Consumer Chemical Products and Biocides Safety Act

Introduction

1. Law
   - Seven chapters and sixty articles (five articles under ADDENDA)

2. Decree
   - Seven chapters and thirty nine articles (two articles under Addenda)
   - Required documents for approval of active substances and biocidal products, grace period for approval of existing active substances, approval of changed information on active substances and biocidal products, etc.

3. Rule
   - Six chapters and fifty seven articles (two articles under ADDENDA)
   - Types of biocidal products, procedure for approval of biocidal substances and products, registration of changed information on active substances and biocidal products, etc.
Introduction

1. Purpose
To set forth the related matters to reinforce safety of consumer chemical products and biocides in order to protect public health and the environment and contribute to public safety

2. Principle
1) Consider potential adverse effects
   - Safety control with prior considerations to prevent harm to humans, animals and the environment
   - Even if the correlation has not been scientifically proven
2) Consider vulnerable groups
   - Consider populations that are especially vulnerable to chemical exposure (e.g. children, pregnant women)
3) Provide product information to consumers in accurate and swift manner
Introduction

3. Definition
1) Consumer chemical product
   - Chemical product that is used in our daily life (e.g. home, office, multi-use facility) and may potentially expose people and/or the environment to chemical
2) Consumer Chemical product subject to Safety check
   - Consumer chemical product that is designated and announced by the Minister of Environment in recognition of its risks found from risk assessment.
3) Biocides (active substance, biocidal product, treated article)
   - Active substance: Chemical, natural substance or microorganism that is used for destroying, rendering harmless, deterring harmful organisms
   - Biocidal product: Product whose main purpose is to destroying harmful organisms(products that consists of one or more active substances or form active substance from mixture)
   - Treated Article: Product that uses a biocidal product for other function, rather than its primary function

Introduction

4. K-BPR is not applicable to followings
1) Health Functional Foods Act: functional health food product
2) Act on Management of Military Supplies
3) Pesticide Control Act: pesticide, technical concentration, etc
4) Drinking water management act: water treatment chemical
5) Control of livestock and fish feed act: single-ingredient feed supplementary feed
6) Ballast water management act: treatment substance
7) Food Sanitation act: food, food additive, apparatus, containers and package
8) Pharmaceutical Affairs Act: drug, sanitary aid (quasi-drug) for human and animal
9) Hygiene products management act: sanitary and hygiene product
10) Medical devices act: medical device
11) Cosmetics act: cosmetic
Consumer chemical products management system

1. Status Survey & Risk assessment
   Status survey and ingredients and their concentrations in product, and risk assessment of the product based on expected exposure (according to use and used volume)

2. Products subject to safety confirmation & safety standards
   Once its risk is confirmed, the product is designated as those subject to management (consumer chemical products subject to safety check), and its safety and labeling standards are developed (e.g. prohibited, substance subject to concentration limits)

3. Self safety check & submission of product information
   Manufacturer/importer of consumer chemical product subject to safety check should carry out self safety check to know whether the product complies with safety standard before placing it on the market. Then they notify the Ministry of Environment of the product’s information

4. Placing on the market
   Product that has been notified can be placed on the market in compliance with the labeling standards

Household product management scheme

- Status investigation (fine when refusing investigation)
- Risk assessment (periodical reassessment on safety standard)
- Designate household product subject to safety confirmation (enlarged to house office and public)
- Notify safety and labeling standard

Companies
- Confirm safety standard adequacy (every 3 years) (manufacturer-importer → evaluating agency)
- Product information (evaluation result, ingredient, labeling) report (manufacturer-importer → ME)
- Meet labeling standard (ingredient, caution and etc.) (manufacturer-importer try to sell product)
- Market distribution (renew every 3 years)
1. Active substance approval

Those wishing to manufacture or import AS for BP must obtain approval from ME.

Active substances announced by the Ministry of Environment to have low risks and those for scientific experiments, analysis and/or research or prototype production are excluded.

2. Registration of existing AS in distribution and grace period

Manufacturer/importers of active substance contained in biocide product that were distributed domestically before December 31st 2018, should report by June 30th 2019 (grace period max 10 yrs) if there are two or more applicants for the same AS, they must submit a joint application for approval (need recognition if equivalence).

