



**An Roinn Talmhaíochta,
Bia agus Mara**
Department of Agriculture,
Food and the Marine

Overview of the BPR

Michelle Whelan, PhD,
12/03/2020

Contents

- Overview of the BPR
- Product Approvals
- Borderline Products
- Record Keeping



Overview of BPR

Introduction

- The Biocidal Products Directive 98/8/EC was repealed by the Biocidal Products Regulation (EU) No 528/2012, it was transposed into Irish Law by:
 - S.I. 427 of 2013** - European Union (Biocidal Products) Regulations 2013.
- The Biocidal Products Regulation (BPR) controls the sale and use of biocidal products in ROI. It covers 22 product types (PTs).
- All products require an Irish registration prior to making available on the market for sale and use
- “**Making available on the market**” means any supply of a biocidal product or a treated article for distribution or use in the course of a commercial activity, whether in return for payment or free of charge.

What is a biocidal product?

- 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,
- any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used 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.

Types of Biocides



- A Biocidal Product under first indent of definition

- A Biocidal Product under the second indent of definition (pre-cursors or device to generate in situ)



- A 'treated article' means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.

A treated article with a primary biocidal function shall be considered a biocidal product.



Product Types (PTs)

- 22 product types broken into 4 main groups
 - Main group 1: Disinfectants (PT 1 – PT 5)
 - Main group 2: Preservatives (PT 6 – PT 13)
 - Main group 3: Pest control (PT 14 – PT 20)
 - Main group 4: Other biocidal products (PT 21 – PT 22)
- <https://echa.europa.eu/regulations/biocidal-products-regulation/product-types>

Disinfectants – Main Group 1

PT 1	Human hygiene	Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.
PT 2	Disinfectants and algaecides not intended for direct application to humans or animals	<p>Used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs. Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities.</p> <p>Used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil.</p> <p>Used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials.</p> <p>Used to be incorporated in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.</p>
PT 3	Veterinary hygiene	<p>Used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function.</p> <p>Used to disinfect the materials and surfaces associated with the housing or transportation of animals.</p>
PT 4	Food and feed area	<p>Used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals.</p> <p>Used to impregnate materials which may enter into contact with food.</p>
PT 5	Drinking water	Used for the disinfection of drinking water for both humans and animals.

Preservatives – Main Group 2

PT 6	Preservatives for products during storage	Used for the preservation of manufactured products, other than foodstuffs, feeding stuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life. Used as preservatives for the storage or use of rodenticide, insecticide or other baits.
PT 7	Film preservatives	Used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.
PT 8	Wood preservatives	Used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms, including insects. This product type includes both preventive and curative products.
PT 9	Fibre, leather, rubber and polymerised materials preservatives	Used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration. This product-type includes biocidal products which antagonise the settlement of micro-organisms on the surface of materials and therefore hamper or prevent the development of odour and/or offer other kinds of benefits.
PT 10	Construction material preservatives	Used for the preservation of masonry, composite materials, or other construction materials other than wood by the control of microbiological and algal attack.
PT 11	Preservatives for liquid-cooling and processing systems	Used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels. Products used for the disinfection of drinking water or of water for swimming pools are not included in this product-type.
PT 12	Slimicides	Used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.
PT 13	Working or cutting fluid preservatives	Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials.

