

Biocide Act and Chemical Safety Comprehensive Data

Korea Chemicals
Management Association

KCMA



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Korea Chemicals Management Association

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Chapter 01

Korea Chemicals Management Association

➤ Background and Process



Consumer products and biocides management challenges

Chemical Information

- Use of active substance without safety confirmation



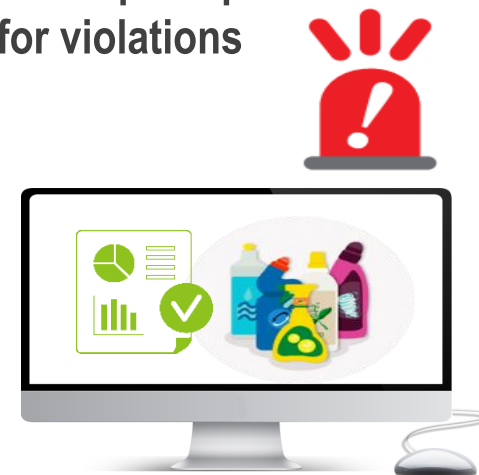
Products Management

- No decision on risk prior to product release
- Lack of standards on uses and volume
- Continuous release of new type of products that are not in the scope of regulation



System

- Absence of consumer information provision system
- Inadequate penalty for violations



2011

Proposition of needs on Consumer chemical products and biocide management

- Consumer Chemical Products and biocides management need rose due to humidifier incident

2016

Establishment of “Consumer chemical Products Safe Management Measures” (2016.11.29.)

- Introduction of Consumer Chemical products and biocides act – Reflection of regulation enactment plan(2016.11.29.)
- Pre-announcement of legislation of Consumer Chemical products and biocides safety act (2016.12.26.)

2018

Enactment & Promulgation of “Consumer Chemical Products and Biocides Safety Act” (2018.3.20.)

- Pre-announcement of legislation of Consumer Chemical products and biocides safety act lower statue (2018.5.30.)
- Enactment and announcement of Consumer Chemical products and biocides safety act enforcement decree (2018.12.24.)
- Enactment and announcement of Consumer Chemical products and biocides safety act enforcement rule (2018.12.28.)

2019

“Enforcement of Consumer chemical products and Biocides Safety Act” (2019.1.1. ~)

- Report and approval of Consumer chemical products subject to safety confirm
- Enforcement of active substance and biocidal products approval
 - Report of existing active substance

Chapter 02

Korea Chemicals Management Association

➤ Consumer Chemical Products and Biocides Safety Act



Total 7 chapters
60 articles

CH1 General Provision (Art.1~6)

CH2 Management of consumer chemical products (Art.7~11)

CH3 Safe management of active substances (Art.12~33)

- Article1 – Active substance approval (Art.12~19)
- Article2 – Biocidal product approval (Art. 20~27)
 - Management of treated article (Art. 28)
- Article3 – Information disclosure and CBI (Art. 29~33)

CH4 Post management of consumer chemical products and active substances (Art.34~40)

CH5 Establishment of basis for safe management of consumer chemical products and active substances (Art. 41~48)

CH6 Supplementary Provisions (Art. 49~55)

CH7 Penalty Provisions (Art. 56~60)

CH1 Provision

Purpose

(Article 1)

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**

Management Principles

(Article 2)

- Consider risk to human and environment beforehand
- Consider vulnerable groups to chemical exposure
- Provide product information to consumers in accurate and swift manner

CH1 Provision

Definition (Article 3)

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

e.g) antifreeze, bathroom air freshener and etc.

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

- Products (35 kinds) that need safety and labelling standard on chemical risk such as detergent, Air freshener, synthetic detergent, deodorizers, bleach and fabric softener
 - Products of risk concern in accordance with 'ARECs' (23 kinds)
 - Quasi-drug in accordance with 'Pharmaceutical Affairs Act' (7 kinds)

Biocides

Active substance, biocidal product and treated article



CH1 Provision

Active substance

Chemical, natural substance or microorganism that is used for destroying, rendering harmless, deterring harmful organisms

e.g) PHMG, PGH, CMIT/MIT, lavender oli and etc.

Biocidal product

Product whose main purpose is to destroying harmful organisms

- Product that consist of one or more active substances or from active substance from mixture
- Product that create active substance from chemical, natural substance or microorganism mixture

e.g) disinfectant, repellent, pesticide, preservative humidifier disinfectant, ion generator and etc.

