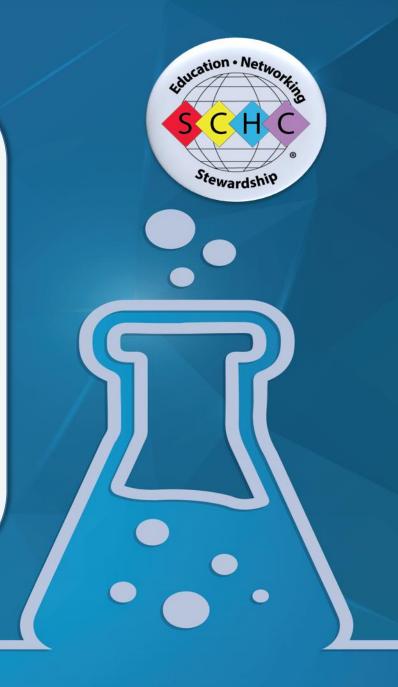
"Biocide Regulations – A Comparison of EU/UK/K-BPR"

Robert Kiefer REACH24H USA Inc.

SCHC Annual Meeting 2021 November 5, 2021





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Biocide Regulations – A Comparison of EU/UK/K-BPR

Robert J. Kiefer

General Manager, REACH24H USA Inc.

REACH24H Consulting Group

Value In Compliance

Overview



1. EU BPR Introduction

2. UK BPR Introduction

3. Korea BPR Introduction



4. A Comparison of EU/UK/K-BPR





Before:

DIRECTIVE 98/8/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 February 1998

concerning the placing of biocidal products on the market

(OJ L 123, 24.4.1998, p. 1)

(OJ L 123, 24.4.1998, p. 1)

After:

REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 May 2012

concerning the making available on the market and use of biocidal products

(Text with EEA relevance)

(OJ L 167, 27.6.2012, p. 1)

Product Type (PT)



Disinfectants

- PT 1 Human hygiene
- PT 2 Disinfectants and algaecides not intended for direct application to humans or animals
- PT 3 Veterinary hygiene
- PT 4 Food and feed area
- PT 5 Drinking water

Preservatives

- PT 6 Preservatives for products during storage
- PT 7 Film preservatives
- PT 8 Wood preservatives
- PT 9 Fiber, leather, rubber and polymerized materials preservatives
- PT 10 Construction material preservatives
- PT 11 Preservatives for liquid-cooling and processing systems
- PT 12 Slimicides
- PT 13 Working or cutting fluid preservatives

Pest Control

- PT 14 Rodenticides
- PT 15 Avicides
- PT 16 Molluscicides, vermicides and products to control other invertebrates
- PT 17 Piscicides
- PT 18 Insecticides, acaricides and products to control other arthropods
- PT 19 Repellents and attractants
- PT 20 Control of other vertebrates

Other Biocidal Products

- PT 21 Antifouling products
- PT 22 Embalming and taxidermist fluids



Product Type (PT)



For example,

Disinfectants

- PT 1 Human hygiene
- PT 2 Disinfectants and algaecides not intended for direct application to humans or animals
- PT 3 Veterinary hygiene
- PT 4 Food and feed area
- PT 5 Drinking water



Rinse-Free Disinfectant Gel



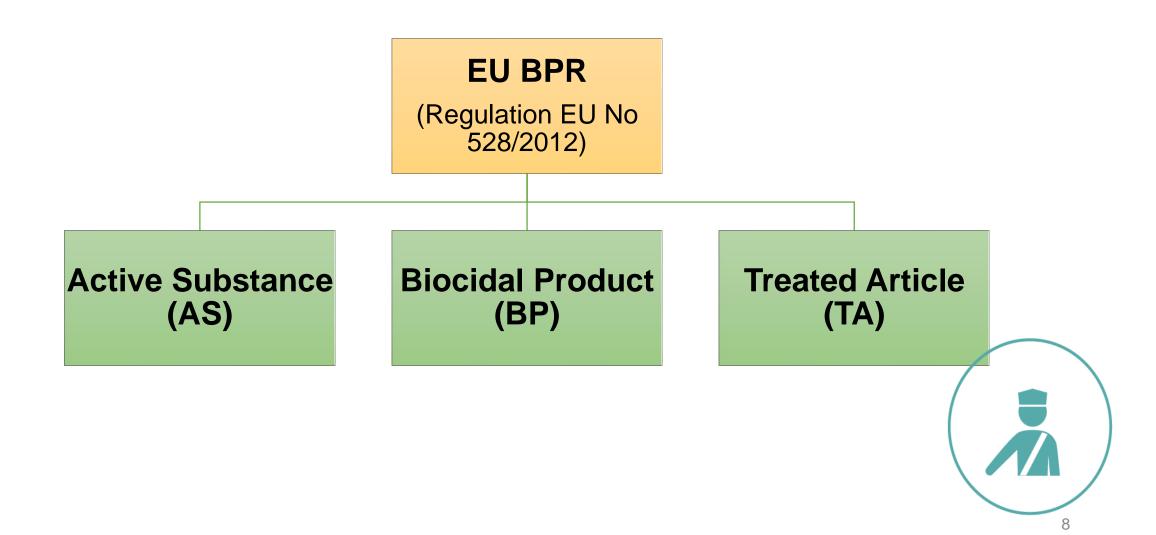
Hygienic Handwash



Hard Surface Disinfectant

Regulatory Contents





Regulatory Contents





According to Art 3-1:

