Consumer Chemical Products and Biocides Safety Act

Registration evaluation
SoonKwang KWON
wordtest@kcma.or.kr

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

- **'Enactment & promulgation of the 'Consumer Chemical Products and Biocides Safety Act' ('18. 3. 20)**
- **'Preparation of subordinate statutes of the Consumer Chemical Products and Biocides Safety Act' ('18. 1~3)**
- **Consultation with stakeholders and relevant ministries('18. 4~7)**

This process will be completed by the End of 2018, will come into effect on '19.1.1

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 woma

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

ME	Companies
Status investigation (fine when refusing investigation)	Confirm safety standard adequacy(every 3years) (manufacturer·importer → evaluating agency)
Risk assessment (periodical reassessment on safety standard	Product information(evaluation result, ingredient, labelling) report (manufacturer·importer→ ME)
Designate household product subject to safety confirmation(enlarged to house office and public)	Meet labelling standard(ingredient, cautious and etc.) (manufacturer·importer try to sell product)
Notify safety and labelling standard	Market distribution (renew every 3 years)

Active substance approval

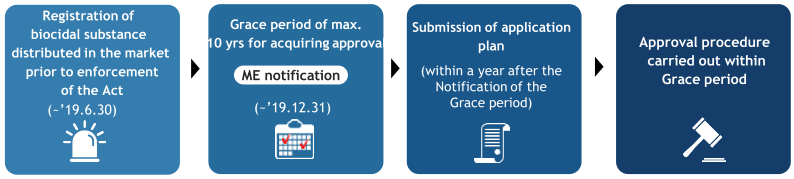
1. Active substance approval

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

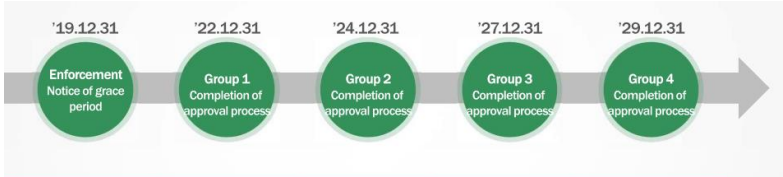
(categorized into four main and fifteen product type, refered to EU BPR)

Disinfectant	01 Disinfectants	Products used for antibiotic purposes or for the purpose of killing germs or disinfection/ sterilization in homes, offices, multi-user facilities and other spaces of everyday use or any other spaces
	02 Algicides	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
Pest Control	03 Rodenticides	Products used for the purpose of eliminating rodents such as mice and rats
	04 other vertebrates	Products used for the purpose of eliminating harmful vertebrates other than rodents
	05 Insecticides	Products use for the purpose of eliminating insects such as files, mosquitoes, ants and cockroaches
	06 other invertebrates	Products use for the purpose of eliminating harmful invertebrates other than insects
	07 Repellent	Products use for the purpose of inhibiting harmful organisms an preventing harm by using repellant methods
Preservative	08 for product storage	Products used for the purpose of storing or preserving products to guarantee shelf life
	09 for product surface treatment	Products used for the purpose of preserving the product surface or coating in order to protect the initial properties of the product surface
	10 for fibers and leather	Products used for the purpose of preserving fiber, leather, rubber, etc.
	11 Wood preservatives	Products used for the purpose of preserving wood or wooden products
	12 for building materials	Products used for the purpose of preserving non-wood construction materials, stone construction or composite materials
	13 for materials and equipment	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 or treatment systems
	14 Embalming & taxidermist fluids,	Products used for the purpose of preserving corpses or carcasses or parts thereof
Others	15 Antifoulants & others	Products used for the purpose of inhibiting the growth and development or attachment of harmful organisms in vessels, aqua-farming equipment or any other underwater structures

Active substance approval

4. Existing grace period for AS approval

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



Category	Group 1	Group 2	Group 3	Group 4
Daily exposure level	High	Medium	Medium	Low
BP type	Disinfectants, algicides, rodenticides, insecticides, repellants	Wood preservatives, product for vertebrates and invertebrates control	Preservatives for product storage, product surface treatment, fibers and leather	Preservatives for building materials, materials and equipment, embalming and taxidermist fluids, antifoulants