Pest Control – Main Group 3

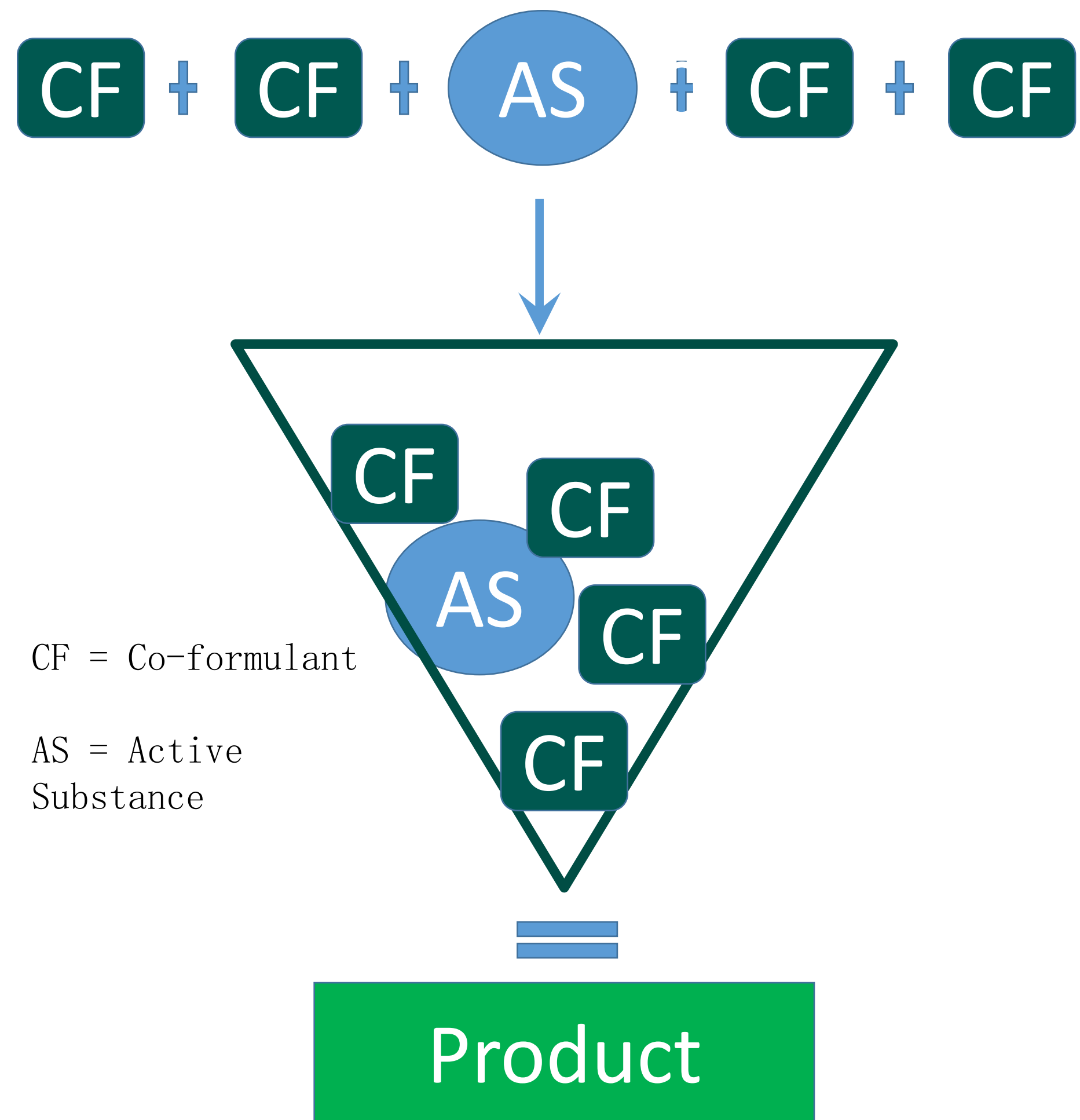
PT 14	Rodenticides	Used for the control of mice, rats or other rodents, by means other than repulsion or attraction.
PT 15	Avicides	Used for the control of birds, by means other than repulsion or attraction.
PT 16	Molluscicides, vermicides and products to control other invertebrates	Used for the control of molluscs, worms and invertebrates not covered by other product types, by means other than repulsion or attraction.
PT 17	Piscicides	Used for the control of fish, by means other than repulsion or attraction.
PT 18	Insecticides, acaricides and products to control other arthropods	Used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction.
PT 19	Repellents and attractants	Used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds, fish, rodents), by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of humans or animals.
PT 20	Control of other vertebrates	Used for the control of vertebrates other than those already covered by the other product types of this main group, by means other than repulsion or attraction.

Other Biocides – Main Group 4

PT 21	Antifouling products	Used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.
PT 22	Embalming and taxidermist fluids	Used for the disinfection and preservation of human or animal corpses, or parts thereof.

Product Approvals

2-Stage Process



Stage 1

- The AS is what makes the product efficacious (does what it claims to do)
- The AS are evaluated at EU level which is expected to be complete by 2024
- Whilst the AS evaluation is 'in-progress' or up to 'date of approval' of AS, a transitional period (Art 89) applies.
 - Notification application (PCS NO)

Stage 2

- When AS is approved, the product is then evaluated and authorised (IE/BPA No or EU No)
- Authorised products can only be used as described on the label

Active Substance Review Programme

- All biocidal products must contain an **active substance (AS) – Product Type (PT)** combination listed in the EU active substance review programme 1062/2014/EU.
- Products must contain an AS sourced from companies listed on **Art 95** list to prevent free loaders.
- Three different status of AS in the review programme;
 - Initial application for approval in progress
 - Approved
 - Non-Approved

1- Review Programme 1062/2014/EU

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-propylpiperonyl ether (Piperonyl butoxide/PBO)	EL	200-076-7	51-03-6															x			
9	Bronopol	ES	200-143-0	52-51-7		x				x			x		x	x						x
29	Chlorocresol	FR	200-431-6	59-50-7	x	x	x			x			x					x				
36	Ethanol	EL	200-578-6	64-17-5	x	x		x														
37	Formic acid	BE	200-579-1	64-18-6		x	x	x	x	x					x	x						
40	Propan-2-ol	DE	200-661-7	67-63-0	x	x		x														