'Active Substance' (AS) means a substance or a micro-organism that has an action on or against harmful organisms





Under Review

'Biocidal Product' (BP) means any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action

Regulatory Contents



According to Art 3-1:

'Treated Article' (TA) means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products;













Existing and New Active Substances/Product Type: Review Program

- More than 650 AS/PT combinations are included in the programme.
- The combinations are listed in Annex II of the Review Programme Regulation ((EU) No 1062/2014)

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) No 1062/2014

of 4 August 2014

on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council

ANNEX II

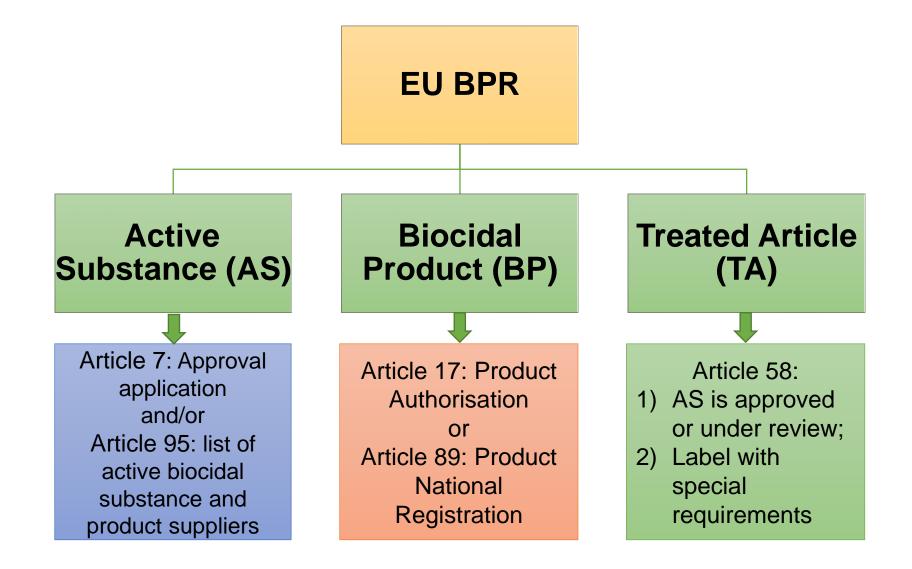
SUBSTANCE/PRODUCT-TYPE COMBINATIONS INCLUDED IN THE REVIEW PROGRAMME ON 4 AUGUST 2014

PART 1

Active substance/product-type combinations supported on 4 August 2014, excluding any other nanomaterial than those explicitly mentioned in entries 1017 and 1019

Entry number	Substance name	Rapporteur Member State	EC number	CAS number	1	2	3	4	5	6	7	8	9	10	11	12	13	17	18	19	21	22
1	Formaldehyde	DE	200-001-8	50-00-0		x	x															x
6	2-(2-butoxyethoxy)ethyl 6-propylpiper-	EL	200-076-7	51-03-6															x			





For Example:



Article 7: Approval application and/or Article 95: Listing



Step 1

The AS is Ethanol (CAS No. 64-17-5) and the PT is PT 1 Human hygiene.

Regulatory	Requirements	Investigation	Strategy				
Article 7: Approval application	The AS/PT is under review or approved	Ethanol and PT 1 is under review.	$\sqrt{}$				
https://echa.europa.eu/information-on-chemicals/biocidal-active-substances							

Article 95: List of active biocidal substance and product suppliers	The AS manufacturer or the BP formulator should be listed in the Art 95 list.	No, no one in the supply chain is listed in the Art 95 listing	Apply for Art 95 listing
---	---	--	-----------------------------

https://echa.europa.eu/information-on-chemicals/active-substance-suppliers

For Example:



Article 17: Product
Authorisation
or
Article 89: Product
National
Registration



Step 2

The BP is 75% (v/v) Ethanol and PT 1 Human hygiene.

Regulatory	Requirements	Investigation	Strategy			
Article 17: Product Authorisation	If the AS/PT is approved	Ethanol and PT 1 is existing active substance/PT in the	At present, the applicant should do the National Registration. Once the			
Article 89: Product National Registration	If the AS/PT is existing active substance/PT in the review program and under review	review program and under review	Ethanol/PT 1 is approved, the applicant could apply for the product authorization in the Member State(s) or EU.			

Article 89

Transitional measures

 The Commission shall carry on with the work programme for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of Directive 98/8/EC with the aim of achieving it by 31 December 2024. To that end, the Commission shall be empowered to adopt delegated acts in accordance with Article 83 concerning the carrying out of the work programme and specification of the related rights and obligations of the competent authorities and the participants in the programme.