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

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

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 s whole are excluded

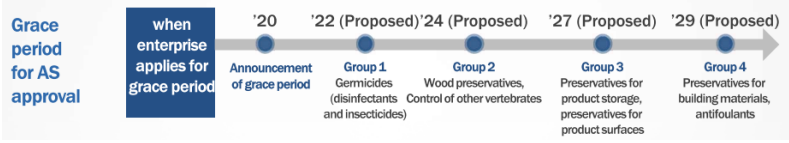
1. Product must not have adverse effect on humans, animals and the environment
2. All active substances in a biocidal product should be those approved
3. Product should have sufficient effect and efficacy in destroying harmful organisms
4. Product should not lead to resistance or cause unnecessary pain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



Active substance approval

3. Data requirement for BP authorization

Similar to data requirements for AP approval

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

Differences from AS data requirements	Physicochemical or biological properties	Harms to the human body	Manufacturing and storage facility standards
	'Pharmaceutical characteristics' additionally required	(BP) only ask irritation, sensitization, corrosion, acute toxicity	Additional data : those proving compliance with manufacturing and storage facility standards

No.	Required documents for submission	Specified in Statutes		Testing
		Act	Presidential Decree	
1	Applicant information	○		×
2	Basic product information (product name, formulation, standard amount of use, shelf life, etc.)	○	○	○
3	Physical, chemical and/or biological properties (incl. physical hazards, and pharmaceutical properties)	○		○
4	Classification and labeling	○		×
5	Purpose of use and exposure information (incl. biocidal product type)	○		×
6	Manufacturing process, etc.		○	×
7	Effects & Efficacies	○		○
8	Harm to the human body (limited to irritation, hypersensitivity, corrosiveness and acute toxicity)	○		○
9	Harm to the environment	○		○
10	Handling precautions and disposal method		○	×
11	Information on domestic and overseas uses and regulations		○	×
12	Comprehensive information on safety (incl. risk assessment)	○		×
13	Documents proving compliance with the manufacturing and storage facility standards		○	×

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

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

<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. 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

2Labeling 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

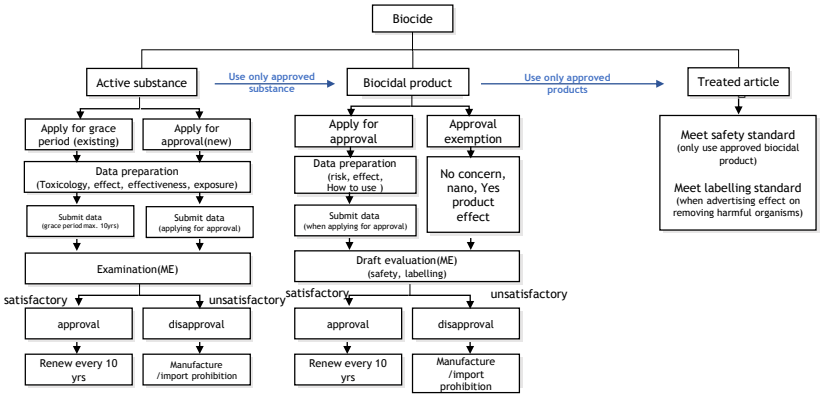
3) Risks of the biocidal product, and its handling precautions

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)

List of ME public Notices to be ussued

Subject	Notice Title
Consumer chemical product subject to safety check	01 Designation of and Safety Standards for Consumer Chemical Products Subject to Safety Check 02 Labeling 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) 06 List of Existing Active Substances Granted Grace Period for 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 10 Specific Scope of Data Requirements for Product Authorization and Preparation Method 11 Product Similarity Recognition Criteria and Preparation Method for Required Documents 12 Biocidal Product Labeling Standards
Other	13 Detailed Calculation Standards for Penalty Surcharges 14 Detailed Designation Standards for Testing and Inspection Agencies 15 Evaluation Standards of Testing and Inspection Agencies

Thank you

Korea Chemicals Management Association