Treated Article

Product that is uses a biocidal product for other function, rather that its primary function

e.g) antimicrobial air conditioner filter, deodorized underwear, preserved furniture, products containing Preservatives and ertc.



CH2 Management of consumer chemical product

Status survey

(Article 7)

- Prevent human health and environment risk
 - Decision on consumer chemical product subject to safety check } Data gathering
 - Request data* submission on subjects to report
- * Kind, manufacture/import volume, use, chemical composition, hazard

Risk assessment

(Article 8)

- When there is a risk as a result of risk assessment, relevant products are designated and announced as **consumer chemical product subject to safety check**
- Product manufacture or import is prohibited, if risk is very high and emergency measure is needed

Safety standard

(Article 9)

- Safety standard announced for each kind of product subject to safety check
 - Chemicals cannot be contained, contents, yield, emission volume and etc.
 - Container or packaging standard when risk is concerned by its leakage
- ☞ Refer to MOE notification on Designation of consumer chemical product subject to safety check and its safety and labelling

Safety Check

(Article 10)

- Check adequacy on safety standard and labelling standard once every three years with Test/Inspection organization → Report appropriateness within 30 days^(KEITI)
- Get approval for products with no safety standard^(NIER)

CH2 Management of consumer chemical product

Consumer chemical product subject to safety check (35kinds)

Category	Product Type	Category	Product Type
Cleaning	Detergent, remover	Disinfectant	Disinfectant, algaecide, antimicrobial disinfectant for humidifier, antimicrobial disinfectant to prevent infection, other preventive disinfectant
Washing	Washing detergent, bleach, softener		
Coating	Gloss coating, coating for specific purpose, antirust, ironing auxiliaries	Aid products	Repellent, Hygiene extermination·prevention·insecticide, Disease prevention rodenticide, pesticide
Adhesive·binding	Adhesive, glue		
Air freshener·deodorant	Air freshener, deodorant	Preservative·Preserved products	Preservative for wood. Filter type Preservation finished product
Dye·painting	Product dye, product paint		
Car exclusive product	Car washer fluid, antifreeze	Etc.	candle, moisture repelling agent, artificial snow spray
Printing and document related	ink·tonner for printing		
beauty	Beauty glue, ink for tattoo		



CH3 Safe management of Biocide

Active substance approval

Biocidal product approval

Subject

Manufacturers/importers of AS to use AS for the product

Manufacturers/importers of biocidal product To distribute within territory of Korea

Exemption

- publicly notified by the Minister of Environment for its low risk
- scientific experiment, analysis or chemical research
- pilot production of product
- Export the whole amount

- scientific experiment, analysis or chemical research
- product for test trial and not for sale
- Export the whole amount

Data

- **AS approval application**
(Enforcement decree annex 8)
 - Physico · chemical or biological properties
 - use and exposure information
 - hazard · risk information
 - effect, potency, classification and labeling and etc.

- **BP approval application**
(Enforcement decree annex 21)
 - general information
(chemical, composition, use purpose and object)
 - hazard · risk information
 - effect, potency, classification and labeling and etc

