「Act on Consumer Chemical Products and Biocides Safety」(amended March 24, 2020)

Guideline for the 『Act on Consumer Chemical Products and Biocides Safety』

Focusing on biocides safety management

October 2020

<Notes>

◆This guideline is intended solely as a convenience to the non-Korean-reading public and are not legally binding. If there is any conflict or inconsistency between the original Korean version and the English version, the Korean version will prevail.

◆ This guideline explains about the overall management system for biocides safety prescribed by『Act on Consumer Chemical Products and Biocides Safety』(hereinafter referred to as "the Act").

◆ This guideline only acts as a reference without any legally-binding or compulsive effect. The liability to observe obligations under the Act shall be imposed to the persons who are obliged to do so pursuant to the Act.

◆ Interpretation and application of this guideline should be based on full and overall consideration over the Act and its subordinate laws such as the Enforcement Decree, the Enforcement Rules, MOE Public Notice and Established Rules. If there is any conflict or inconsistency between this guideline and the Act, including its subordinate laws, the Act and its subordinate laws will prevail.

◆ This guideline is prepared in accordance with the Act, which was amended on March 24, 2020. It can be revised in the future if any amendment or change is made in the Act, its subordinate laws, administrative condition or policy-based decision.

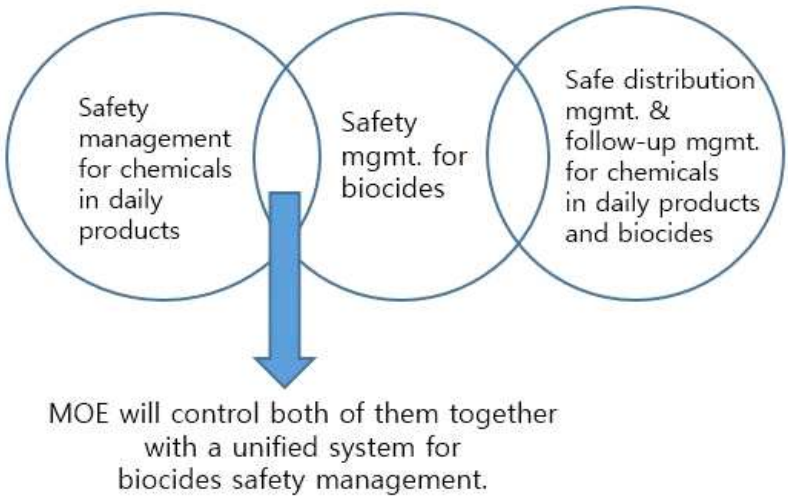
『Act on Consumer Chemical Products and Biocides Safety』

Introduction

Background for the law

- Public concerns over chemical products keep increasing since the toxic humidifier disinfectant case in Korea.
- Therefore, prevention-focused management system is established, including systematic management on chemicals in daily products.

Key Points of the law



Obligation of Manufacturer/Importer under the law

■ Biocides control

- Notify of existing active substance (AS)
- Get approved for active substance
- Get approved for biocidal product (BP)
- Comply with safety and labelling standards for treated article (TA).

■ Distribution & Follow-up management on the Market

- Regulate labelling and advertisement
- Impose fine and/or penalty

Biocides Control

Definition (Article 3 of the Act)

■ Active substance (AS)

- A chemical or natural substance, or micro-organism used for destroying, rendering harmless or dettering the action of any harmful organism

■ Biocidal product (BP)

- Product that its primary function is to destroy harmful organisms, etc.

① product containing at least one AS, or product that AS and non-AS (e.g. chemicals, natural substance, micro-organism) are mixed

② product creating biocidal substances by mixing chemical substance, natural substance or micro-organism

- BP types

Category	Product Type
Disinfectants	Disinfectants
	Algaecides
Pest control	Rodenticides
	Insecticides
	Repellents
	Control of other vertebrates
	Control of other invertebrates
Preservatives	Wood preservatives
	Preservatives for product
	Film preservatives
	Fiber and leather preservatives
	Construction material preservatives
	Material and equipment preservatives
	Embalming and taxidermist fluids
Other BPs	Antifouling products

■ Treated article (TA)

- Product that uses biocidal product(s) for the purpose of destroying harmful organisms, etc., which is aside from its primary function.

■ Exclusion (Article 5 of the Act)[1)]

- This Act shall exclude biocides that fall under any of the following paragraph.

○ Consumer chemical products or biocides controlled by other Acts - the purpose and use thereof	○ Products excluded from "safety standard test and labelling standard" or "biocides safety management" (by the Amendment)
1. Health Functional Foods Act - health functional food 2. Act on the Management of Military Supplies & Defense Acquisition Program Act - military supplies 3. Pesticide Control Act - pesticide, biopesticide, technical concentrate, and pest control equipment 4. Drinking Water Management Act - water treatment chemicals 5. Control of Livestock and Fish Feed Act - single-compound feed and supplementary feed 6. Ballast Water Management Act - treatment substance 7. Food Sanitation Act - food, food additives, apparatus, and containers and packages 8. Pharmaceutical Affairs Act - drug, quasi-drug, animal drug, and animal quasi-drug 9. Hygiene Products Control Act - cleansing and hygiene products 10. Medical Devices Act - medical devices 11. Cosmetics Act - cosmetics	1. Any daily chemical products or biocides for scientific test, analysis, or study 2. Any test product of daily chemical products or biocides which is not for sale 3. Any daily chemical products or biocides that the entire quantity of which shall be exported 4. Any daily chemical products or biocides which is only used for products prescribed by the above paragraphs of 1 to 3 5. Any daily chemical products or biocides that are prescribed by the Presidential Decree, including but not limited to products which shall not be sold in the Korean market.

Amendment (effective from Jan 1, 2021)

Previously, exclusion was only allowed to biocidal substances for scientific test/analysis/study, prototypes, and those to be exported entirely. However, such exclusion has been expanded to include consumer chemical products and biocides.

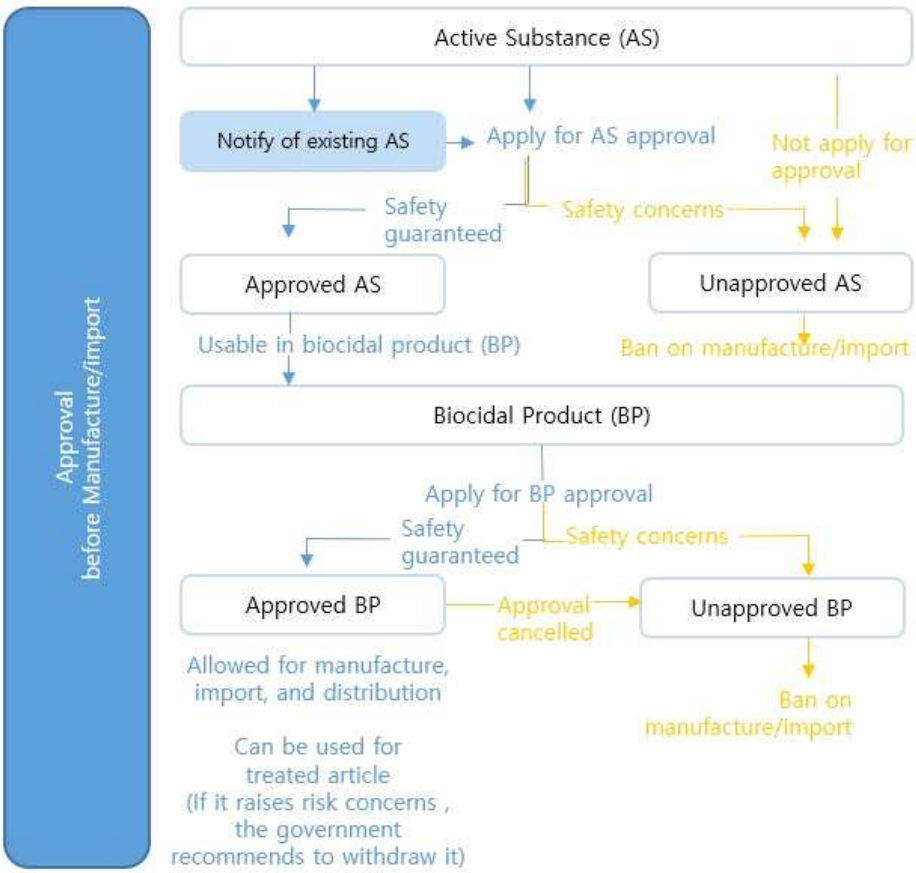
Upcoming Amendment (this partial amendment was pre-announced on July 30, 2020.)

