

Scope for the notification and authorization of biocides in Belgium

General comment: if a product dossier is submitted for different applications (ex: PT1 and PT2 or PT7 and PT11) and if one of those applications needs to be authorized (ex: PT2 and PT11), then the full dossier for all PTs will have to be authorized by default. This is because it is not possible to provide in the same time a notification number and an authorization number for the same commercial product name.

The applicant should in this case:

- specify in the section A10 of the electronic application form (B10), which PTs have to be authorized and which PTs have to be notified. They don't have to introduce specific test for the PT to be notified (*e.g.* stability test);
- select in the application form, all PTs for which the product is intended for, no matter if they require a notification or an authorization;
- introduce only efficacy data are required for the PTs which have to be authorized;
- introduce a label covering all PTs.

Group/Product Type	Justification for autorisation procedure (B10)	Justification for notification procedure (B11)	Other comments	Source
GROUP 1 : Disinfectants and general biocides				
PT 1 : Human Hygiene biocides	Not described in R.D of 1975. Not to be authorized.	To be notified. Examples (in general): disinfectant for the skin, alcohol based gel (60 to 80% V/V), soap with antibacterial/antiseptic/disinfectant properties mentioned (= biocidal claims)	Depending on the claims, composition and destination, a product can be biocide or medicinal product or cosmetic Advice: → Check the document of the Mixed Commission if any doubt for the classification	Lignes directrices relatives à la frontière Biocide-Cosmétique-Médicament à usage humain/Richtstnoer m.b.t. de Borderline Biocide-Cosmetica- Geneesmiddel voor humaan gebruik. (Commission mixte/Gemengde Commissie; 17/06/2010)
PT2: Private area and public health area disinfectants and other biocides	To be authorized: since and according the R.D of 1975	/	/	Royal Decree of 05 June 1975
PT3: Veterinary Hygiene Biocides	Authorization according to R.D. of 1975 for products intended to: « Fight or eliminate pest animals, plants or microorganisms in housing, buildings, means of transportation , swimming pools, rubbish dumps and sewers. (c) » → hygiene for animals, application on surfaces	Notification for products to be applied on the skin of animals.	Depending on the claims, composition and destination, a product to be used on the skin of an animal can be biocide or medicinal veterinary product. The biocidal products cannot be claimed to have preventive and/or therapeutical indications. <u>Specific case: hygiene of teat dips</u>	Explications relatives au cas borderline biocide-médicament vétérinaire/Toelichting m.b.t. de borderline biocide-diergeneesmiddel (Commission mixte/Gemengde Commissie; 17/06/2010) ; Conclusion de la Commission mixte de juin 2011 ; R.D. of 5/06/1975

			<p>Biocide: Product used before the milking to clean the udder but not to prevent mastitis or an infection. The teat dips is wiped and dried before the milking (mentioned on the label) → Notification required as a biocide</p> <p>Medicinal Veterinary product: Product dipping or spraying the udder. Product used after the milking to prevent mastitis and infection. → authorization required as a medicinal veterinary product.</p> <p>Remark: if the product is intended to be used before and after the milking, the product is considered as a medicinal veterinary product and should be authorized as such.</p>	
PT4 : Food and feed area disinfectants	To be authorized: since and according the R.D of 1975 (a)	/	/	Royal Decree of 05 June 1975
PT5: Drinking water disinfectants	To be authorized: since and according the R.D of 1975 (e)	/	/	Royal Decree of 05 June 1975