Organization

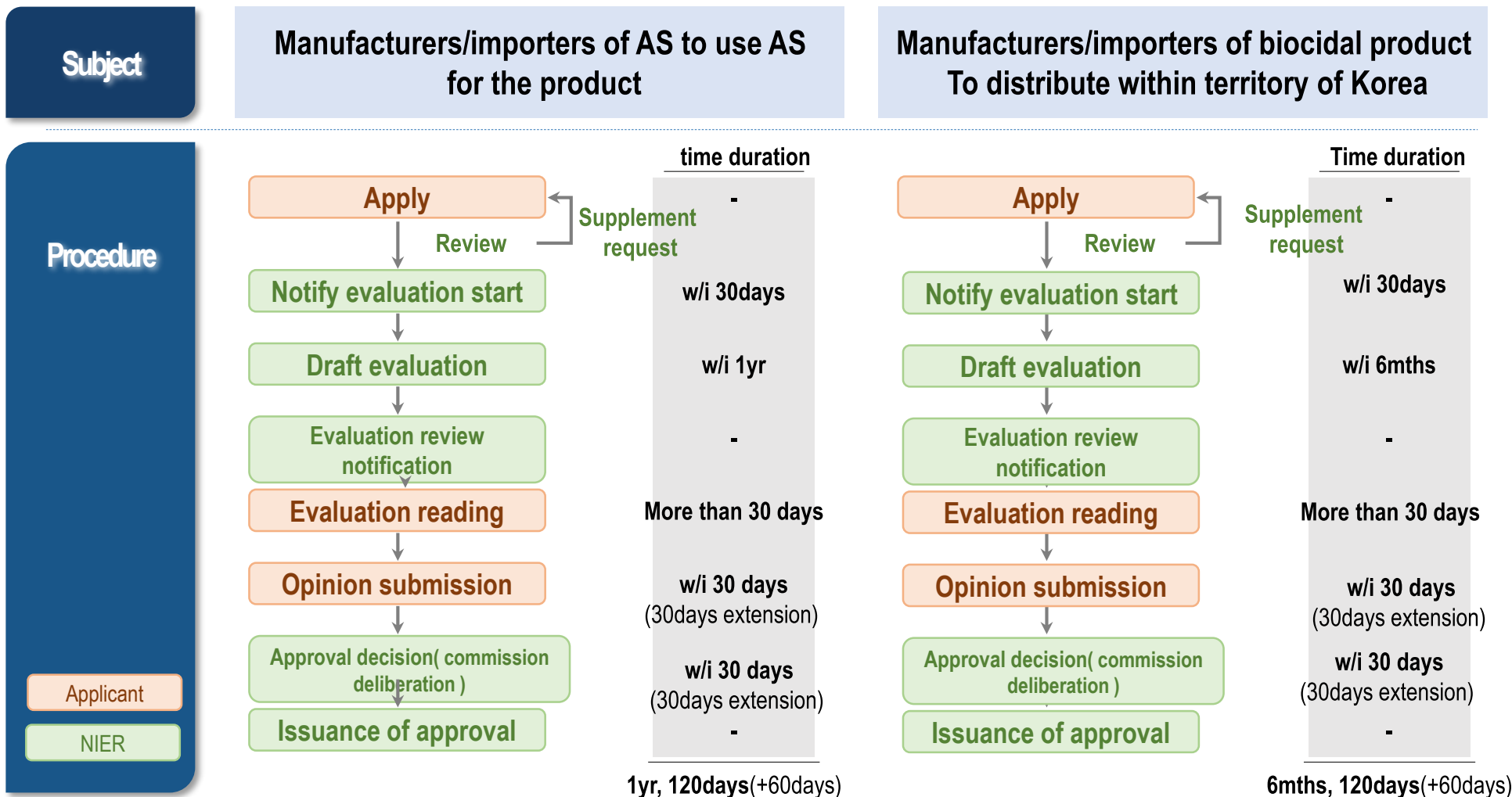
- **NIER**
 - Chemical product management system(chemp.me.go.kr)

- **NIER**
 - Chemical product management system(chemp.me.go.kr)

CH3 Safe management of Biocide

AS approval procedure

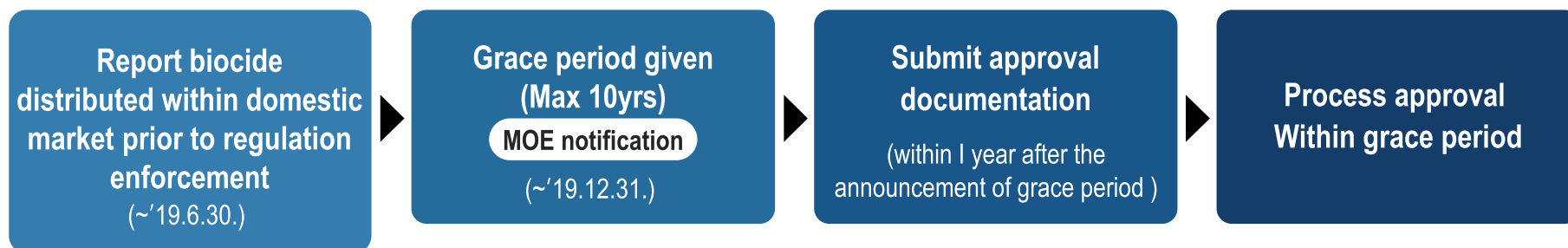
BP approval procedure



CH3 Safe management of Biocide

Grace period for existing substance

- Report biocide that are distributed within territory of Korea prior to 2018.12.31



- Grace period(Enforcement decree CH14)