Some provisions in the subordinate laws will be added to include the procedure for checking exclusion of consumer chemical products and biocides.

[1)] pursuant to the Amendment (effective from January 1, 2021)

Biocides: Approval before manufacture/import

- Manufacturer/importer of active substance and biocidal product shall get approved by the National Institute of Environmental Research (NIER).

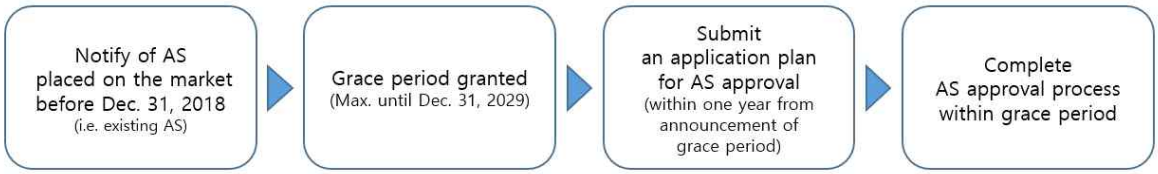


01. Existing Active Substance

: Notification

Notification of existing AS &
Relevant transitional measures (Article 18)

Application for AS approval (Article 19)



< Existing AS : from notification to approval >

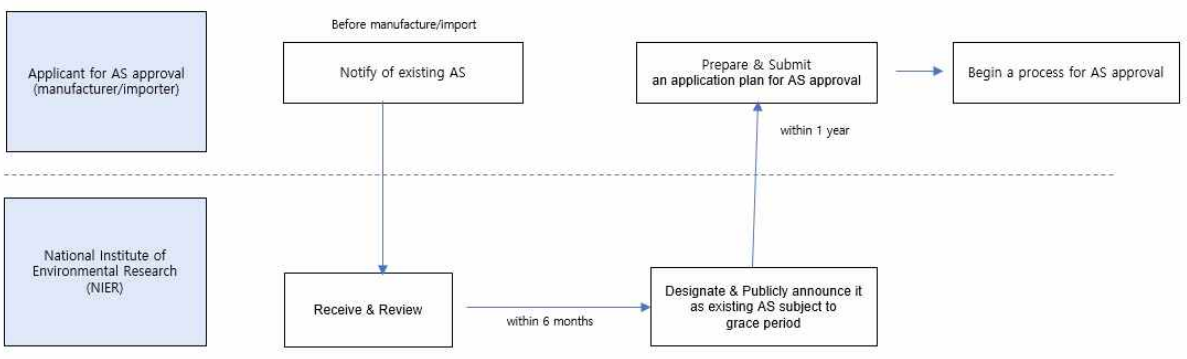
Notification of Existing Active Substance (AS) & Relevant Transitional Measures (Article 18)

1) Notification of existing AS (Article 18 of the Act & Article 14 of the Enforcement Rule)[2)]

■ Notification of existing AS shall be submitted to the Ministry of Environment before its manufacture or import.

- **(Purpose)** Transitional measures can be applied once after exsitng AS is designated and publicly announced as "Existing AS subject to Grace Period". Such AS can be manufactured or imported without approval during the grace period.
- **(Definition) AS**(s) in biocidal product or treated article, which were placed on the market before December 31, 2018.

※ **Amendment** (effective from March 24, 2020): manufacturer/importers are allowed to submit a notification whenever possible before the manufacture or import of existing AS even after the deadline of June 30, 2019.



■ **(How to Notify)** Submit a notification via the website of Chemical Products Management System (CHEMP) to the National Institute of Environmental Research.

- (Applicant) Person who intends to manufacture or import an existing AS

Information Requirements for Notification
- Notification on manufacture/Import of existing AS (※ Please use the form in Annex 18 of the Enforcement Rule.)
- (Information on manufacturer/importer) Name or company name, address, contact information
- (Information on AS) Name, chemical composition, the amount to be manufactured/imported, range of purity
- (Product Type) Type(s) of biocidal product that the existing AS can be used for
- (In case of contact manufacturer) Documents proving such contract (e.g. copy of entrusting agreement)

※ More information is available at the CHEMP website (https://chemp.me.go.kr/)

→ Please look at the Notice of the News. ※ This website is currently available only in Korean.

[2)] pursuant to the Amendment (effective from January 1, 2021)

2) Grace period for existing AS (Article 18 of the Act & Article 14 of the Enforcement Decree)

■ Grace period : Approval of existing AS

- A person who intends to manufacture or import a new AS shall obtain an approval before its manufacture or import because the grace period is not granted for new AS.
- Once a person who intends to manufacture or import an existing AS notifies of existing AS, an grace period will be granted depending on bioicidal product type and hazard level. During the grace period, the existing AS can be manufactured or imported without AS approval.
- When AS is not designated and publicly announced as "Existing AS subject to Grace Period", manufacture and import of such AS shall be prohibited from the date of such announcement. This measure came into effect on January 1, 2020.

Grace Period	Dec 31, 2022	Dec 31, 2024	Dec 31, 2027	Dec 31, 2029
Product Types	Disinfectants	Control of other vertebrates	Preservatives for product	Construction material preservatives
	Algaecides	Control of other invertebrates	Film preservatives	Material and equipment preservatives
	Rodenticides	Wood preservatives	Fiber and leather preservatives	Embalming and taxidermist fluids
	Insecticides			Antifouling products
	Repellents			
※ We recommend you to check the MOE Public Notice regarding the designation of "Existing AS subject to Grace Period". Please note that grace period is determined differently depending on product type and risk level of biocide thereof.				

Upcoming Amendment (this partial amendment was pre-announced on July 30, 2020.)

Some provisions will be amended to specify the termination dates of each grace period, which is different way of notation from the initial version of the Act. (i.e. three/five/eight/ten years from the date when MOE Public Notice was announced).

Application Plan for AS Approval (Article 19 of the Act)

- Application plan for AS approval shall be submitted within one year from when the MOE Public Notice regarding the existing AS subject to grace period was publicly announced.

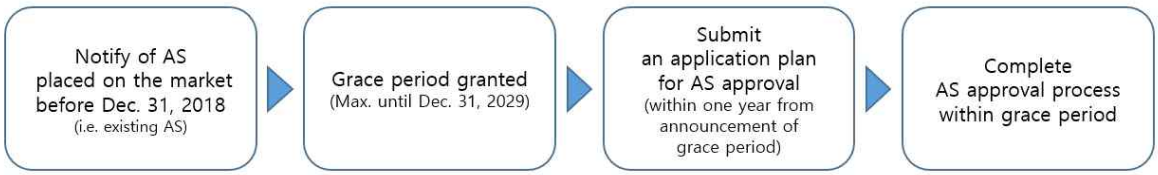
Applicant	A person who notifies of the existing AS subject to grace period
Requirements	Prepare and Submit an application plan for AS approval - Included Content: Detailed schedule & methods to prepare such application Expected date to submit such application - Deadline: No later than one year from the date when the substance is designated and publicly announced as "Existing AS subject to Grace Period" by MOE Public Notice.
Competent authority	National Institute of Environmental Research (via CHEMP website)
Relevant measures	The Ministry of Environment (MOE) may prohibit manufacture or import of existing AS subject to grace period, if those who made a notification fails to submit an application plan by the deadline, or seems not to submit an application and required information thereof for AS approval within the granted grace period.

Upcoming Amendment (this partial amendment was pre-announced on July 30, 2020.)

If grace period ends within one year from the date when notification is made, the application for AS approval may not be submitted in accordance with provisions of the subordinate laws.