GROUP 2: Preservatives				
PT6: In-can preservatives	To be authorized: since and according the R.D of 1975 (k+ j for certain products)	Exemption: Notification for products intended to avoid the decay of non-professional water-based products and their adjuvants.	/	Royal Decree of 05 June 1975 (modified by R.D. of 5/11/1991); R.D of 12 March 2010
PT7: Film preservatives	Not described in R.D of 1975.	To be notified.		R.D of 12 March 2010; Manual of decision
PT8: Wood preservatives	To be authorized: since and according the R.D of 1975 (c)	/	/	Royal Decree of 05 June 1975
PT9: Fiber, leather, rubber and polymerized materials preservatives	To be authorized: since and according the R.D of 1975 (d, h & k)	/	/	Royal Decree of 05 June 1975 (modified by R.D. of 5/11/1991)
PT10: Masonry preservatives	To be authorized: since and according the R.D of 1975 (c&d)	Notification for products used as preventive applied as a film or layer (up to 1-2 cm thick) onto the surface of buildings (e.g. cement layer, plaster for outdoor use)		Royal Decree of 05 June 1975 (modified by R.D. of 5/11/1991); R.D of 12 March 2010
PT11: Preservatives for liquid-cooling and processing systems	Authorization required. According to R.D. of 1975 (amended by R.D. of 5/11/1991): Products used for treatment of industrial water to fight or eliminate animals, plants or microorganisms (i) → to be authorized. Examples: - Products used in recirculating water processes in paper and	/	/	Royal Decree of 05 June 1975 (modified by R.D. of 5/11/1991)

	paperboard industry - Products used in recirculating cool water systems			
PT12: Slimicides	To be authorized according to R.D. of 1975 (amended by R.D. of 5/11/1991): Products to prevent the decomposition of industrial water products and their adjuvants (j)	/	According to the manual of decision (59), PT6 is the most appropriate for biocidal products used in the storage of other raw materials in paper mill (e.g. starch before its cooking) and prior to the supply of raw materials to a paper mill (e.g. during transport). Preservation of paper itself or other final products belongs to PT9. PT12 is suited for product used in industrial processes, e.g. paper industry. As a general rule, biocidal products used at the wet-end of a paper machine would be regarded as PT 12, whilst those used at the dry-end would be regarded as PT 6.	Royal Decree of 05 June 1975 (modified by R.D. of 5/11/1991); Manual of decision
PT13: Metal working-fluid preservatives	To be authorized since and according R.D. of 1975 (j)	/	/	Royal Decree of 05 June 1975
GROUP 3: Pest Control				
PT14: Rodenticides	To be authorized: since and according the R.D of 1975 (c)	/	/	Royal Decree of 05 June 1975
PT15: Avicides	Not described in R.D of 1975. Not to be authorized.	To be notified	/	Royal Decree of 12 March 2010

PT16: Molluscicides	Not described in R.D of 1975. Not to be authorized.	To be notified	/	Royal Decree of 12 March 2010
PT17: Piscicides	Not described in R.D of 1975. Not to be authorized.	To be notified	/	Royal Decree of 12 March 2010
PT18: Insecticides, acaricides and products to control other arthropods	To be authorized: since and according the R.D of 1975 (c)	/	/	Royal Decree of 05 June 1975
PT19: Repellent and attractants	To be authorized: since and according the RD of 1975 (c&f) e.g: products to be used on surfaces (c); products to be used on the animal skin of small pets (cat, rabbit, dog, etc.)(f).	Notification required for products used on human skin. Notification required for products used on the animal skin of big pets (horses, etc.)	/	Royal Decree of 05 June 1975 ; Royal Decree of 12 March 2010
GROUP 4 : Other biocides				
PT20: Preservatives for food or feedstock's	To be authorized: since and according the R.D of 1975 (b)	/	/	Royal Decree of 05 June 1975
PT21: Antifouling products	To be authorized: since and according the R.D of 1975 (g)	/	/	Royal Decree of 05 June 1975
PT22: Embalming and taxidermist fluids	Not described in R.D of 1975. Not to be authorized.	To be notified	/	Royal Decree of 12 March 2010
PT23: Control of other vertebrates (vermin +	Not described in R.D of 1975.	To be notified	/	Royal Decree of 12

others?)	Not to be authorized.			March 2010
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