Grace period MOE notification (~'19.12.31.)	3yrs (~'22.12.31.)	5yrs (~'24.12.31.)	8yrs (~'27.12.31.)	10yrs (~'29.12.31.)
BP Type	1. Disinfectants 2. Algaecide 3. Rodenticide 4. Insecticide 5. Repellent	6. Wood preservative 7. Product for vertebrates control 8. Product for invertebrates control	9. Preservatives for product storage 10. Preservatives for product surface 11. Preservatives for product for fivers and leather	12. Preservatives for building materials, 13. materials and equipment, 14. embalming and taxidermist fluids, 15. antifoulants

CH3 Safe management of Biocide

Safe management of treated article

Safety standard

- **Use biocidal product with approval or satisfy similarity standard**
 - Biocidal product that has safety confirmation from foreign government

Labelling standard

- **Do not use expression causing misconception**
- **When informing effect on removing hazard organism**
 - Phrase that biocidal product is used
 - All active substance name and function
 - Danger and precautions when using biocidal product

} Labelling



Information offering

Manufacturers/importers are obliged to provide information when consumer Requested information offering or reading

※ However, reader should not use the information for unfair purpose

CH4 Post management of consumer product and biocide

Limitation on labelling and advertisement

Subject

- Consumer chemical product subject to safety check
- Biocidal product

Term of compliance

- 'non-toxic'
- 'harmless'
- 'environment·nature friendly'
- 'human·animal' friendly
- **Limitation on similar expression**
- Indicate expression suggesting product name, kind, how to use, precaution



Prohibition on sale

Subject

- Consumer chemical product
- Consumer chemical product subject to safety check
- biocidal product
- Treated article

Term of compliance

- Violated products should not be**
- on sale·given or display·store for the purpose
 - mediated for sale or substituted for purchasing



CH4 Post management of consumer product and biocide

Report of new risk
and recommend to
take relative measures

- Immediately report to MOE when **new information** is found
 - Hazard·Risk information on consumer chemical product subject to safety check and biocide
 - when effect·potency information lacks on biocide and biocidal products

Recommendation on recovery·disposal·exchange·refund·improvement

Recovery order

- **Violation**
 - Consumer chemical product
 - Consumer chemical product subject to safety check
 - Biocidal product
 - Treated article

Recovery,
disposal
order



Penalty

- Charge penalty for unjustified profit from violated products
 - Amount equivalent to sale price



Sales volume



price

of products sold during the
illegal time period

Price for
each duration



- Less than 10 hundred million won when hard to compute the sale amount

Chapter 03

Korea Chemicals Management Association

➤ Chemical Safety Comprehensive Data



CH1 Biocide approval data

Active substance

1. Applicant information
2. Substance identity
3. Exposure information
4. Safety use information
5. Classification and labelling
6. Manufacturing process, etc.
7. Information on domestic and overseas uses and regulations
8. Physical, chemical and biological properties
9. Harm to human body
10. Harm to the environment
- 11. Risk to human and the environment**
12. Efficiency and efficacy
13. Comprehensive information on safety

Biocidal product

1. Applicant information
2. Substance identity
3. Exposure information
4. Safety use information
5. Classification and labelling and **packaging**
6. Manufacturing process and **facility for manufacture or storage**
7. Information on domestic and overseas uses and regulations
8. Physical, chemical and biological properties
9. Hazard to human body
10. Hazard to the environment
- 11. Risk to human and the environment**
12. Efficiency and efficacy
13. Comprehensive information on safety