Depending upon the progress of the work programme, the Commission shall be empowered to adopt delegated acts in accordance with Article 83 concerning the extension of the duration of the work programme for a determined period.

In order to facilitate a smooth transition from Directive 98/8/EC to this Regulation, during the work programme the Commission shall adopt either implementing regulations providing that an active substance is approved, and under which conditions, or, in cases where the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, implementing decisions stating that an active substance is not approved. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3). Regulations approving an active substance shall specify the date of approval. Article 9(2) shall apply.



National Registration









For Example...

□ Poland



• If the active substance of the product you would like to register in Poland is still in the review program and is not approved yet, the biocidal product should be registered under the national procedure.





National Registration

Regular Authorisation under Polish Transitional Law

What materials should be prepared?



No.	Application Materials
1	Application form which should be filled in electronically
2	Evidence of payment concerning submission of the application
3	Document certifying the legal status of the applicant
4	Data report - efficacy of the biocidal product.
5	Information given on the label.
6	Safety Data Sheet (SDS)
7	Power of Attorney (PoA)
	Note: All documents in foreign languages require sworn translation into Polish





For Example...

□ Netherlands



- If one or more of the active substances are included in the review programme for the relevant biocidal product type, then the procedure under transitional law is applicable: Dutch transitional law, and
- If you wish to put a product on the market which is not identical to an already authorised product or you have no Letter of Access (LoA) then you are required to obtain a Regular Registration.

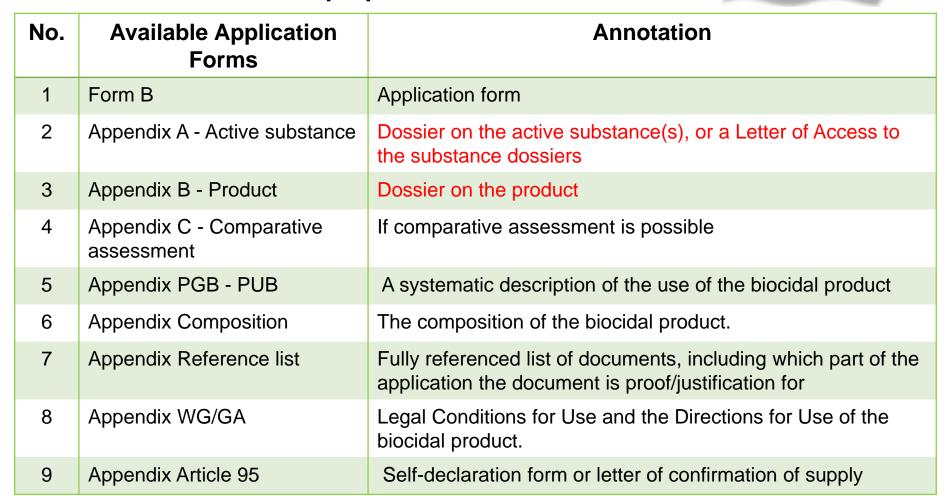






Regular Authorisation under Dutch Transitional Law

What materials should be prepared?



Product Authorisation



CHAPTER IV

GENERAL PRINCIPLES CONCERNING THE AUTHORISATION OF BIOCIDAL PRODUCTS

Article 17

Making available on the market and use of biocidal products

- Biocidal products shall not be made available on the market or used unless authorised in accordance with this Regulation.
- Applications for authorisation shall be made by, or on behalf of, the prospective authorisation holder.

Applications for national authorisation in a Member State shall be submitted to the competent authority of that Member State ('the receiving competent authority').

Applications for Union authorisation shall be submitted to the Agency.

An authorisation may be granted for a single biocidal product or a

CHAPTER XI TECHNICAL EQUIVALENCE

Article 54

Assessment of technical equivalence

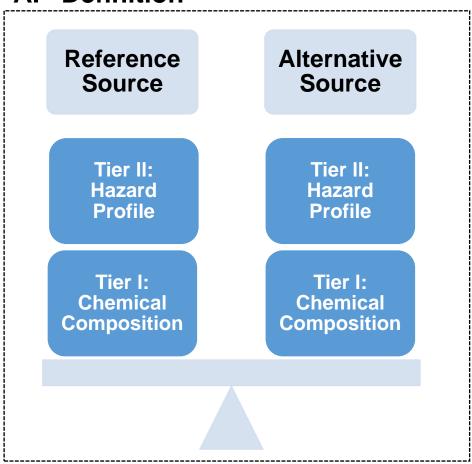
- 1. Where it is necessary to establish the technical equivalence of active substances, the person seeking to establish that equivalence ('the applicant') shall submit an application to the Agency.
- The applicant shall submit all data that the Agency requires to assess technical equivalence.

Product Authorisation



Phase 1: Technical Equivalence (TE)

A. Definition



According to Article 3(w) of BPR

'Reference source' is the previous applicant who completed the AS approval.