### Active substance approval

#### 3. BP Types

The product type is decided when approving biocide active substance (categorized into four main and fifteen product type, referred to EU BPR)

<table>
<thead>
<tr>
<th>Disinfectant</th>
<th>01 Disinfectants</th>
<th>Products used for antibiotic purposes or for the purpose of killing germs or disinfection/sterilization in homes, offices, public facilities and other places of everyday use or any other places</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>02 Algicides</td>
<td>Products used for the purpose of killing algae present in indoor and outdoor water facilities such as swimming pools as well as water tanks and aquariums by inhibiting their growth</td>
</tr>
<tr>
<td>Pest Control</td>
<td>03 Rodenticides</td>
<td>Products used for the purpose of eliminating rodents such as mice and rats</td>
</tr>
<tr>
<td></td>
<td>04 other vertebrates</td>
<td>Products used for the purpose of eliminating harmful vertebrates other than rodents</td>
</tr>
<tr>
<td></td>
<td>05 Insecticides</td>
<td>Products used for the purpose of eliminating insects such as flies, mosquitoes, ants and cockroaches</td>
</tr>
<tr>
<td></td>
<td>06 other invertebrates</td>
<td>Products used for the purpose of eliminating harmful invertebrates other than insects</td>
</tr>
<tr>
<td></td>
<td>07 Repellent</td>
<td>Products used for the purpose of inhibiting harmful organisms by generating a smell using repellent methods</td>
</tr>
<tr>
<td>Preservative</td>
<td>08 for product storage</td>
<td>Products used for the purpose of storing or preserving products to guarantee shelf life</td>
</tr>
<tr>
<td></td>
<td>09 for product surface treatment</td>
<td>Products used for the purpose of preserving the product surface or ensuring in order to protect the initial properties of the product surface</td>
</tr>
<tr>
<td></td>
<td>10 for fibers and leather</td>
<td>Products used for the purpose of preserving fiber, leather, rubber, etc.</td>
</tr>
<tr>
<td></td>
<td>11 Wood preservatives</td>
<td>Products used for the purpose of preserving wood and wooden products</td>
</tr>
<tr>
<td></td>
<td>12 for building materials</td>
<td>Products used for the purpose of preserving new or used construction materials, stone construction or composite materials</td>
</tr>
<tr>
<td></td>
<td>13 for materials and equipment</td>
<td>Products used for the purpose of preserving fluids, etc. used in the processing or cutting of metals, glass or any other materials or liquids such as freshwater used in the materials, equipment or structures used in industrial processes or cooling in treatment systems</td>
</tr>
<tr>
<td></td>
<td>14 Embalming &amp; coldremedial fluids</td>
<td>Products used for the purpose of inhibiting the growth and development or attachment of harmful organisms in vessels, aquaculture equipment or any other underwater structures</td>
</tr>
<tr>
<td></td>
<td>15 Antifoulants &amp; others</td>
<td>Products used for the purpose of preventing the growth and development of unwanted substances in water, aquarium or any other aquatic media environments</td>
</tr>
</tbody>
</table>

Korea Chemical Management Association
Active substance approval

4. Existing grace period for AS approval

Grace period is given according to level of daily life exposure (max. 10 yrs)

<table>
<thead>
<tr>
<th>Category</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>Group 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily exposure level</td>
<td>High</td>
<td>Medium</td>
<td>Medium</td>
<td>Low</td>
</tr>
<tr>
<td>BP type</td>
<td>Disinfectants, aldehydes, nematicides, insecticides, repellants</td>
<td>Wood preservatives, product for vertebrates and invertebrates control</td>
<td>Preservatives for product storage, product surface treatment, fibers and leather</td>
<td>Preservatives for building materials, materials and equipment, embalming and tuineteer fluids, antifoulants</td>
</tr>
</tbody>
</table>

Active substance approval

5. Data Requirements for AS Approval

Based on data requirement for registering substance of 1,000o or more in accordance with ARECs