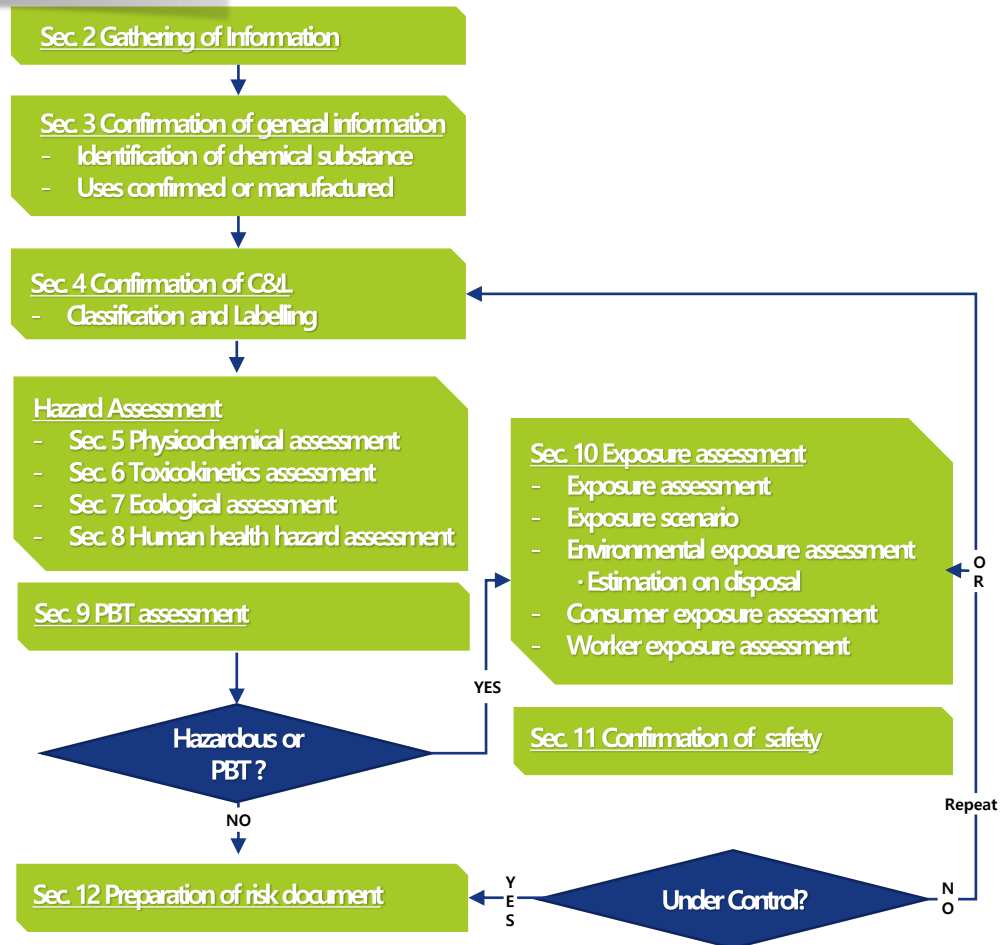
CH2 Drafting Chemical safety comprehensive data

Contents

1. Summary and result
 - ① Summary and result
 - ② Active substance evaluation
2. Active substance information and safety evaluation result
 - ① Active substance information
 - ② Human hazard evaluation
 - ③ Environment hazard evaluation
 - ④ Efficiency and efficacy evaluation
3. Information on biocidal product can be used(representative) and evaluation result on its safety
 - ① Information on biocidal product can be used
 - ② Human hazard evaluation
 - ③ Environment hazard evaluation
 - ④ Efficiency and efficacy evaluation
4. Comprehensive result on safety
5. Appendix

Risk Assessment

Ch. 3 Preparation of risk document



「Rule on how to perform risk assessment」 (NIER notification)

CH2 Drafting Chemical safety comprehensive data

Standard for risk

1. CMR
2. EDCs
3. PBT or vPvB
4. MOE(Non-carcinogenic) <100
 - NOAEL: repeated dose toxicity(more than 12mths)
 - NOAEL: repeated dose toxicity (less than 12mths): apply UF
5. HQ(Hazard Quotient): > 1
6. MOE(Carcinogenic) <10,000

CH2 Drafting Chemical safety comprehensive data

Pending issues

1. Standard on selecting hazard data and correlation coefficient for unique biocide dose-response evaluation
2. Standard on utilizing alternative test result such as QSAR and extrapolation allowance
3. Standard on selecting biocide exposure scenario (concerning biocides' diversity)
4. Range of exposure evaluation (2nd exposure_indirect exposure)
5. Exposure tool development

CH3 Risk assessment tool

K-Chesar

Background

- Need to develop tool that industry can utilize to develop risk assessment as ARECs implemented and risk assessment data submission became obligation