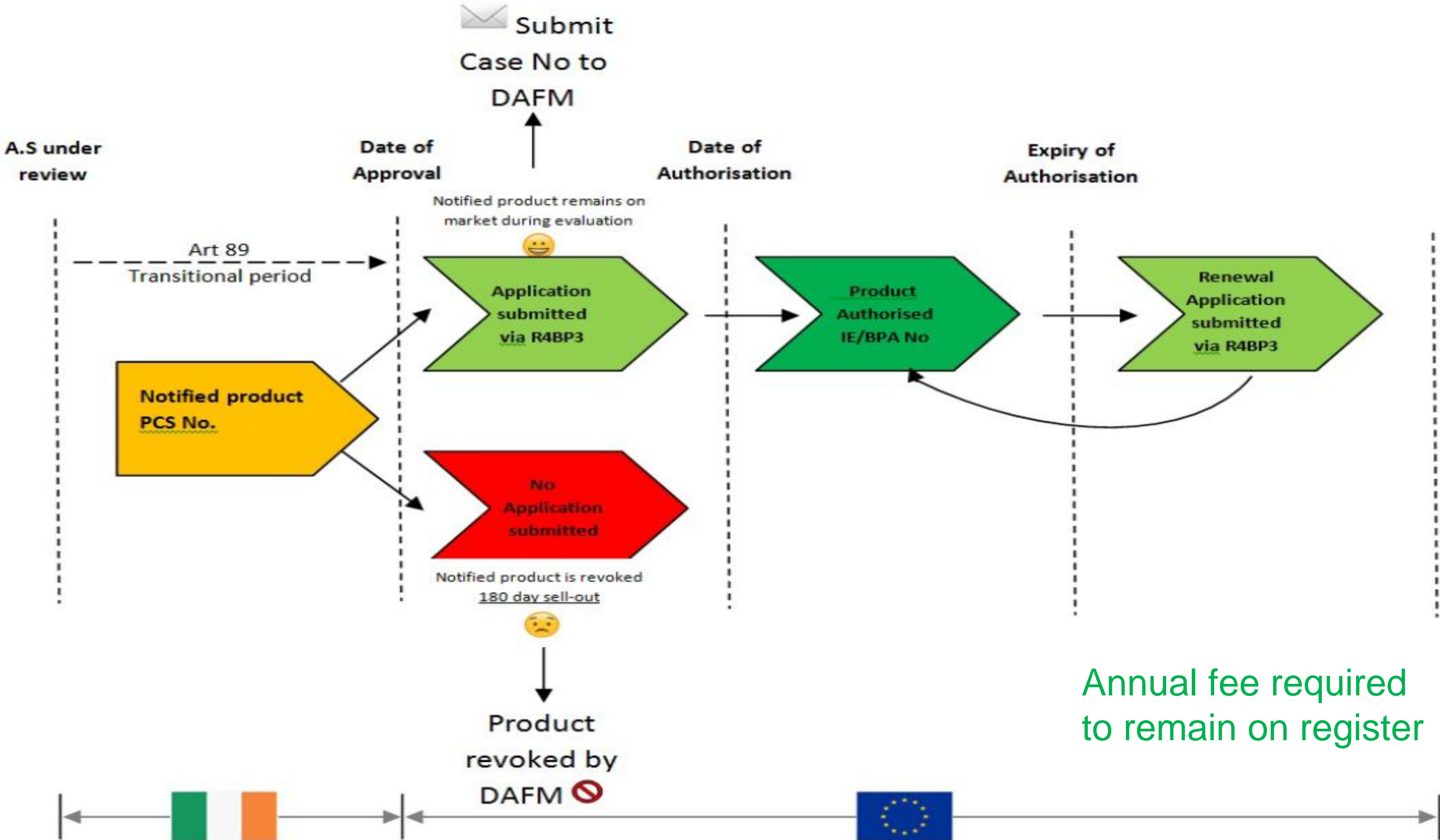
2 - Art 95 listing

Silver nitrate		EC: 231-853-9	CAS: 7761-88-8
Product Type:	1		
Dow Europe GmbH		Switzerland	Substance Supplier
Sanosil Hungaria KFT		Hungary	Substance Supplier
			RP Participant
			17-Aug-15
			RP Participant
			24-Sep-14
Product Type:	2		
Sanosil Hungaria KFT		Hungary	Substance Supplier
			New Active
			24-Sep-14
Product Type:	3		
Sanosil Hungaria KFT		Hungary	Substance Supplier
			New Active
			24-Sep-14
Product Type:	4		
Brita GmbH		Germany	Substance & Product Supplier
Sanosil Hungaria KFT		Hungary	Substance Supplier
			Art.95 submission
			29-Jul-15
			New Active
			24-Sep-14

