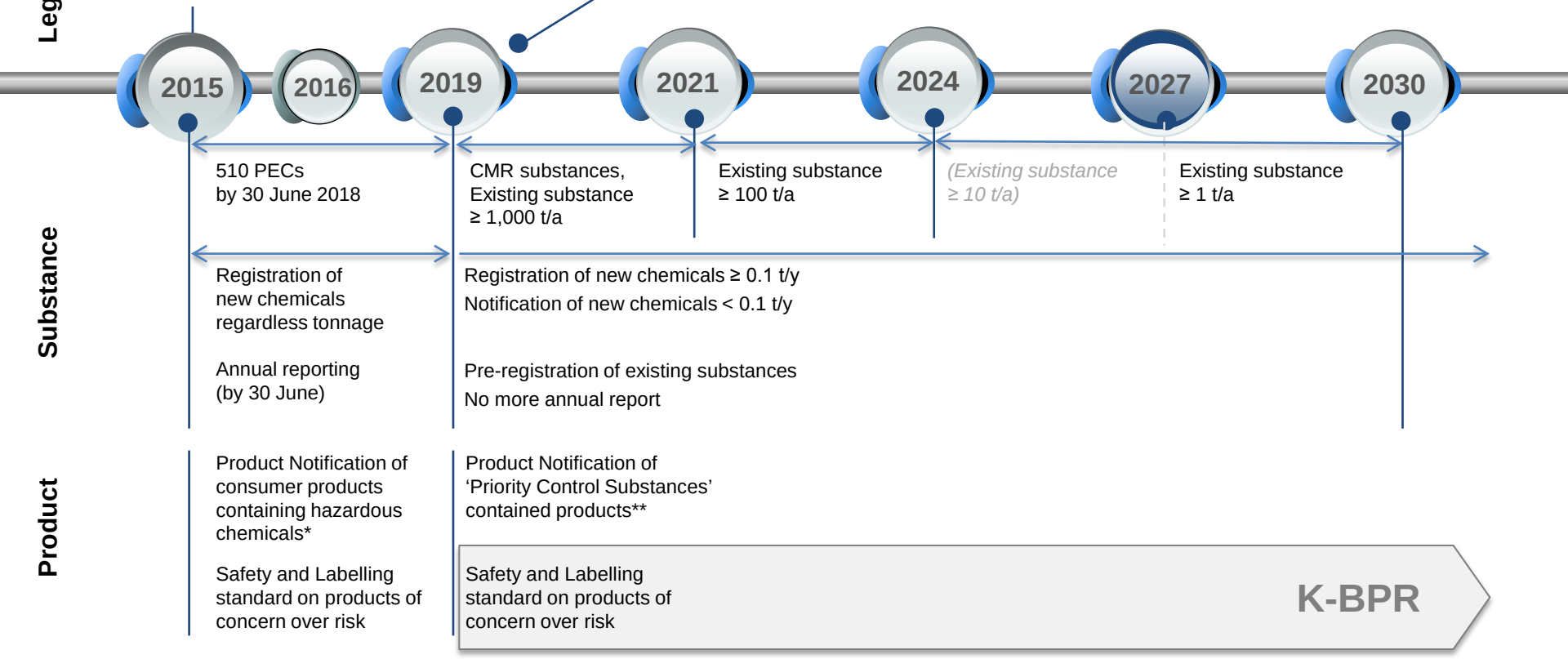
- To be effective from 1st January 2019
- Approval of biocidal substances
- Authorisation of biocidal products
- Labelling of treated articles
- Safety and labelling standard of consumer products

Obligations under K-REACH

Legislation

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

Enforcement of the Amendment (1 January 2019)



* 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.