02. Active Substance (AS)
: Approval

Approval of Active Substance (Article 12 of the Act)



< Existing AS : from notification to approval >

Active Substance: Approval (Article 12 of the Act)

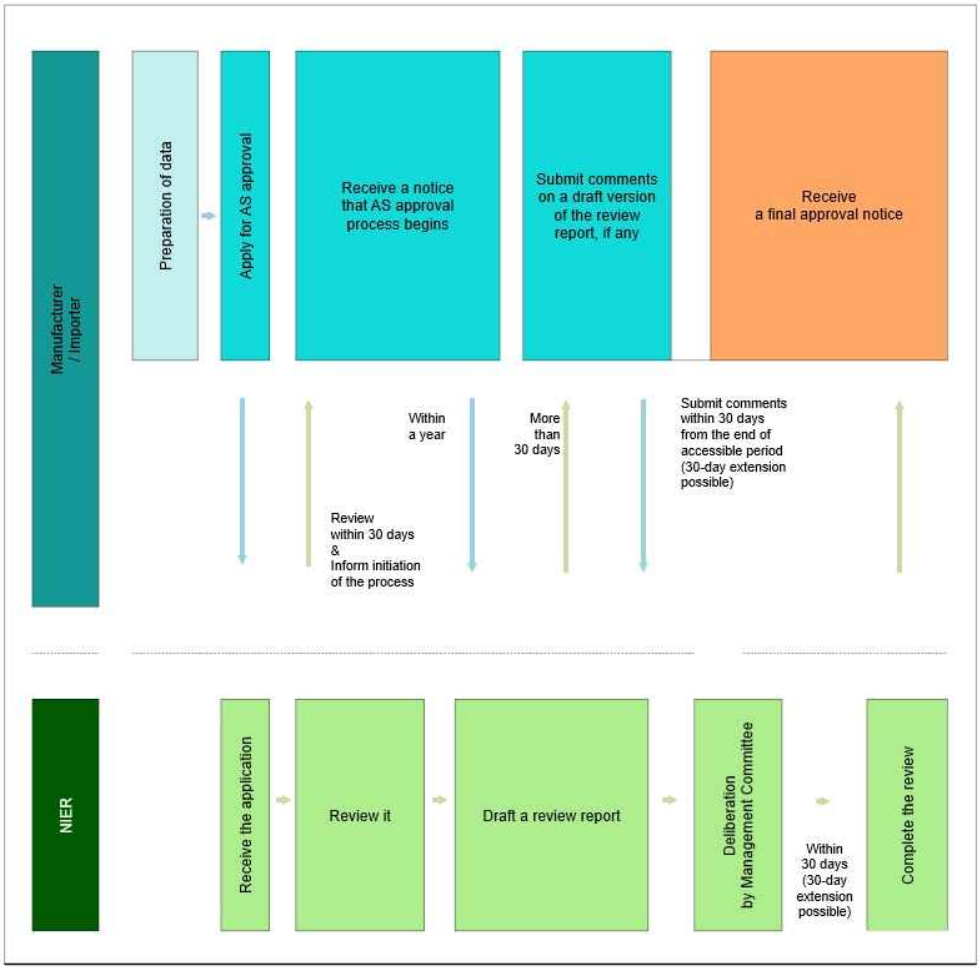
■ What is an approval of active substance?

- Any person who intends to manufacture or import an active substance shall get approved by the Ministry of Environment before manufacture or import such AS.

■ How to get approved?

- (Applicant) A person who intends to manufacture or import an existing AC for use in biocidal product
- (Competent Authority) National Institute of Environmental Research (via CHEMP)

<Procedure of AS Approval>



<Information Requirements for AS Approval> (Article 13 of the Act & Annex 8 of the Enforcement Rule)

No.	Information	Details
1	Identity of manufacturer/importer	- Name, company name, address, and contact number of the applicant
2	Identity of AS	- Name, identity information (e.g. molecular formula, chemical composition)
3	BP type	- Type(s) of biocidal product that the active substance can be used
4	Information on AS	- Physico-chemical properties and biological features - Exposure information (i.e. use, major exposure route, exposure type, etc.) - Hazards and risks on human, animal, and the environment - Efficacy and effect - Classification and labelling
5	Document proving the AS is subject to less strict approval criteria	- (When falling under any of the conditions for less strict approval criteria) Document proving that it fulfills one of the conditions
6	Raw materials & Processing for manufacturing AS	- Raw materials and processing for manufacturing AS - Precautions for handling the AS, and disposal method - Information about uses and regulations on AS in Korea and other countries - Confirmation of individual submission - (In case of contract manufacturer) Documents proving such contract (e.g. copy of entrusting agreement)
7	Comprehensive safety data	- Comprehensive data about safety of the AS, including risk assessment

※ The above documents may not be submitted if it falls under any of the following conditions:

① When proven that the effect on human, animal and the environment is insignificant because the reliable information on use and exposure of BP or AS(s) therein is identified.

② When proven based on scietific evidence that data submission is not necessary.

③ When any relevant data is submitted for the purpose of registration in accordance with Article 10 of the Act on Registration and Evaluation of Chemical Substances.[3)]

■ Joint data submission for AS approval

(Article 19 of the Act & Article 15 of the Enforcement Rule)

- **(Joint Submission of Required Data)**[4)] If more than two companies intend to obtain an approval for same existing AS subject to grace period with the same name and chemical composition, both companies shall submit jointly some of the required data.
- **(Consultative Body)** For the joint submission, such companies shall establish and participate in Consortium and its activities, including election of the lead registrant.

  ※ Please refer to the Practical Guideline for Lead Registrants for Joint Submission.

Upcoming Amendment **(this partial amendment was pre-announced on July 30, 2020.)**

In the initial version of the law, provisions for joint submission are only applied to biocides that can

3) pursuant to the Amendment (effective from March 24, 2020)

4) pursuant to the Amendment (effective from March 24, 2020)

be even used for the same PT(s). However, the Amendment states that joint submission is also applied to potential applicants of same existing AS subject to grace period, and consortium of same PT.

- **(Individual Submission)** Joint submission is a basic requirement for the companies. Provided, That individual submission may be allowed in any of the followings:

① When joint submission can cause a disclosure of confidential business information (CBI), which can lead to significant damage to the company; or

② When joint submission consumes more money than individual submission; or

③ When existing AS subject to grace period has different classification and labelling; or

④ When potential applicants have different opinions about the date to be submitted.

※ A person who wants to submit an application for AS approval individually shall attach and submit the data proving that it meets condition required for individual submission to the National Institute of Environmental Research (NIER).

■ AS with Less Strict Approval Criteria (Article 12 of the Act)

- In case of AS satisfying one of the following conditions, partial or entire criteria may be eased.

Case	Condition
1	If possible exposure to human or the environment is insignificant due to the limited purpose and use of AS subject to approval.
2	If AS is necessary for public health and the environment because the risk of other substances is not low enough to substitute the AS.

■ Valid Term of AS Approval

(Article 12 of the Act & Article 9 of the Enforcement Decree)

- Regardless of whether AS approval got approved for its modification or was notified, the valid term of AS approval shall be maximum 10 years, taking into account hazards and risks of AS.

- Any person who wants to obtain re-approval shall apply for it before the valid term of existing approval is terminated.

Valid Term	Condition
10 years	- General AS
7 years	- AS subject to less-strict AS approval criteria - AS with sensitization on respiratory organs - AS with more than two properties out of the followings: persistence, bioaccumulation, or toxicity.
5 years	- AS that falls under all of the above conditions for 7-year valid term

■ Modification of Granted Approval (Article 15 of the Act)

What you need to get	Reason for Modification
Approval	1. Change in hazard or risk information on AS
	2. Change in effect and efficacy of AS
	3. Change in AS name
	4. Change in address of AS-manufacturing facility
	5. Change in AS use
	6. Change in AS-manufacturing method, including processing
	7. Other reasons related to Article 14(6)1, 2 and 4 of the Act
Notification	1. Name, company name, address, contact information and other information related to approval

■ Acceptance of AS Equivalence (Article 16 of the Act)

- **(Definition of Equivalence)** Different ASs are technically same in chemical composition, risk, and effect or efficacy (e.g. destroy harmful organisms).
- If an AS is proven its technical equivalence with an already-approved AS (i.e. "Standard AS") and is admitted by the Management Committee, such AS shall be considered as approved.
- In this case, a consent on data use should be made pursuant to Article 32(1) of the Act.

■ Cancellation of AS Approval (Article 17 of the Act)

- If a person who gained an AS approval or modified his/her own granted approval (hereinafter referred to as "AS Approval"), or AS equivalence approval falls under any of the following conditions, the MOE may cancel such AS approval or AS equivalence approval. Otherwise, the MOE may order a suspension of manufacturing or importing such AS for less than one year.

Case	Reason of Cancellation
1	If the person received such AS approval or AS equivalence approval by fraud or other improper means.
2	If the AS is manufactured or imported different from the granted details of AS approval or equivalence approval.
3	If the AS continues to be manufactured or imported without re-approval or equivalence re-approval after termination of the valid approval pursuant to Article 12(4) of the Act, or termination of AS equivalence approval pursuant to Article 16(4) of the Act.
4	If any new risk of the AS is found, which was not known when obtaining existing AS approval or equivalence approval.
5	If other government or international organization admits that such AS has a risk.