3- Status of substance in Review Programme

1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole (Propiconazole)	262-104-4	60207-90-1	PT08	01/04/2010	31/03/2021	Finland	Approved - Renewal in progress Competent authority evaluation		1019
1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole (Propiconazole)	262-104-4	60207-90-1	PT09	01/06/2015	31/05/2025	Finland	Approved		
1-ethynyl-2-methylpent-2-enyl 2,2-dimethyl-3-(2-methylprop-1-enyl) cyclopropanecarboxylate (Empenthrin)	259-154-4	54406-48-3	PT18			Belgium	Not approved		
1R-trans phenothrin	247-431-2	26046-85-5	PT18	01/09/2015	31/08/2025	Ireland	Approved		21
2,2-dibromo-2-cyanoacetamide (DBNPA)	233-539-7	10222-01-2	PT02			Denmark	Initial application for approval in progress Competent authority evaluation		
2,2-dibromo-2-cyanoacetamide (DBNPA)	233-539-7	10222-01-2	PT04			Denmark	Initial application for approval in progress Commission decision		

Product Life-Cycle



Biocidal Product Registers



You are here: [Home](#) » [Registers](#) » Biocidal Product Registers

Biocidal Product Registers

The Product Registers for biocidal products contain details of Notified and Authorised biocidal products for sale and use on the market in Ireland. Existing stocks of biocidal products for which the notification or authorisation has recently expired, been withdrawn or been revoked may in some instances continue to be sold-out or used-up as part of the phase-out of existing stocks of the product.

Notified products - The live register for notified biocidal products contains details of both notified and revoked products. For revoked products, the sell-out and use-up are detailed for each product.

[Biocidal Product Register - Notified Products](#)

Authorised products - The link below contains a pdf register of authorised products and a pdf register of revoked authorised products including their sell-out and use-up dates.

[Biocidal Product Register - Authorised Products](#)

<http://www.pcs.agriculture.gov.ie/registers/biocidalproductregi>

Borderline Products

Biocide Borderlines

- Biocides have multiple “overlaps” or borderlines with other pieces of chemical legislation ;
 - **Veterinary Medicines**
 - **Plant Protection Products**
 - **Detergents**
 - **Cosmetics**
- IND are responsible for placing their product in the correct legislative area based on the intent of the product.

Vet Med – Biocide Claims for Teat Dips

- **Animal medicinal claims** on the label will highlight the intent of the product as a veterinary medicinal product (VMP).
 - VMP = “Mastitis control” or “Reducing/Preventing mastitis” or “”Post-milking teat dipping to prevent mastitis”
- **Biocidal claims** on the label will highlight the intent of the product as a biocide.
 - Biocide = “For sanitising cow udders” or “Effective disinfectant/bactericidal base” or “Gives teat-end barrier protection between milking”

Detergent – Biocide Claims

- **Detergent claims** on the label will highlight the intent of the product as a detergent.

–Detergent = “Clean” or “Remove dirt”



- **Biocidal claims** on the label will highlight the intent of the product as a biocide.

–Biocide = “Sanitise” or “Disinfection” or “Kills 99.9% bacteria” or “controls bacteria, e-coli, TBCs, etc.”



Cosmetic – Biocide Claims = for human hygiene

- **Cosmetic claims** on the label will highlight the intent of the product as a cosmetic.

–Cosmetic = “Clean” or “Remove dirt” from hands



- **Biocidal claims** on the label will highlight the intent of the product as a biocide.

–Biocide = “Antibacterial hand wash” or “Kills 99.9% bacteria” or “controls bacteria, etc.” on hands.



How to select the correct legislation?

- Does your product contain an AS? Does it fall under an AS-PT in review programme? Is it efficacious? What is the intent of your sales team, advertisement and the end-user?
- What is the function of the product?
 - Clean → Use detergent or cosmetic products
 - Disinfect/control harmful organisms → Use a biocidal product
 - Control/prevent disease/illness in animals → Veterinary medicinal product



Record Keeping



Compliance with Requirements – Art 62(2)

- Manufacturer... shall maintain, appropriate documentation in paper or electronic format relevant for the quality and safety of the biocidal product to be placed on the market and shall store production batch samples. The documentation shall include as a minimum:
 - (a) safety data sheets and specifications of active substances and other ingredients used for manufacturing the biocidal product;
 - (b) records of the various manufacturing operations performed;
 - (c) results of internal quality controls;
 - (d) identification of production batches.

Records should be kept for 10 years – Art 68

Thank you for listening

Any Questions?

T: 01 615 7552

E: Biocides@agriculture.gov.ie