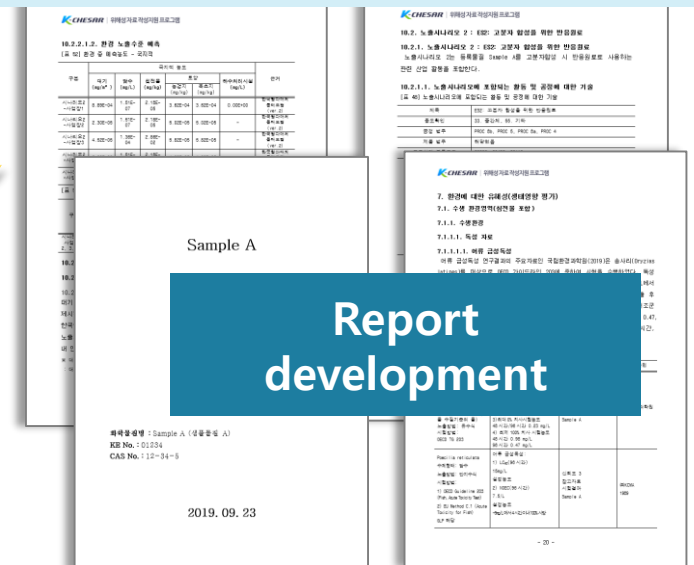


Ties hazard data and perform risk assessment

- Ties hazard information that are input into registration system
- Reflected EU and EPA assessment factors for computation on PNEC and DN(M)EL
- Can use computed allowance level for safety check

- Can confirm safety and environment, employee and consumer by one click
- Environment: SimpleBox Korea
- Employee: ECETOC TRA
- Consumer: ECETOC TRA

Risk assessment and safety check



CH3 Risk assessment tool

K-Chesar

- Provide risk assessment draft template for each registration type and chemical properties

Template for each kind

- Can draft and print out chemical safety information based on hazard data
- Can deliver to downstream users by email

Chemical Safety data

Exposure evaluation model expansion

- Loaded exposure route and properties specified model
- Loaded tier 2 level upper exposure evaluation tool

Hazard evaluation model

-Introduced carcinogenic evaluation tool

Use map

- Use investigation platform and provide use map for main type of business

➡➡ Provide useful risk assessment drafting function to industry ⚡⚡

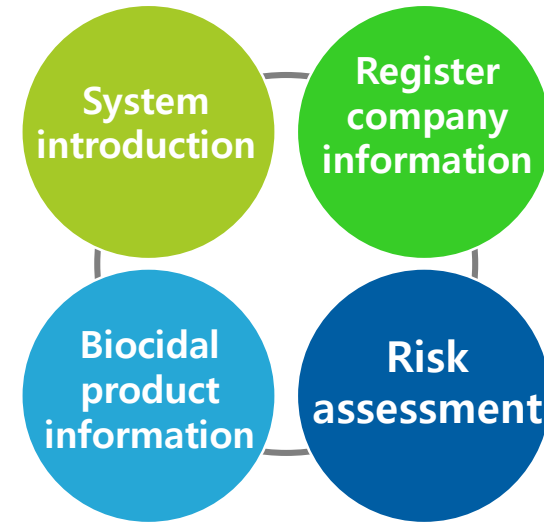
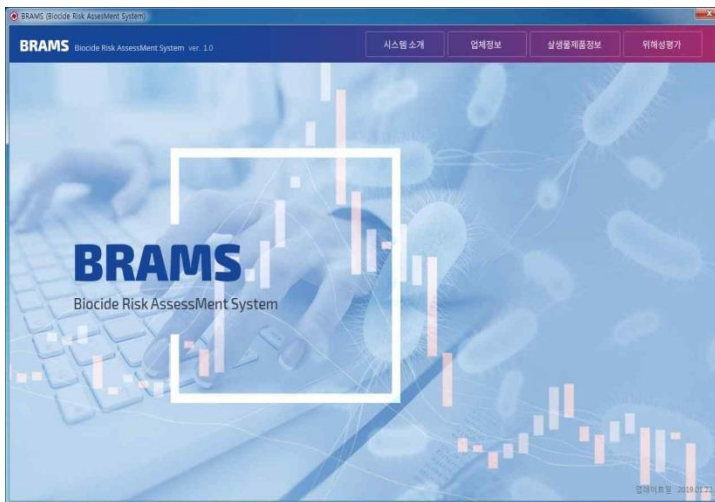
CH3 Risk assessment tool

BRAMS (Biocide Risk Assessment System)

Purpose

- **Convenient check on biocidal product exposure evaluation and risk result**
 - NIER(2018), Result on biocidal product evaluation model operation environment

Planning big-data platform for supporting rapid safety re-assessment of already registered chemicals in Korea



CH3 Risk assessment tool

BRAMS (Biocide Risk Assessment System)

Main function

- **can evaluate 15 types of biocidal products**
 - Input biocidal product exposure scenario and exposure coefficient gathered up to date
 - Can evaluate exposure using initial coefficient value for each product type
 - Can input initial coefficient value and reference toxic value for each consumer's exposure scenario
- **Can evaluate on Consumers** (cannot evaluate environment and workers)



Thank you