※ Attachment

[Penalty] Amendment (effective from January 1, 2021)

Penalty & Fine	Details
Imprisonment for not more than 7 years or a fine not exceeding 70 million won	- Any person who manufactures or imports an active substance without approval or under the approval obtained by fraud or other improper means (except a AS considered to have obtained AS approval pursuant to the former part of Article 16(4)). - Any person who manufactures or imports an active substance different from details of the granted AS approval. - Any person who manufactures or imports an active substance that AS approval or AS equivalence acceptance was canceled or that is ordered to suspend manufacture or import. - Any person who fails to follow an order of administrative measures such as withdrawal or disposal. ※ If an appointed person fulfills the obligations in lieu of a person obliged to do so, such appointed person shall be considered as obliged to meet the obligations. Therefore, in case of violation, only such appointed person shall be punished. Provided, That the foregoing shall not apply when such appointed person proves that the imported AS is different from the reported information. ※ Any person who kills or wounds other person(s) due to any act described above shall be punished by imprisonment not more than 10 years or a fine not exceeding 100 million won. In this case, imprisonment and a fine may be imposed concurrently.
Imprisonment for not more than 5 years or a fine not exceeding 50 million won	- Any person who manufactures or imports an active substance after having failed to obtain a modified approval or having obtained a modified approval by fraud or other improper means. - Any person who manufactures or imports an active substance different from the details of modified approval. - Any person who obtains AS equivalence acceptance by fraud or other improper means, or who manufactures or imports the AS different from the details of AS equivalence acceptance. - Any person who continues to manufacture or import AS substance without re-obtaining AS equivalence acceptance. ※ If an appointed person fulfills the obligations in lieu of a person obliged to do so, such appointed person shall be considered as obliged to meet the obligations. Therefore,inc ase of violation, only such appointed person shall be punished. Provided, That the foregoing shall not apply when such appointed person proves that the imported AS is different from the reported information. ※ Any person who kills or wounds other person(s) due to any act described above shall be punished by imprisonment not more than 7 years or a fine not exceeding 70 million won. In this case, imprisonment and a fine may be imposed concurrently.
Imprisonment for not more than 3 years or a fine not exceeding 30 million won	- Any person who sells or gives, or otherwise displays, keeps or stores for the purpose of sales or gift an active substance or a biocidal product, in violation of AS and BP approval. - Any person who refuses, obstructs or evades the access, inspection or collection.
Fine not exceeding 10 million won	- Any person who fails to notify of modified approval; Provided, That when a person appointed pursuant to Article 54(2) meets the obligations of Article 15 or Article 23, the foregoing shall only apply to such appointed person. - Any person who acts as a go-between for sales or purchases on behalf of other person biocides that is prohibited to sell, etc. - Any person who fails to report newly identified risk without delay or who makes false report

	therefor. - Any person who fails to make a report according to an order of administrative measures, or who makes a report therefore by fraud or other improper means. - Any person who fails to record or retain data, or falsely records. - Any person who fails to report or falsely reports data.

03. Biocidal Product : Approval & Treated Article : Management

Approval of Biocidal Product (BP)
(Article 20 of the Act)

Management of Treated Article (TA)
(Article 28 of the Act)

<BP Approval & TA's Safety and Labelling Standards>

Biocidal Product: Approval (Article 20 of the Act)

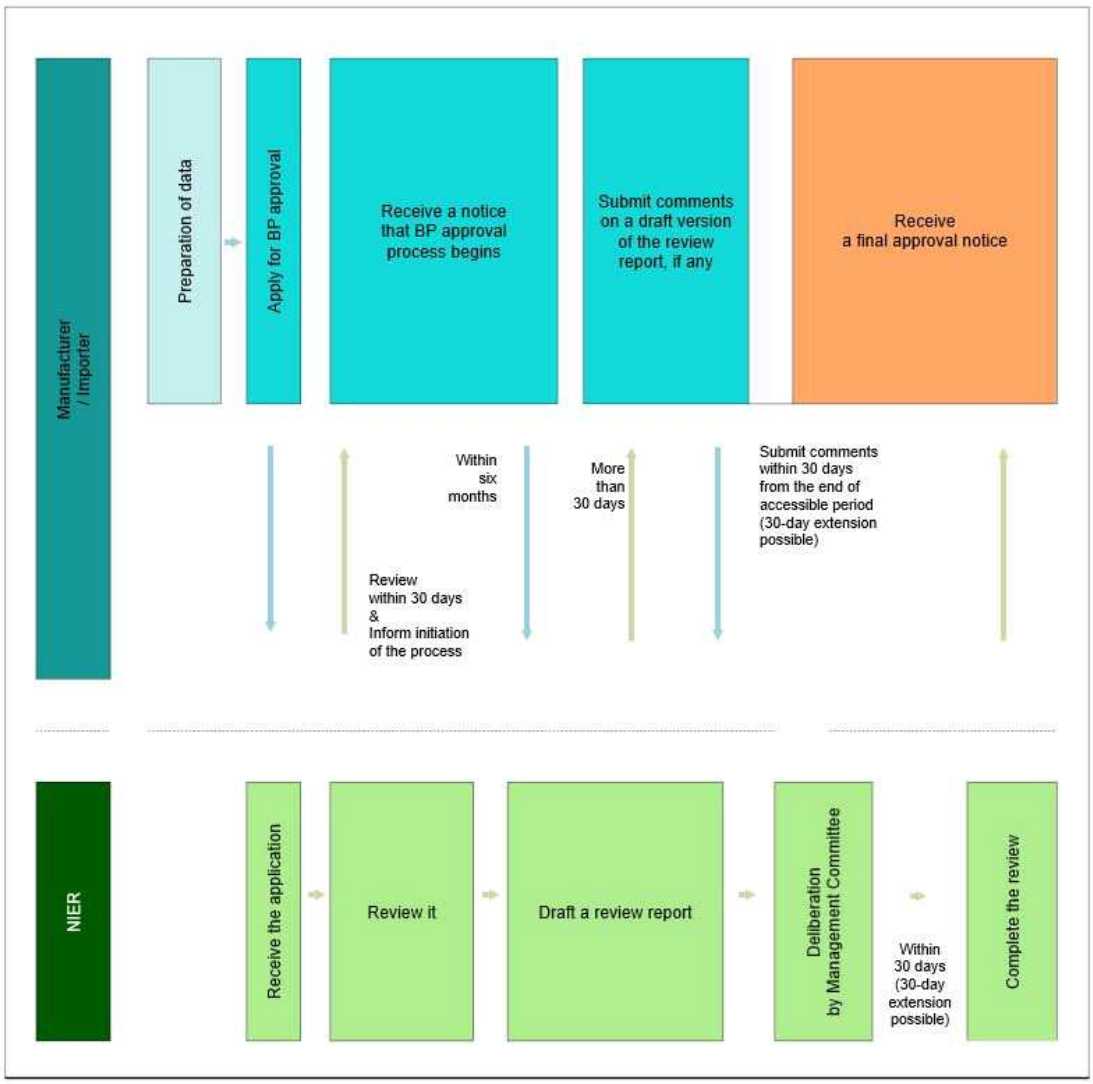
■ What is the approval system for biocidal product (BP)?

- Any person who intends to manufacture or import BP for sales or distribution in Korea shall be approved it by the Ministry of Environment.

■ BP Approval Method

- (Applicant) Any person who intends to manufacture or import BP for sales or distribution.
- (Competent Authorities) the National Institute of Environmental Research (via CHEMP)

<Procedure of BP Approval>



- Information requirements for BP approval (Article 21 of the Act & Annex 21 of the Enforcement Rule)

No.	Information	Details
1	Identity of manufacturer/importer	- Name, company name, address, and contact information
2	Identity of BP	- Product name, BP type
3	Information on substances in BP	- Components, mixing ratio, intended purpose and use of all substances in BP - Name and address of AS supplier - (In case of containing nanomaterials on purpose) Name, intended purpose and use of such nanomaterial(s)
4	Information on BP	- Physico-chemical properties, or biological features - Exposure information (i.e. use, major exposure route, exposure type, etc.) - Hazards and risks on human, animal, and the environment - Efficacy and effect - Classification, labelling, and packaging
5	Documents for less-strict BP approval criteria	- (In case of satisfying any of the conditions for less-strict criteria) Document proving the conformity
6	Raw materials & Processing to manufacture BP	- Raw materials and manufacture processing of BP - Precautions for handling BP, and disposal method thereof - Information about BP's domestic/international use and relevant regulations - Information evidencing the use of safety container or package that meets quality control standards - Current status and plan of the compliance with manufacturing/storaging facility standards - (In case of contact manufacturer) Documents proving such contract (e.g. copy of entrusting agreement)
7	Comprehensive safety report	- Comprehensive safety report regarding BP, including risk assessment

※ The above documents may not be submitted if it falls under any of the following conditions:

① When proven that the effect on human, animal and the environment is insignificant because the reliable information on use and exposure of BP or AS(s) therein is identified.