'Alternative source' is either from a source different to the reference source, or from the reference source but following a change to the manufacturing process and/or manufacturing location.

TE Decision Number for Product Authorisation

Product Authorisation



Phase 2: BP Authorisation

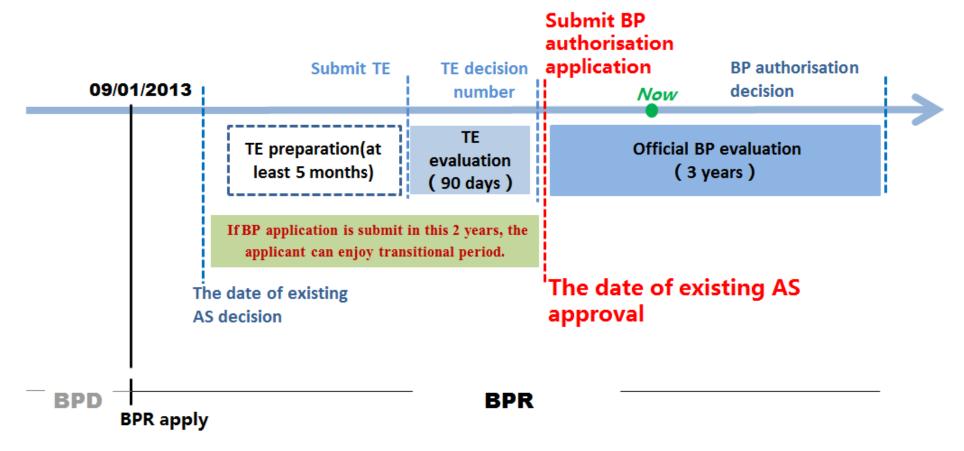
No.	Forms	Requirements		lain Materials	Timeline
1	National Authorisation (NA) and Mutual Recognition	Plan to sell a product in one EU Member State (NA).		S dossier or LoA P dossier or LoA	2 years (case by case)
2	Union Authorisation (UA)	 i. At Union level ii. Used under similar conditions across all Member States iii. Exceptions: PT 14, 15, 17, 20 and 21 	bio	SPC, a summary of the biocidal product characteristics	At least 2.5 years
3	Simplified Authorisation	 i. Contain only AS laid down in Annex I of BPR ii. Cannot contain any substance of concern or nanomaterials iii. Sufficiently effective iv. Handling of the product must not require protective equipment. 	c. Ar	PC fficacy data ny other relevant formation	90 days
	(eg. BPF / SBP)				