<table>
<thead>
<tr>
<th>No.</th>
<th>Data Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Applicant Information</td>
</tr>
<tr>
<td>2</td>
<td>Substance Identity (molecular/chemical composition, etc.)</td>
</tr>
<tr>
<td>3</td>
<td>Physical, chemical and/or biological properties (incl. physical danger)</td>
</tr>
<tr>
<td>4</td>
<td>Classification and labeling</td>
</tr>
<tr>
<td>5</td>
<td>Use and exposure data (incl. biocidal product type)</td>
</tr>
<tr>
<td>6</td>
<td>Data and information on representative</td>
</tr>
<tr>
<td>7</td>
<td>Manufacturing process, etc.</td>
</tr>
<tr>
<td>8</td>
<td>Effects &amp; Efficacies</td>
</tr>
<tr>
<td>9</td>
<td>Harm to human body</td>
</tr>
<tr>
<td>10</td>
<td>Harm to the environment</td>
</tr>
<tr>
<td>11</td>
<td>Handling precautions and disposal method</td>
</tr>
<tr>
<td>12</td>
<td>Information on domestic and overseas uses and regulations</td>
</tr>
<tr>
<td>13</td>
<td>Comprehensive information on safety (incl. risk assessment)</td>
</tr>
</tbody>
</table>
Active substance approval

1. Active substance approval
   A person who intends to manufacture or import a BP for sales or distribution in Korea, shall obtain an approval of the BP from ME.
   Products for scientific test and research prototype production, or export as a whole are excluded.

   1. Product must not have adverse effect on humans, animals and the environment
   2. All active substances in a biocidal product should be those approved
   3. Product should have sufficient effect and efficacy in destroying harmful organisms
   4. Product should not lead to resistance or cause unnecessary pain to harmful organisms
   5. Product should use safe container or packaging

   1. Industrial biocidal product
   2. Product that there is no alternatives yet

Active substance approval

2. Grace period for FP authorization
   Grace period for BP available on the Korean market (up to 12 years)

Grace period for AS approval

When enterprise applies for grace period

- Announcement of grace period
- 20
- 22 (Proposed) / 24 (Proposed)
- 27 (Proposed)
- 29 (Proposed)

Grace period for BP authorization

- Two additional years, in case all of active substances of a biocidal product have been granted a grace period for approval

Step 1. Grace period for AS
- Use in Insecticides
- 3 years
- Use in Wood preservatives
- 6 years

Step 2. Grace period for BP
- AS A
- AS A + AS B
- AS A + AS B
- 3 years + 2 years
- Dec. 31, 2020
Active substance approval

3. Data requirement for BP authorization

Similar to data requirements for AP approval

Data requirements are decided, taking into account BP's own approval issues

<table>
<thead>
<tr>
<th>No.</th>
<th>Required documents for submission</th>
<th>Specified in Statutes</th>
<th>Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Act</td>
<td>Presidential Decree</td>
</tr>
<tr>
<td>1</td>
<td>Applicant Information</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Basic product information (product name, ingredients, standard amount of use, shelf life, etc.)</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>3</td>
<td>Physical, chemical and/or biological properties (toxicological, and pharmaceutical properties)</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>4</td>
<td>Classification and labeling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Purpose of use and exposure information (toxicological product type)</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Manufacturing process, etc.</td>
<td></td>
<td>○</td>
</tr>
<tr>
<td>7</td>
<td>Effects &amp; Efficacies</td>
<td></td>
<td>○</td>
</tr>
<tr>
<td>8</td>
<td>Harm to the human body (limited irritation, hypersensitivity, sensitization and acute toxicity)</td>
<td></td>
<td>○</td>
</tr>
<tr>
<td>9</td>
<td>Harm to the environment</td>
<td></td>
<td>○</td>
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<td>Comprehensive information on safety (incl. risk assessment)</td>
<td></td>
<td>○</td>
</tr>
<tr>
<td>13</td>
<td>Documents proving compliance with the manufacturing and storage facility standards</td>
<td></td>
<td>○</td>
</tr>
</tbody>
</table>