② When proven based on scietific evidence that data submission is not necessary.

③ When any relevant data is submitted for the purpose of registration in accordance with Article 10 of the Act on Registration and Evaluation of Chemical Substances.[5)]

■ (Transitional Measure)

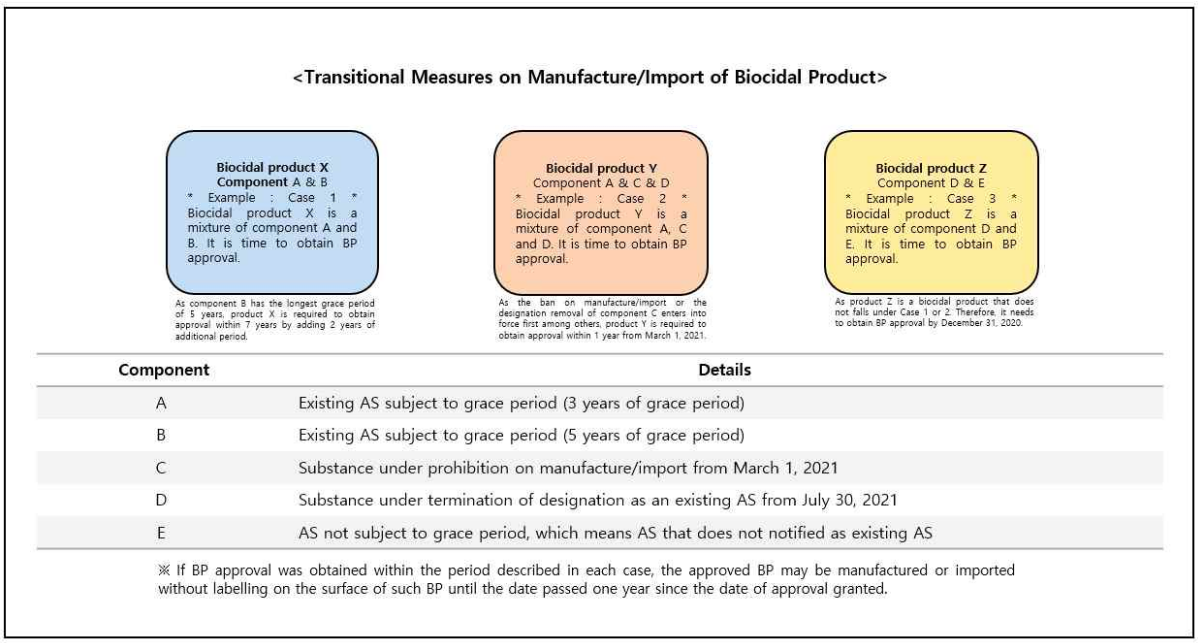
- A person who manufactures or imports BP may manufacture or import such BP without BP approval until certain date according to the following conditions.[6)]

5) pursuant to the Amendment (effective from March 24, 2020)

6) pursuant to the Amendment (effective from January 1, 2021)

Condition for Transitional Measure	Valid Term	Applicable provisions
(Case 1) If all of ASs in BP are "existing AS subject to grace period".	Within two years from AS grace period (In case where the BP contains various ASs with each different grace period, the lastest expiry date among them shall be applied.)	Addendum Article 3(1)1
(Case 2) If all of ASs in BP are "existing AS subject to grace period", but more than one of which is proved inappropriate to submit an application according to an application plan for BP approval. Therefore, manufacture or import of such AS(s) thereafter is prohibited, or designation of existing AS subject to grace period is terminated.	Within one year since the date prohibitting manufacture/import or the date terminating designation, whichever date is earlier.	Addendum Article 3(1)2
(Case 3) Any BP that does not fall under either of the above Case 1 or 2.	By December 31, 2020	Addendum Article 3(1)3
(Case 4) If a person manufactures or imports BP without approval, falling under either of the above Case 1, 2 or 3, but obtains BP approval within the above time limit.	Until one year since the date of such BP approval, the person may manufacture or import the BP without meeting labelling standard on the surface of BP.	Addendum Article 3(2)

- (Examples) Transitional measures



■ Biocidal Products subject to Less-strict Approval Criteria (Article 20 of the Act)

- In any of the following conditions, a partial or entire criteria for BP approval may be relaxed.

Condition	Details
1	If approval-required BP is used for industrial purpose only.
2	If approval-required BP is necessary for public health and the environment, and there is no other alternatives with lower risk.

■ Valid Term of BP Approval (Article 17 of the Enforcement Decree)

- Any person who wants to manufacture or import biocidal product shall gain an approval again before the valid term of existing approval is terminated.

Valid Term	Conditions
10 years	- General biocidal product
5 years	- Biocidal product subject to less-strict BP approval criteria - Biocidal product that contains any AS subject to less-strict AS approval criteria
3 years	- Biocidal product that falls under both of the above conditions for 5-year valid term

■ Modification of Granted BP Approval (Article 23 of the Act)

- Any person who intends to modify important matters regarding BP, including the information about its hazard/risk or effect/efficacy, shall obtain an approval or notify of such modification.

Condition	Reason for Modification
Approval-required Modification of Granted Approval	1. Change in hazard or risk information of BP
	2. Change in effect or efficacy of BP
	3. Change in product name, product type, target user, use scope of BP
	4. Change in product type or direction for use of treated article, in which the BP is used
	5. Change in components or mixing ratio of active substance in BP, or those of "hazardous substance" or "chemical substance subject to intensive control" in BP (pursuant to the definition in the Act on Registration and Evaluation of Chemical Substances)
	6. Change in the matters prescribed in Article 19(7) of the Enforcement Decree (i.e. formulation, reference amount to use, direction for use, expiry date, precautions for use, use of BP)
Notification-required	Name, company name, address, contact information and so on

Modification of Granted Approval	

■ Acceptance of BP Similarity (Article 25 of the Act)

- (Definition) Two different BPs contain identical AS(s), have similar components and mixing ratio of substances therein, and have similar use, risk and effect/efficacy of BP (e.g. destroying harmful organisms).
- If a BP is proven to have similarity to an already-approved BP (i.e. Standard BP), and the Management Committee admits such similarity, the BP shall be considered as approved.
- In this case, consent on data use between Standard BP and the similar BP should be made pursuant to Article 32(1) of the Act.

■ Cancellation of BP Approval (Article 26 of the Act)

- If any person who gained a BP approval, or modified already-granted BP approval (hereinafter collectively referred to as "BP approval") or obtained acceptance of BP similarity falls under any of the following conditions, the Ministry of Environment may cancel such BP approval or similarity acceptance, or may order a suspension of manufacturing/importing the BP for less than one year.

Condition	Reason of Cancellation
1	If such person received such BP approval or similarity acceptance by fraud or other improper means
2	If such BP is manufactured or imported differently from the details of granted BP approval or similarity acceptance
3	If such BP continues to be manufactured or imported without additional BP approval or similarity acceptance after the termination of valid term in accordacne with Article 20(5) and the latter part of Article 25(4) of the Act
4	In case of failure to follow a corrective order pursuant to Article 36-2(2)
5	If any risk regarding such BP is newly found, which was not known at a time when such BP approval or similarity acceptance was granted
6	If other government or international organization admits that such BP has a risk

■ Special Cases of BP Approval (Article 24 of the Act)[7)]

- If a BP meets **all** of the followings, less data requirements are applied.

Special Case	Condition

7) pursuant to the Amendment (effective from March 24, 2020)

Exemption from data requirements (i.e. application, procedure, modification)	1. All ASs in BP are publicly announced to have a low level of risk.
	2. BP contains none of the followings: substance subject to intensive control, nanomaterial, and persistent pollutant with hazard or risk.
	3. BP has sufficient effect and efficacy, including but not limited to destorying harmful organisms.
	4. Personal protective equipment (PPE) is not necessary for handling or using the BP.

※ The special case shall be applied only when BP fully meets all of the foregoing requirements.

- If a BP is needed urgently for the purpose of public health and there is no alternatives, the BP or AS(s) therein may be temporarily allowed to manufacture or import without approval upon the request by the head of relevant ministries of the central government.[8)]

■ Labelling of BP (Article 27 of the Act)

Applicant	- A person who intends to manufacture or import an approved BP for sales or distribution in Korea
Labelling requirement	- Components and mixing ratio of all ASs in BP - Manufacturer/importer's name or company name, address, and contact information - Dangers that can be caused by using the BP, and first-aid treatment - Expiry date and disposal method - (In case of containing nanomaterials on purpose) Name, purpose and use of such nanomaterial(s) - Others
Labelling method	- All information shall be written in Korean (In case of adding words in foreign language, those shall be smaller letters than Korean ones.) - Every letter shall be labelled with a color distinctive from the background color. - Label shall be placed without the likelihood of being erased or detached from the product.