Product Authorisation



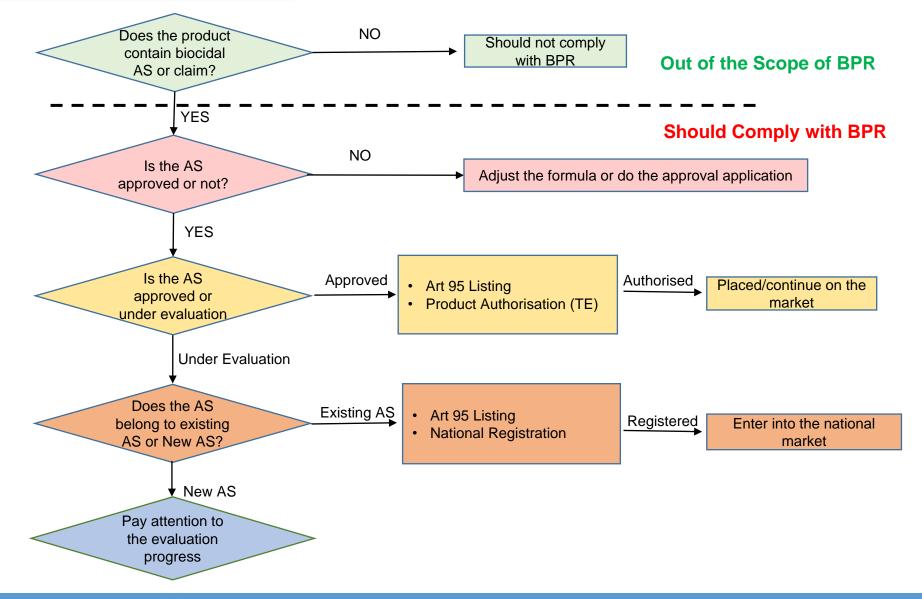
♦ Important Deadline











Product

Analysis

Conclusion

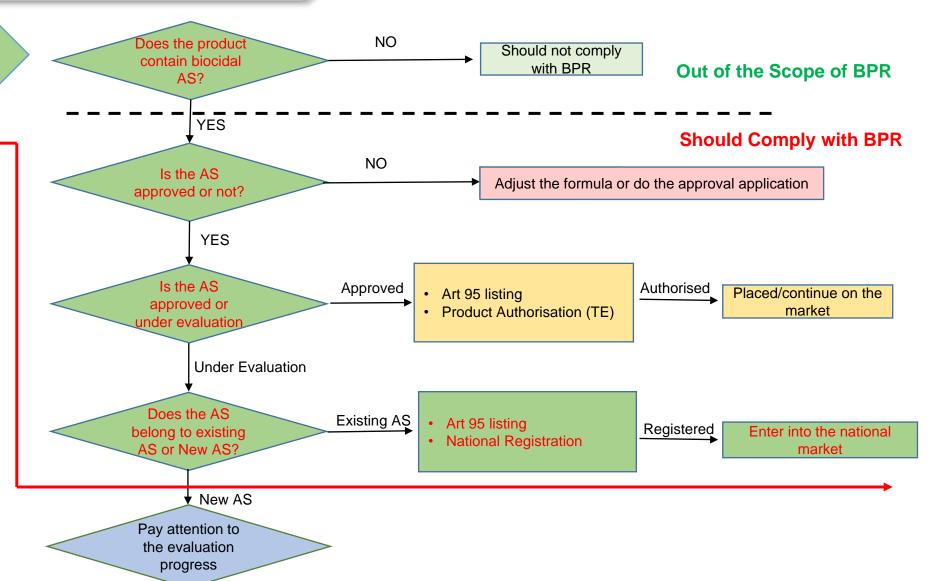




AS: Ethanol PT 1 Under Evaluation

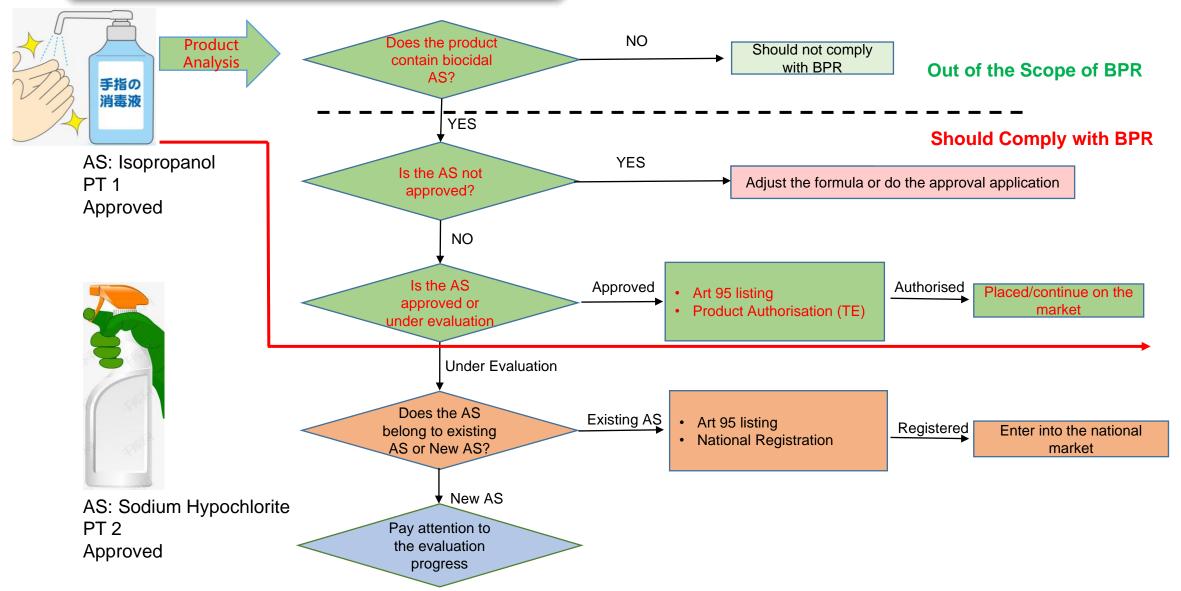


AS: Hypochlorous Acid PT 1
Under Evaluation











Before 31 December 2020:

Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) (EU BPR)

After 31 December 2020 (BREXIT Transition Period):

- Great Britain (England, Scotland and Wales) under the GB Biocidal Products Regulation (GB BPR)
- Northern Ireland (NI) under the EU Biocidal Products Regulation (EU BPR)
- GB Biocidal Products Regulation (GB BPR) effective at 11pm on 31 December 2020



Product Types

Disinfectants

- PT 1 Human hygiene
- PT 2 Disinfectants and algaecides not intended for direct application to humans or animals
- PT 3 Veterinary hygiene
- PT 4 Food and feed area
- PT 5 Drinking water

Preservatives

- PT 6 Preservatives for products during storage
- PT 7 Film preservatives
- PT 8 Wood preservatives
- PT 9 Fibre, leather, rubber and polymerised materials preservatives
- PT 10 Construction material preservatives
- PT 11 Preservatives for liquid-cooling and processing systems
- PT 12 Slimicides
- PT 13 Working or cutting fluid preservatives