Approval or Relieve standard

1. Biocide active substance and biocidal product approval or relieve standard

<Active substance>

1. Shall not have negative effect on human, animal and the environment
2. Active substance should have efficient effect for removing harmful organisms
3. Should not have tolerance to harmful organisms
4. Do not induce unnecessary pain for vertebrate animal removal

<Biocidal product>

1. Shall not have negative effect on human, animal and the environment
2. All active substance contained in biocidal product should already be approved
3. Biocidal product should have efficient effect for removing harmful organisms
4. Do not induce unnecessary pain for vertebrate animal removal
5. Should use safe container or packaging

1. There are minimal chance of exposure to human or the environment due to limited purpose and use
2. No alternatives

1. Industrial biocidal product
2. No alternatives
Treated articles

1. Safety Standard for Treated articles

Should only use on approved biocidal products only for approved use

2. Labeling standard for treated article

Only when promoting biocidal functions (e.g., destroying harmful organisms, antibiosis)

1) Texts indicating that a biocidal product is used
2) Names and functions of all active substances in the biocidal product in the product
3) Risks of the biocidal product, and its handling precautions

3. Biocidal product

When it directly claims “biocidal” as primary function
When product has “biocidal function” and that is its primary function

Biocide management flowchart
Dangerous products management

1. Illegal product
   Prohibition against selling products that violate the law
   e.g., consumer chemical product subject to safety check that violates the safety and labelling standard
   biocidal product that has not been approved
   treated article that violates the safety and labelling standard
   Product prohibited from sale of which new risks have been found

2. Notification of New risk
   Upon discovery of new risk and hazard
   Upon discovery of insufficient effect or efficacy of active substance or biocidal product

Penalty Surcharge

1. Subject
   Recovery of illegitimate profits from sales of illegal products
   1) Manufacturer/importer of consumer chemical product subject to safety check but violated safety standard
   2) Manufacturer/importer of biocide who has not been approved

2. Amount
   The amount of penalty surcharge is the total sales of the illegal product (reduced or increased depending on seriousness of the violation)
   - Sales price: If the supply price has fluctuated, then the price shall be calculated for each sales period
   - Sales volume: The number of products sold during the entire period of violation
Addena (Transitional provisions)

Enforcement Date
Jan. 1, 2019

- Products in distribution prior to the enforcement date that pose risk concerns
  - Grace period for the approval of A5 and authentication of B5
  - A grace period of 3 to 10 years granted to biocidal substances depending on the biocidal products where they are used as active substances and biocidal products are granted additional 2 years

Enforcement Degree
Jan. 1, 2019

- Non-pharmaceuticals for which the form approval or registration has been completed prior to the enforcement date
  - Deemed to have been approved as consumer chemical products subject to safety check

Enforcement Rule
Jan. 1, 2019

- The provisions on the labeling and advertising restrictions to be applied to consumer chemical products and biocidal products manufactured or imported on Jan. 1, 2020 and onwards

List of ME public Notices to be issued

<table>
<thead>
<tr>
<th>Subject</th>
<th>Notice Title</th>
</tr>
</thead>
</table>
| Consumer chemical product subject to safety check | 01. Designation of and Safety Standards for Consumer Chemical Products Subject to Safety Check  
02. Labelling/standards for Consumer Chemical Products Subject to Safety Check  
03. Testing, Inspection, etc. Standards and Methods for Consumer Chemical Products Subject to Safety Check  
04. Products Subject to Risk Assessment and Methods Thereof |
| Active substance         | 05. Biocidal Substances with Low Risk Level (List of Active Substances Exempted from the Approval)  
07. Specific Scope of Data Requirements for Substance Approval and Preparation Method  
08. Equivalence Recognition Criteria and Preparation Method for Required Documents |
| Biocidal product         | 09. Safety Container and Packaging Standards for Biocidal Products  
11. Product Similarity Recognition Criteria and Preparation Method for Required Documents  
12. Biocidal Product Labelling Standards |
| Other                    | 13. Detailed Evaluation Standards for Penalty Surcharges  
14. Detailed Designation Standards for Testing and Inspection Agencies  
15. Evaluation Standards of Testing and Inspection Agencies |
Thank you