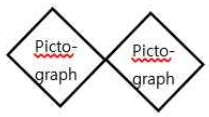
※ Labelling Requirements & Example

Product name
Product type
Expiry date
Weight/Quantity
Effect/Efficacy
Target user/Use scope
Regular quantity to use
Manufacturer, address, contact number (products manufactured in Korea only)
Manufacturing country & manufacturing company (imported product only)
Importer (address, contact info.) (imported product only)
Indication of child-resistant packaging
(only for product subject to child-resistant packaging)
AS(s) in the product:
Nanomaterial(s) in the product:
Other substance(s) therein:
Hazard/Risk:
Direction for use:
Precautions:
Approval No.:
Manufacturing No.:

Biocidal Product's Labelling in Korean

Approval No.: ####-####

Product name: BP type:
Expiray date: Weight/Quantity:
Effect/Efficacy: Target user & Use scope:
Regular quantity to use:
Manufacturer (address, contact info.):
Made in (country name) & Manufacturing company:
Importer (address, contact info.):



in the product:
nomaterial in the product:
ıer substance(s):

Signal Words:
(those for hazards or risks)
(those for preventive measures)

Direction for use:
①
Precautions for use:
①

8) pursuant to the Amendment (effective from Jan. 1, 2021)

Treated Article : Management (Article 28 of the Act)

■ Safety & Labelling Standards for Treated Article (TA)

Applicant	- A person who intends to manufacture or import a TA for sales or distribution in Korea
Safety Standard (Article 23, Enforcement Decree)	- Only approved BP shall be allowed for use. - In the case of importing a TA, it shall use BP(s) granting an BP approval or fulfilling similarity criteria to already-approved BP* only.
Labelling Standard	- Indication that BP is used. - Names and functions of all ASs in BP that is used for TA. - (In case of BP containing nanomaterial on purpose) Indication that BP used for the TA contains nanomaterial. - Dangers and precautions for handling BP that is used for TA.
Labelling Method	- All components shall be indicated in Korean. (In case of adding words in other language, those shall be indicated with smaller letters than Korean ones.) - Every letter shall be labelled with a color distinctive from the background color. - Label shall be placed without the likelihood of being erased or removed from the surface of the product.

* Similarity criteria
  · If AS is used for an approved BP type; or
  · If AS is publicly announced; or
  · If other government publicly admits that it is safe to use the AS for the intended use; or
  · If the safety of BP used for TA is admitted by approval or confirmation of other government.

■ (Transitional Measure)

- A person who intends to manufacture or import TA may do so without observing safety standard and labelling standard untill certain date according to the followings.[9)]

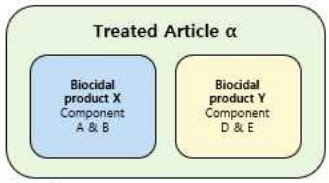
Transitional Measure	Valid Term of Transitional Measure	Applicable Provisions
Case 1. If all ASs in BP used for TA are "existing ASs subject to grace period" (including imported TA that all BPs used for it satisfy the similarity criteria)	Within two years from the date of termination of transitional measure on BP that all ASs therein are existing AS(s) subject to grace period	Addendum Article 4(1)1
Case 2. If all of existing ASs in BP that is used for TA are prohibited from manufacturer/import, or their designation is terminated	Within two years from the date of prohibition on manufacture/import, or the date of designation termination, whichever date is earlier	Addendum Article 4(1)2
Case 3. Any TA that does not fall under either of the above Case 1 or 2	Until December 31, 2022	Addendum Article 4(1)3

9) pursuant to the Amendment (effective from Jan 1, 2021)

Case 4. If a person who manufactures or imports TA within the period of Case 1 to 3, submits evidence documents prescribed by Presidential Decree, including reason(s) of non-compliance with safety standard and/or labeling standard.	Transitional measure may be extended by up to one year.	Addendum Article 4(2)

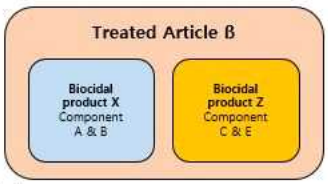
※ Examples

<Transitional Measures on Manufacture/Import of Treated Article>



Example of Case 1
Biocidal product X and Y are used for making treated article α. If biocidal product X and Y respectively contains component A, B, D and E, all of which existing AS subject to grace period, then from when should the treated article α comply with the safety and labelling standards?

As the termination date of grace period of component E is the latest one among other components, the treated article α should meet safety and labelling standards within 12 years: the sum of grace periods of component A and B (8 years), BP approval (2 years), and TA approval (2 years).



Example of Case 2
Biocidal product X and Z are used for making treated article ß. If biocidal product X and Z respectively contains A, B, C, and E, all of which existing AS subject to grace period, then from when should the treated article ß comply with safety and labelling standards?

As the designation of existing AS that was granted on component C will be terminated on July 30, 2021, it is the latest one among others in termination of designation or ban on manufacture/import. Therefore, treated article ß shall meet safety and labelling standards within 2 years from July 30, 2021.

Component	Details
A	Existing AS subject to grace period (3 years of grace period)
B	Existing AS subject to grace period (5 years of grace period)
C	Substance under termination of designation as existing AS from July 30, 2021
D	Existing AS subject to grace period (3 years of grace period)
E	Existing AS subject to grace period (8 years of grace period)

※ If a person who manufactures or imports TA submits the documents prescribed by Presidential Decree, including rightful reasons why he/she cannot comply with safety and/or labelling standards in the given period of Case 1, 2, or 3, then transitional measure may be extended by up to one year.

[Penalty] Amendment (effective from January 1, 2021)

Penalty and Fine	Details
Imprisonment for not more than 7 years or a fine not exceeding 70 million won	- Any person who manufactures or imports a biocidal product after having failed to obtain BP approval or having obtained such approval by fraud or other improper means. - Any person who manufactures or imports a biocidal product different from details of the granted BP approval. - Any person who manufactures or imports a biocidal product that BP approval or similarity acceptance was canceled, or that is ordered to suspend manufacture or import. - Any person who fails to follow an order of administrative measures such as withdrawal or disposal. ※ If an appointed person fulfills the obligations in lieu of a person obliged to do so, such appointed person shall be considered as obliged to meet the obligations. Therefore, in case of violation, only such appointed person shall be punished. Provided, That the foregoing shall not apply when such appointed person proves that the imported BP is different from the reported information. ※ Any person who kills or wounds other person(s) due to any act described above, shall be punished by imprisonment not more than 10 years or a fine not exceeding 100 million won. In this case imprisonment and a fine may be imposed concurrently.
Imprisonment for not more than 5 years or a fine not exceeding 50 million won	- Any person who manufactures or imports a biocidal product after having failed to obtain modified approval or obtaining modified approval by fraud or other improper means. - Any person who manufactures or imports a biocidal product different from the details of modified BP approval. - Any person who obtains BP similarity acceptance by fraud or other improper means, or manufactures or imports the biocidal product different from the details of granted BP similarity acceptance. - Any person who manufactures or imports a biocidal product after having failed to re-obtain BP similarity acceptance. - Any person who manufactures or imports a biocidal product without labelling or with false labelling not in conformity with the labeling standard for the biocidal product. - Any person who manufactures or imports a treated article, not in conformity with the safety standard. - Any person who manufactures or imports a treated article without labelling or with false labelling not in conformity with the labeling standard for the treated article. ※ If an appointed person fulfills the obligations in lieu of a person obliged to do so, such appointed person shall be considered as obliged to meet the obligations. Therefore, in case of violation, only such appointed person shall be punished. Provided, That the foregoing shall not apply when such appointed person proves that the imported BP is different from the reported information. ※ Any person who kills or wounds other person(s) due to any act described above, shall be punished by imprisonment not more than 7 years or a fine not exceeding 70 million won. In this case imprisonment and a fine may be imposed concurrently.
Imprisonment for not more than 3 years or a fine not exceeding 30 million won	- Any person who fails to observe requirements of packaging or advertisement for biocidal product, in violation of provisions on restriction of labeling and advertisement. - Any person who manufactures, imports, sells or distributes products other than approved biocidal product or treated article, but labels or advertises the products as a biocidal product or treated article, or otherwise makes consumers mistake them for biocidal or treated ones. - Any person who sells or gifts, or otherwise displays, keeps or stores an active substance or a biocidal product for the purpose of sales or gifts, in violation of approval for active substance or biocidal product. - Any person who refuses, obstructs, or evades the access, inspection, or collection.
Fine not exceeding	- Any person who sells or gifts, or otherwise imports, displays, keeps or stores a TA for sales or gifts

10 million won	without satisfying safety standard or labeling standard. - Any person who acts as a go-between for sales or purchases on behalf of other person biocides that is prohibited to sell, and etc. - Any person who fails to report newly identified risk without delay or who makes false report therefor. - Any manufacturer or importer of BP who fails to comply with a quality control standard. - Any person who fails to make a report according to an order of administrative measures, or who makes a report therefor by fraud or other improper means. - Any person who fails to record or retain data, or falsely records. - Any person who fails to report or falsely reports data.