Pest control

- PT 14 Rodenticides
- PT 15 Avicides
- PT 16 Molluscicides, vermicides and products to control other invertebrates
- PT 17 Piscicides
- PT 18 Insecticides, acaricides and products to control other arthropods
- PT 19 Repellents and attractants
- PT 20 Control of other vertebrates

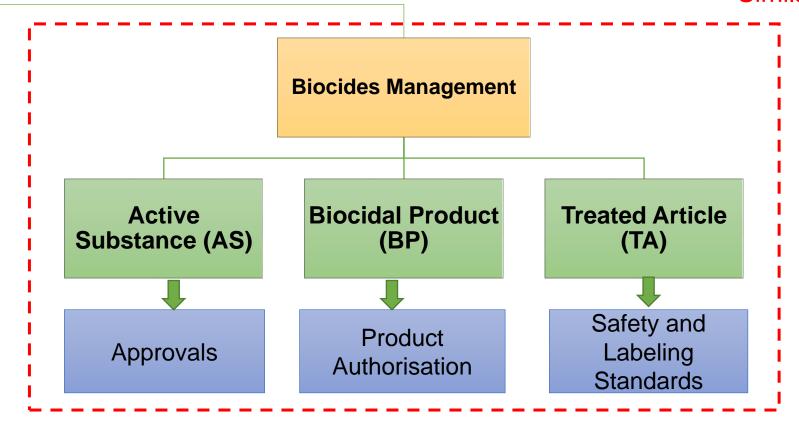
Other biocidal products

- PT 21 Antifouling products
- PT 22 Embalming and taxidermist fluids



GB Biocidal Products Regulation (GB BPR) Competent
Authority
Health and Safety Executive
(HSE)

Similar as EU BPR





Active Substance Approvals

'New Active Substances' to be used in biocidal products and biocidal product families under the GB Biocidal Products Regulation (GB BPR) Existing Active Substances for product types that have not been supported under the review programme – 'Non-Review Programme existing active substances' Changes to 'Review Programme active substances', such as when a new company wants to take over support of the active substance in the review programme from the existing participant



GB Review Programme

- Active Substances that were already in the EU Review Programme on 31 December 2020 are intended to be included in the GB Review Programme.
- Where an AS/PT combination had previously been considered to be outside the scope of the EU BPR, but new guidance or an Article 3(3) decision is published which confirms it is within scope, you will continue to be able to submit a declaration of interest in notifying the active substance / product type combination for review.



Adding Active Substances in GB Review Programme

- 1) You have placed a product on the GB market either:
 - a. prior to 01 January 2021, based on published guidance or written advice from the EU Commission, and EU Competent Authority or HSE; or
 - b. after 31 December 2020, based on published guidance or written advice from HSE

AND

- 2) That guidance or advice stated that either:
 - a. the product was excluded from the scope of EU/GB BPR; or
 - b. the relevant active substance / product type combination was one which was already notified

AND

- 3) That guidance or advice has subsequently been reviewed by either:
 - a. new guidance published by the EU Commission prior to 01 January 2021, or HSE after 31 December 2020; or
 - b. a decision published in accordance with Article 3 (3) of EU BPR prior to 01 January 2021, or Article 3 (3) of GB BPR after 31 December 2020



Applications for Inclusion on the GB Article 95 List can be made to HSE by:

UK based companies who make active substances available on the market in Great Britain (GB)

UK based companies who make biocidal products available on the GB market

UK representatives of companies based outside the UK who make active substances or biocidal products available on the GB market



How to Get a Biocidal Product on the UK Market



Check your product is regulated as a biocidal product

Step 2

Check active substance status

Step 3

Check your active substance supplier



Product Authorisation Deadlines

You must tell HSE that you are established in the UK by:

31 December 2021 if:

you are an existing UK authorisation holder – this includes Union authorisations and simplified authorisations and notifications

31 December 2022 if:

you were included on the GB Article 95 List on 1 January 2021

The date HSE grants your authorisation if:

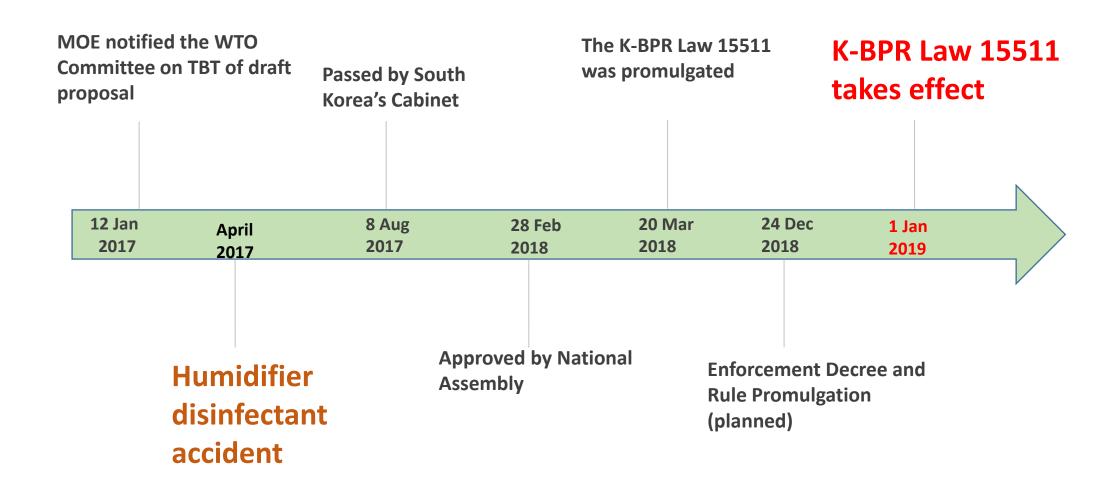
you are resubmitting a pending application – this excludes changes and renewals