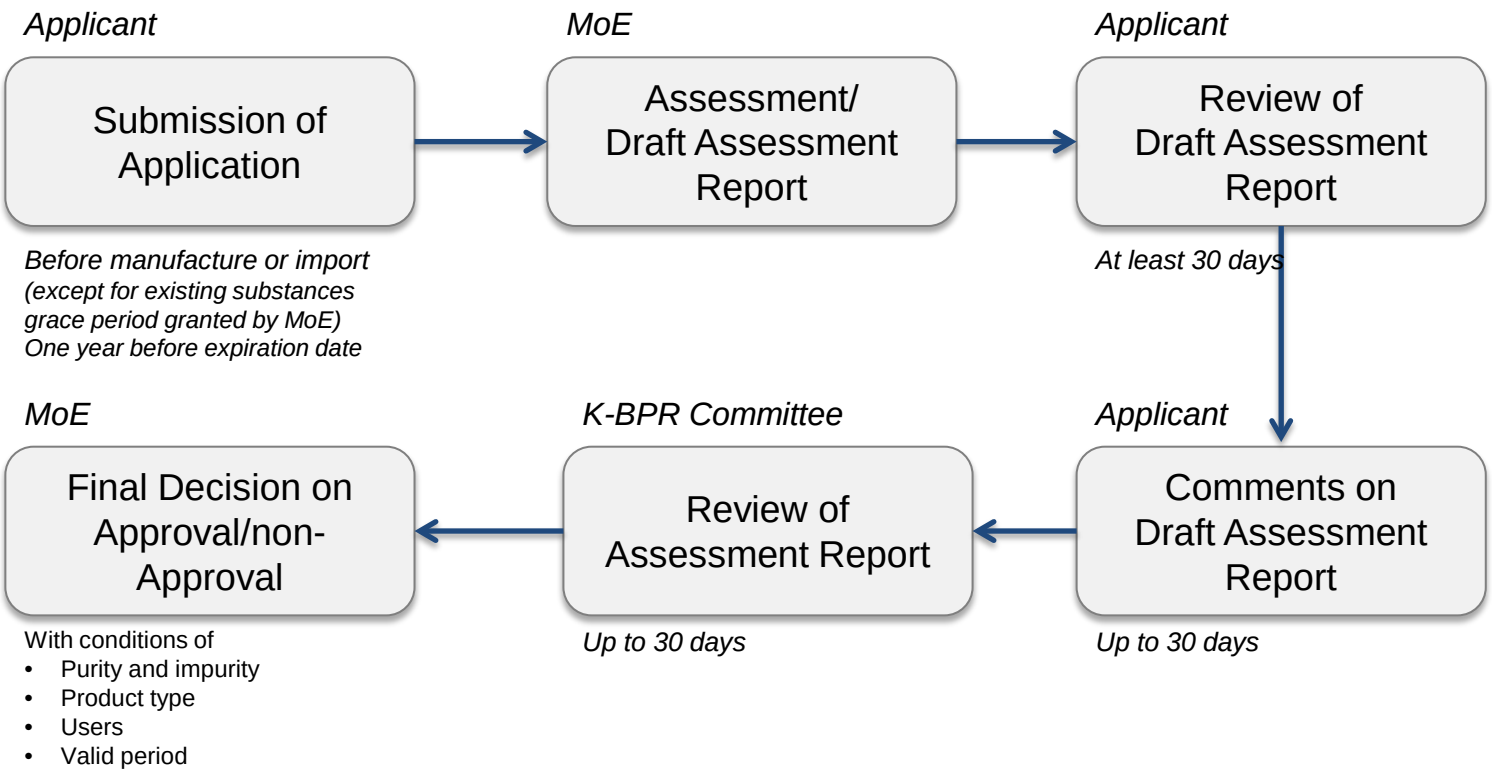
Approval of biocidal product

- 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.