04. Information Disclosure & Follow-up Management

Information Disclosure and Data Protection, etc. (Article 29, 30, 31)

Follow-up Management on Biocides (Article 35 & 36-2)

Recording and Reporting (Article 49)

Reward (Article 52-2)

Penalty Surcharge (Article 38)

Information Disclosure and Data Protection, etc.

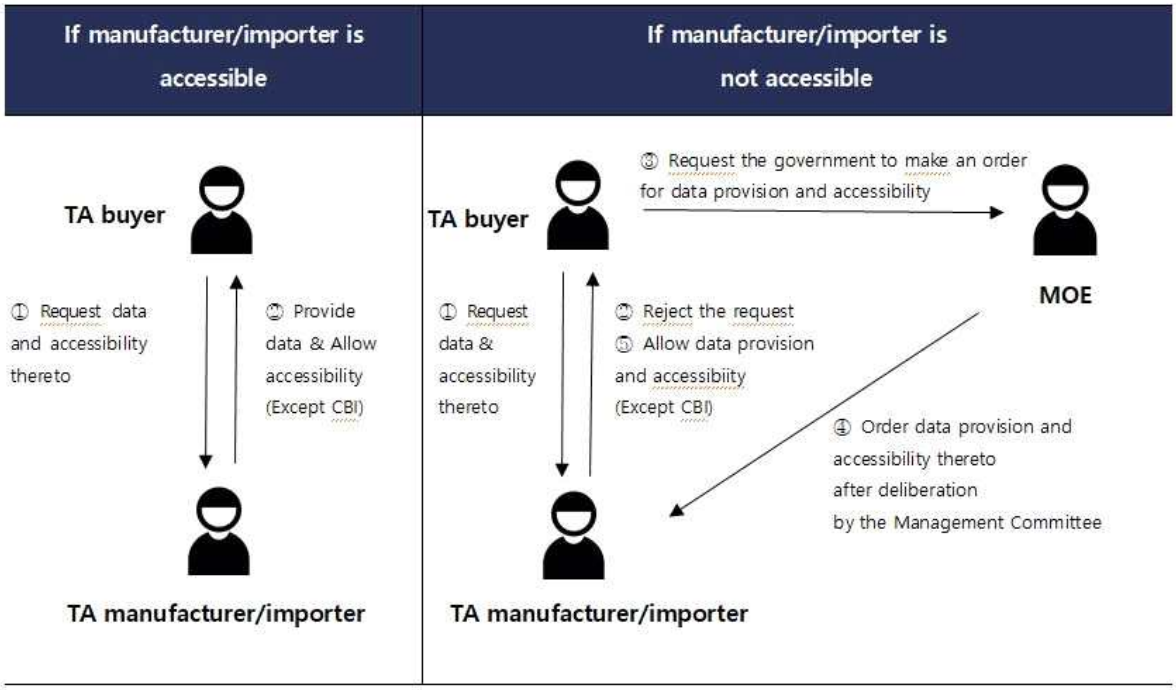
■ Disclosure of AS and BP Information (Article 29 of the Act)

- The Ministry of Environment shall disclose the following information on approved AS and BP.

Category	Details
AS Information	1. Name of AS, valid term of AS approval
	2. Hazard and risk levels of AS
	3. Name, company name, address, and contact number of a person who obtained AS approval
	4. BP type(s) in which the approved AS may be used
	5. Physical, chemical or biological property of AS
	6. Classification and labelling of AS
BP Information	1. Name of BP, valid term of BP approval
	2. Hazard and risk levels of BP
	3. Name, company name, address, and contact number of a person who obtained BP approval
	4. (In case of using BP to make a treated article) Treated article's type and directions for use thereof, in which such approved BP may be used
	5. BP type
	6. Components and Mixing ratio of all ASs in BP
	7. "Hazardous substance" or "substance subject to intensive control" in BP (Please refer to the definitions under the Act on Registration and Evaluation of Chemical Substances)
	8. Physical, chemical or biological property of BP
	9. Effect/efficacy, classification/labelling, and packaging of BP
	10. Safety rules for using the BP, including but not limited to directions for use and precautions

■ Provision of TA Information (Article 30 of the Act)

- As prescribed by Presidential Decree, any person who purchased a TA may request to provide the information or allow to access the information on BP used for the TA, to manufacturer or importer of the TA. Provided, That the foregoing shall not be applied to management or business confidentiality (i.e. CBI).
- Person who has been provided with or has accessed the information shall not use the information for any purpose other than for which it is requested, or by giving it to any third party.



■ Data Protection (Article 31 of the Act)

- Data submitted for approval shall not be disclosed within 15 years, which is data protection period. (five years of initial protection period shall be given, and additional extension of 5 years is available two times.)
- (Person subject to Data Protection) Applicant of AS and BP approval, AS equivalence acceptance, and/or BP similarity acceptance
- (Exceptions) Data already disclosed in Korea or abroad, certain information regarding AS or BP prescribed by Article 29 of the Act), or any data other than confidential business information (CBI)

Follow-up Management on Biocides

■ BP's Labelling and Advertisement (Article 34 of the Act)

- (Applicant) Any person who intends to manufacture, import, sell or distribute BP

Ban on use of any indication that is likely to cause misunderstanding about adverse effects	- Any expression that may cause misunderstanding about adverse effects on human health or the environment, or otherwise similar expression, i.e. 'non-toxic,' 'eco-friendly,' 'non-hazardous,' and 'human/animal-friendly,' shall not be used.
To prevent risks	- The followings shall be included in advertisement in a visible, legibly and indelibly way.

caused by using BP	· Indication that shows product name and type; and · Indication that invites consumers to follow direction for use and precautions.
To avoid a lablelling or advertisement that may cause	- Any label or advertisement that presents an unapproved BP or TA as approved one, or otherwise that is likely to cause misunderstanding shall be prohibited.

※ BP shall comply with all of the foregoing requirements fully.

■ Prohibition on Sales, etc. (Article 35 of the Act)[10)]

- No one shall not sell or gift, or otherwise, display, keep or store for the purpose of sales or gift substance or product that falls under either of the followings.

Active Substance	- Any AS that fails to obtain an AS approval - Any AS that AS approval or AS equivalence acceptance was canceled or that is ordered to suspend manufacture or import
Biocidal Product	- Any BP that fails to obtain BP approval - Any BP that BP approval or BP similarity acceptance was canceled or that is ordered to suspend manufacture or import - Any BP that fails to comply with labelling requirement for biocidal products
Treated Article	- Any TA that fails to comply with safety standards or labeling standards

※ Amendment (effective from Jan. 1, 2021): Provisions regarding AS are added this time.

■ Obligation on Quality Control (Article 36-2)[11)]

- Any person who manufactures or imports BP shall maintain and manage the quality of such products same as approved.

Standards for Manufacturing/ Storage Facility	- Manufacturer/importer shall be equipped with a manufacturing facility that is necessary for manufacturing works, and a storage facility where keeps raw materials and others that are used for manufacturing BP. - Manufacturer/importer shall be equipped with testing/inspection facility or apparatus which is necessary for manufacturing process or BP quality control.
Standards for Safety Management	- Manufacturer/importer shall employ enough number of staff for BP quality control and safety management. - Manufacturer/importer shall comply with standards for documents of manufacturing, product control, hygiene management, and quality control, which is needed for maintaining BP quality. - Manufacturer/importer shall comply with standards for safety management in order to minimize risks on human body and the environment in the process of manufacture and storage.

10) pursuant to the Amendment (effective from Jan. 1, 2021)

11) pursuant to the Amendment (effective from Jan. 1, 2021)

Recording and Reporting (Article 49 of the Act)

■ A person who manufactures or imports biocides shall record and retain relevant information for 10 years.

■ A person who manufactures or imports biocides shall report such information to the Ministry of Environment every two years.