3. Korea BPR









Introduction



Consumer Chemical Products and Biocide Safety Management Act (K-BPR)

Similar to EU BPR Consumer **Biocides Safety** Chemical Management **Products** Safety Standards Active **Biocidal Product Treated Article** Confirmation **Substance (AS)** Notification (BP) (TA) Safety and **Approval Product** Labeling **Application** Authorisation Standards

Product Types



Consumer Chemical Products

Categories	Items	Categories	Items
1 Cleaning Products	Cleaning agent Removing agent	10 Sterilization Products	Disinfectant Algicide
2 Laundry Products	 Laundry detergent Bleaching agent Fabric softener 		3. Antimicrobial and disinfecting agent for humidifier4. Quarantine sterilization and disinfectant for
3 Coating Products	 Gloss coating agent Special purpose coating agent Rust inhibitor(Antirust) Lubricants Ironing aid 	11 Extirpator Products	the prevention of infectious diseases 1. Insect repellents 2. Health pesticide* 3. Health repellent* 4. Pesticide for preventing infectious disease
4 Adhesive/Bonding Products	 Adhesive agent Bonding agent 		prevention* 5. Rodenticide for infectious disease prevention*
5 Fragrance/ Deodorization Products	 Fragrance Deodorizer 	12 Preservatives and	Preservatives for wood
6 Dyeing/Painting Products	 Material dyeing agent Material coloring agent 	Preservation Treatment Products	2. Filter type preservation treatment product
7 Automotive Use Only Products	 Washer fluid for automobile Antifreeze for automobile 		 Candle Moist remover
8 Printing & Document Related Products	1. Printing Ink / Toner	13 Others	3. Artificial snow spray4. Fog liquid for performances
9 Beauty Products	 Aesthetic adhesive agent Tattoo dyes 		5. Household chemical products for humidifiers

Product Types



K-BPR: Biocides Safety Management **VS** EU BPR

	Biocidal Product Type		
Category	K-BPR: Biocides Safety Management	EU BPR	
Disinfectants	/	1 Human hygiene	
	1 Disinfectant	2 Disinfectants and algaecides not intended for direct application to	
	2 Algaecide	humans or animals	
	/	3 Veterinary hygiene	
	/	4 Food and feed area	
	/	5 Drinking water	
	3 Rodenticide	14 Rodenticides	
	4 Control of other vertebrate	15 Avicides	
Pest control		17 Piscicides	
		20 Control of other vertebrates	
	5 Insecticide	18 Insecticides, acaricides and products to control other arthropods	
	6 Control other invertebrate	16 Molluscicides, vermicides and products to control other invertebrates	
	7 Repellent	19 Repellents and attractants	

• •	Biocidal Product Type		
Category	K-BPR: Biocides Safety Management	EU BPR	
	8 Product preservatives	6 Preservatives for products during storage	
	9 Product surface preservative	7 Film preservatives	
	10 Fiber, Leather preservative	9 Fibre, leather, rubber and polymerised materials preservatives	
	11 Wood preservative	8 Wood preservatives	
Preservatives	12 Construction materials	10 Construction material preservatives	
		11 Preservatives for liquid-cooling and processing systems	
	13 Material / Equipment preservative	12 Slimicides	
		13 Working or cutting fluid preservatives	
	14 Embalming or taxidermist fluid	(Other biocidal products) 22 Embalming and taxidermist fluids	
Other biocidal products	15 Antifouling agent	21 Antifouling products	



Compliance Requirements



□ Active Substances Approval

Pre-Registration

Notification of Active Substance distributed on market before enforcement of the Act (~ June 30, 2019)

Late Pre-Registration

Approval Grace
Period up to 10
years
(MoE Notification 2019-249)

(March 24, 2020)

Approval

Submission of approval application plan (within one year after notification of grace period)

Processing the approval procedure during the grace period

Existing AS List and Grace Period

Application Proposals

Only Representative (OR):

K-BPR uses the OR concept beginning in Jan 1, 2021 and allows non-Korean companies to register through an OR on their behalf. It can prevent their confidential substance information from being disclosed to their importers or to the public in Korea.