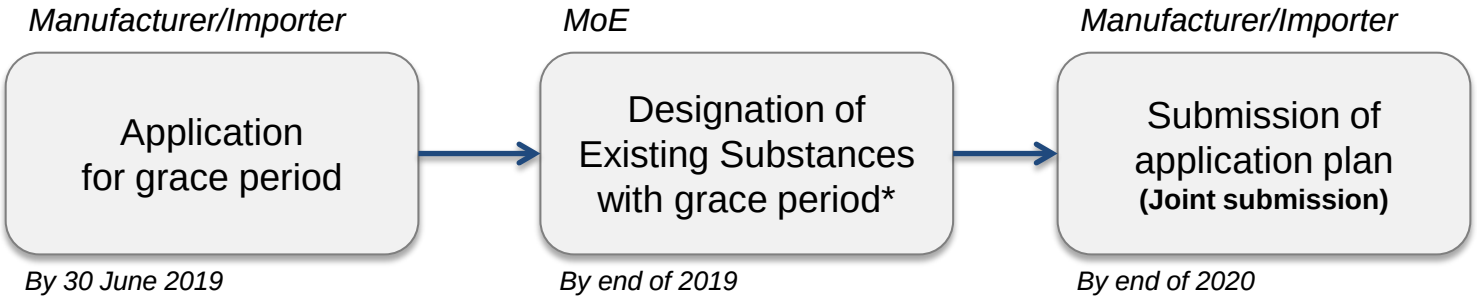
K-BPR: Approval of Active Substance



K-BPR: Approval of Existing Active Substances

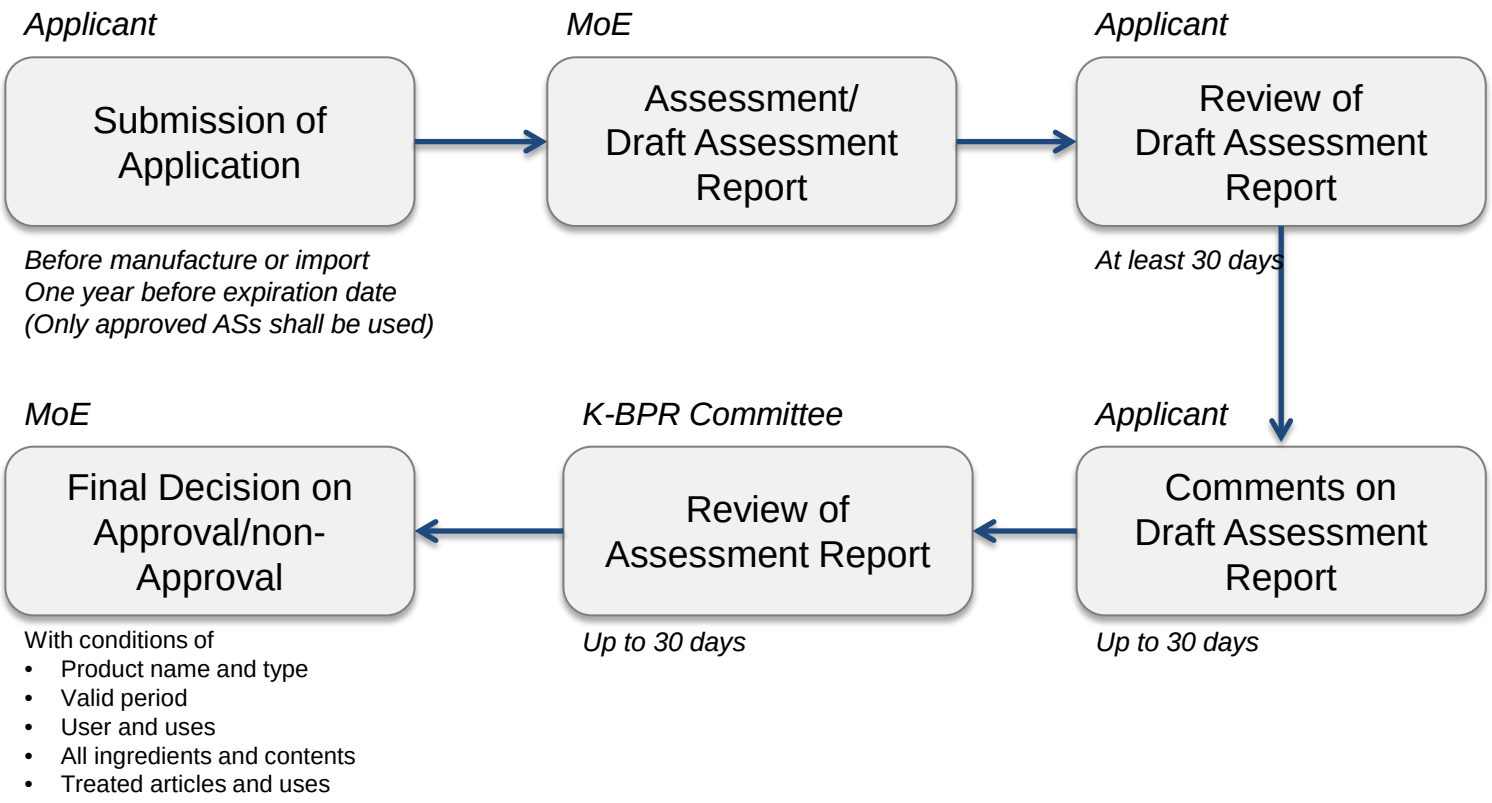
Existing Active Substance

- 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.
  !***NO TRANSITION PERIOD!***

K-BPR: Authorisation of Biocidal Product



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

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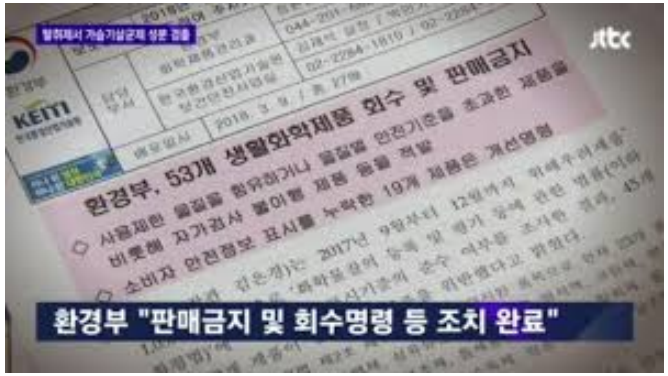

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AK ChemTech CO.,LTD.

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?