- If the first reporting is made on March 31, 2020, the subsequent reporting shall be made on March 31 of every two years.

Reward (Article 52-2 of the Act)[12)]

Non-compliance to detect	- A person who sells or gifts product that falls under any of sales-prohibition standards, or otherwise, displays, keeps/stores such product for the purpose of sales or gift. - A person who manufactures, imports, or sells such biocide despite an order to withdraw or discard such product.
Reward	- Annually three million won per person who reports such violation (prusuant to the Enforcement Decree)[13)]

Penalty Surcharge (Article 38 of the Act)[14)]

■ **The Ministry of Environment, for the purpose of recovering unjust gains of illegal product, may impose a penalty surcharge equivalent to sales of the biocides manufactured/imported.**

- In the case where there are no sales or it is difficult to calculate sales, the MOE may impose a penalty surcharge not exceeding one billion won.

Active Substance	- In case of manufacturing or importing AS (or BP) without proper approval, or otherwise with such approval obtained by fraud or other improper means; or - In case of manufacturing or importing AS that the valid term of AS approval is already terminated; or - In case of manufacturing or importing AS that its approval or equivalence acceptance was canceled or that is ordered to suspend manufacture or import.
Biocidal Product	- In case of manufacturing or importing BP without proper approval, or otherwise with such approval obtained by fraud or other improper means; or - In case of manufacturing or importing BP where the valid term of BP approval is already terminated; or - In case of manufacturing or importing BP that its approval or similarity acceptance was canceled or that is ordered to suspend manufacture or import.

12) pursuant to the Amendment (effective from Jan. 1, 2021)

13) pursuant to the Amendment (effective from Jan. 1, 2021)

14) pursuant to the Amendment (effective from Jan. 1, 2021)

[Penalty] Amendment (effective from January 1, 2021)

Penalty and Fines	Details
Imprisonment for not more than 3 years or a fine not exceeding 30 million won	- Any person who fails to follow an order of providing the information or allowing accessibility to the information, in violation of request to provide the information on TA. - Any person who is provided or allowed to access the information on TA, but uses the information for inappropriate purpose. - Any person who fails to observe requirements of packaging or advertisement for biocidal product, in violation of provisions on restriction of labelling and advertisement. - Any person who manufactures, imports, sells or distributes products other than approved biocidal product or treated article, but labels or advertises the products as a biocidal product or treated article, or otherwise makes consumers mistake them for biocidal or treated ones. - Any person who sells or giftsan active substance or biocidal product, or otherwise displays, keeps or stores them for the purpose of sales or gift, in violation of approval for biocidal substance/biocidal product. - Any person who refuses, obstructs or evades the access, inspection, or collection.
Fine not exceeding 10 million won	- Any person who acts as a go-between for sales or purchases on behalf of other person biocides that is prohibited to sell, and etc. - Any person who fails to report newly identified risk without delay or who makes false report therefor. - Any person who fails to make a report according to an order of administrative measures or who makes a report therefor by fraud or other improper means. - Any person who fails to record or retain data, or falsely records. - Any person who fails to report or falsely reports data.

05. Others

Approval asked by a person whom

the overseas manufacturer appoints, etc.

(Article 54-2 of the Act)

Approval Submitted by a Person whom overseas manufacturer appoints (Article 54-2 of the Act)

Amendment

Relevant provisions are newly inserted in the Amendment on Mar 24, 2020 and **will be effective from Jan. 1, 2021.** They allows overseas manufacturer to appoint a third person as a representative.

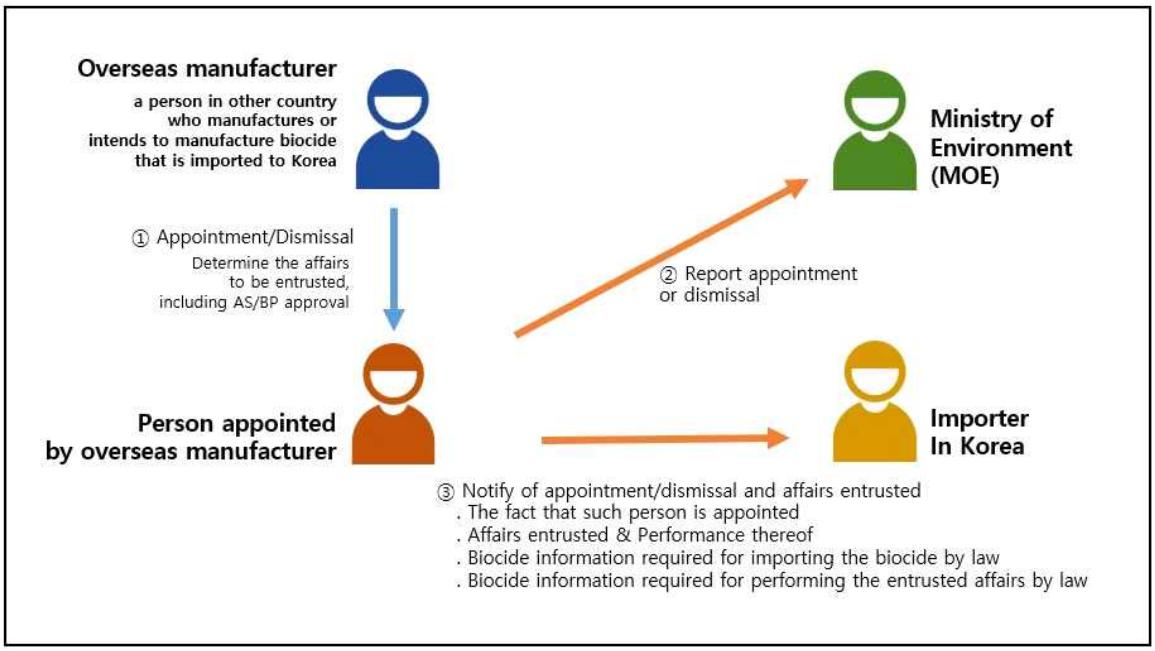
- If an overseas manufacturer (i.e. those manufacture biocides in other country which will be exported to Korea) wants not to provide the information for AS approval plan and AS approval with the importer due to CBI, such overseas manufacturer may appoint a Korean person to fulfill such obligations on behalf of itself.

- **(Penalty)** If an appointed person fails to perform the following affairs in lieu of the importer, or otherwise performs them by fraud or other improper means, the penalty resulting from such non-compliance shall be imposed to the appointed person only. Provided, That the foregoing shall not apply when such appointed person proves that the imported AS or BP is different from the reported information.[15)]

Works to be done by an appointee	- Apply for AS approval - Apply for modification of granted AS approval & Notify of the modification - Apply for AS equivalence acceptance - Make a notification for obtaining a grace period of existing AS - Submit an application for AS approval, etc. - Apply for BP approval - Apply for modification of granted BP approval & Notify of the modification - Apply for special treatment of certain BP - Apply for BP similarity acceptance - Report and take measures for newly identified risk - Works related to submission of application plan for AS approval - Works related to individual data submission to apply for AS approval - Works related to request of data protection - Works related to agreement on data use
Qualification of the appointee	- Person who has Korean nationality and has his/her residence in the Republic of Korea. In case of a corporation, it is a location of office.
Procedure for appointment/dismissal	- Appointment or dismissal of such appointee shall be reported to the National Institute of Environmental Research (NIER).
Documents required to report appointment/dismissal	- Appointment or dismissal forms in Annex 48 of the Act - (Appendix 1) Document proving that the appointed person satisfies qualifications prescribed by Ordinance of the Ministry of Environment - (Appendix 2) Document (appointment agreement, etc.) proving such appointment or

15) This partial amendment was pre-announced on July 30, 2020.

	dismissal - (Appendix 3) Information on importer in Korea, including its name or company name, and contact number, etc.
After reporting	- NIER shall issue a reporting certificate no later than seven days from the date of reporting.



Upcoming Amendment (this partial amendment was pre-announced on July 30, 2020.)

The subordinate laws, including the Enforcement Decree and the Enforcement Rules, will identify the details that the appointee shall offer to importer in Korea.

Relevant Institutes & Their Tasks

Tasks	Competent Authorities	Contact No.
(Notification) existing active substance (Approval) active substance (Approval) biocidal product (Approval) consumer chemical product subject to safety confirmation	Chemicals Research Division National Institute of Environmental Research	+82 32-560-7202
(For consumer chemical product subject to safety confirmation) Where you submit an application and relevant documents to get confirmed the compliance with safety standards	"Household Chemical Products & Biocides Safety Center" in the Korea Environmental Industry & Technology Institute (KEITI)	+82 1800-0490