Compliance Requirements



□ Active Substances Approval

Grace Period of Approval of Existing Biocide Active Ingredient

Classification	Group 1	Group 2	Group 3	Group 4
Grace Period of Biocide A.I. Approval	3 yrs. (31 Dec 2022)	5 yrs. (31 Dec 2024)	8 yrs. (31 Dec 2027)	10 yrs. (31 Dec 2029)
Product Type	DisinfectantsAlgaecidesRodenticidesInsecticidesRepellants	 Wood preservatives Control of other vertebrates Control of other non-vertebrates 	 Product preservatives Product surface preservatives Fabric, leather preservatives 	 Construction material preservatives Material/equipment preservatives Embalming or taxidermist fluids Antifouling agents In situ AS microorganism

If Active Substances are not designated as Existing Active Substances, the *new* substances shall not be manufactured or imported without obtaining Active Substances approval.

Urgent for Group 1



For Group 1 containing:

Disinfectants,

Algaecides,

Rodenticides,

Insecticides,

Repellants,

the approval deadline is 31 Dec 2022!

Content	Deadline		
OR Appointment for non-Korean companies	September 29, 2021		
Pre-Registration for each Korean importer	/		
Join the CICO Consortium	1		
Approval application plan submission	September 30, 2021		
Correction of the Approval application plan	October 31, 2021		
Dossier and risk assessment report preparation	/		
Approval application submission of LR	October 31, 2021		
Correction of the Approval application	November 30, 2021		
Approval application submission of the group members	December 31, 2021		
 Documents Supplement: Three batches analysis report; Sample; Efficacy data; Hazard data of the representative product if available; Manufacturer's certificate 	December 31, 2021		
Completeness check	February 4, 2022, at the latest		
Final approval	December 31, 2022		



Compliance Requirements



☐ Biocidal Product Authorisation

If all active substances contained in Biocidal Products are Existing Biocidal Substances, Authorisation Grace Periods for Biocidal Products will be granted for "Approval Grace Periods for active substances + 2 years"

If there are two or more substances whose Approval Grace Periods are different, Approval Grace Periods will be calculated based on the last end date of the grace period

□ Biocide-Treated Article

If all active substances contained in Biocidal Products used for Biocide-treated Articles are subject to Approval Deferment: Biocide-treated Articles shall be granted "Authorisation Grace Periods of Biocidal Products + 1 year"

If not, Biocide-treated Articles are allowed to be manufactured or imported without complying Safety & Labeling Standards until December 31, 2021

Conclusion



Ways to Comply with K-BPR

- 1. Appoint an Only Representative (OR) or set up branch office in South Korea, or
- 2. Entrust local importers to comply with K-BPR

Late Pre-registration if you have not done the Pre-Registration

- Prepare the Application Proposals
 Enjoy the Grace
- 2. Enjoy the Grace Period and prepare the approval materials

Biocidal Product Authorisation: 2 years later after the Substance Approval Treated Article
complies with Safety &
Labeling standards:

1 year after the product
authorisation or no later
than December 31,
2021

Note: Non-Korean companies can prevent their confidential substance information from being disclosed to their importers or to the public in Korea by appointing an OR in 2021.

New active substance, biocidal product and treated article with new active substance cannot enjoy a grace period. Once they comply with K-BPR, they could be placed on the Korea Market.

4. A Comparison of EU/UK/K-BPR



Country	EU	UK GB	Korea
Competent Authority	ECHA and the MS National Competent Authority	Health and Safety Executive (HSE)	Ministry of the Environment (MOE) Korea Chemical Management Association (KCMA) Korea Environmental Industry Technology Research Institute (KEITI)
Main Regulations	EU BPR (Regulation EU No 528/2012)	GB BPR	Consumer Chemical Products and Biocide Safety Management Act (K-BPR)
Product Types	Four (4) Main Groups containing 22 Product Types: 1) Disinfectants 2) Preservatives 3) Pest Control 4) Other Biocidal Products	Same as EU BPR	Consumer Chemical Products: 13 Categories containing 37 Product Types. Biocides Safety Management: Four (4) Main Groups containing 15 product types: 1) Disinfectants 2) Pest Control 3) Preservatives 4) Other Biocidal Products
Compliance Requirements	 Active Substance Approval and Art. 95 Listing Product Authorization or Registration Treated Article Compliance 	Same as EU BPR	 Safety Check and Notification; Pre-Registration; Active Substance Approval; Biocidal Product Authorization; Treated Article Compliance

Our Compliance Services







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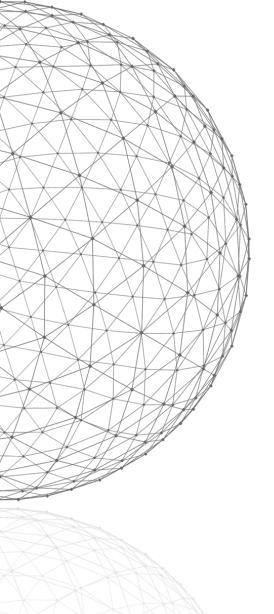
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Thank you for your attention!

Questions?