

Application fees for biocidal products

Application forms (in Word format) are available at www.kemi.se

TABLE 1. Biocidal products: Chemical or biological (containing micro-organisms)											
Category of application	Type of application	Rule (Ordinance 2013:63)	Basic fee (SEK)	Additional fees (SEK)							
				A Assessment by the National food Agency, SLV	Each additional			E Comparative assessment	F New, or partly new, dossier for active substance/micro-organism	G Active substance not assessed previously by KemI	Amendment of on-going application
					B Active substance	C Product type	D User category				
Product authorisation (new or renewal)	1. Sweden is the evaluating Member State <i>Evaluation according to Swedish rules</i>	4 chapt. 2 § 10	300 000	60 000	50 000	50 000	50 000	50 000		160 000	50 000 (KemI) 20 000 (SLV)
	2. Sweden is the evaluating Member State <i>Authorisation of a product</i>	4 chapt. 2 § 10	300 000	60 000	50 000	50 000	50 000	50 000	850 000		50 000 (KemI) 20 000 (SLV)
	3. Sweden is the evaluating Member State <i>Authorisation of a product family</i>	4 chapt. 2 § 7	600 000	60 000	50 000	50 000	50 000	50 000	850 000		50 000 (KemI) 20 000 (SLV)
	4. Sweden is the evaluating Member State <i>Simplified authorisation procedure. Authorisation of a product</i>	4 chapt. 2 § 5	60 000	60 000							
	5. Sweden is the evaluating Member State <i>Simplified authorisation procedure. Authorisation of a product family</i>	4 chapt. 2 § 6	120 000	60 000							

TABLE 1. Biocidal products: Chemical or biological (containing micro-organisms)											
Category of application	Type of application	Rule (Ordinance 2013:63)	Basic fee (SEK)	Additional fees (SEK)							Amendment of on-going application
				A Assessment by the National food Agency, SLV	Each additional			E Comparative assessment	F New, or partly new, dossier for active substance/micro-organism	G Active substance not assessed previously by KemI	
					B Active substance	C Product type	D User category				
Product authorisation (new or renewal)	6. Sweden is the evaluating Member State <i>Union authorisation of a product</i>	4 chapt. 2 § 3	600 000	60 000	50 000	50 000	50 000	50 000	850 000		50 000 (KemI) 20 000 (SLV)
	7. Sweden is the evaluating Member State <i>Union authorisation of a product family</i>	4 chapt. 2 § 4	900 000	60 000	50 000	50 000	50 000	50 000	850 000		50 000 (KemI) 20 000 (SLV)
	8. Sweden is the evaluating Member State <i>Provisional authorisation of a product</i>	4 chapt. 2 § 9	360 000	60 000	50 000	50 000	50 000	50 000			50 000 (KemI) 20 000 (SLV)
	9. Sweden is the evaluating Member State <i>Provisional authorisation of a product family</i>	4 chapt. 2 § 8	660 000	60 000	50 000	50 000	50 000	50 000			50 000 (KemI) 20 000 (SLV)
	10. Sweden is the evaluating Member State <i>Authorisation of the same biocidal product by the same or different enterprises under the same terms and conditions</i>	4 chapt. 12 §	20 000							850 000	
	11. Mutual recognition <i>Product</i>	4 chapt. 2 § 1	120 000	30 000						850 000	

TABLE 1. Biocidal products: Chemical or biological (containing micro-organisms)											
Category of application	Type of application	Rule (Ordinance 2013:63)	Basic fee (SEK)	Additional fees (SEK)							
				A Assessment by the National food Agency, SLV	Each additional			E Comparative assessment	F New, or partly new, dossier for active substance/micro-organism	G Active substance not assessed previously by KemI	Amendment of on-going application
					B Active substance	C Product type	D User category				
	12. Mutual recognition <i>Product family</i>	4 chapt. 2 § 2	240 000	30 000					850 000		
Amendment of product authorisation	13. Sweden is the evaluating Member State <i>Major change</i>	4 chapt. 10 § 1	120 000	60 000							
	14. Mutual recognition <i>Major change</i>	4 chapt. 10 § 2	60 000	30 000							
	15. Sweden is the evaluating Member State <i>Minor change</i>	4 chapt. 10 § 3	40 000								
	16. Mutual recognition <i>Minor change</i>	4 chapt. 10 § 5	8 000								
	17. Administrative change	4 chapt. 10 § 4	8 000								
Notification	18. Addition of a biocidal product within a product family	4 chapt. 13 §	8 000								
	19. Making available on the market of a biocidal product authorised in accordance with the simplified authorisation procedure	4 chapt. 14 §	8 000								
Derogation	20. Experiment or test for research and development	4 chapt. 15 § 1	8 000								

TABLE 1. Biocidal products: Chemical or biological (containing micro-organisms)											
Category of application	Type of application	Rule (Ordinance 2013:63)	Basic fee (SEK)	Additional fees (SEK)							
				A Assessment by the National food Agency, SLV	Each additional			E Comparative assessment	F New, or partly new, dossier for active substance/micro-organism	G Active substance not assessed previously by KemI	Amendment of on-going application
					B Active substance	C Product type	D User category				
Derogation	21. Other cases than experiment or test for research and development	4 chapt. 15 § 2	15 000								
Parallel trade permit	22. The biocidal product is authorised in another member state and is identical to a biocidal product already authorised in Sweden	4 chapt. 16 §	20 000								

TABLE 2. Description of additional fees	
A	Additional fee for assessment of residues by the National Food Agency. Applicable for biocidal products that are used in a way that it might come into contact with food, fodder or drinking water or if it should be used in the vicinity of or directly on animals that can be used in food production.
B	Additional fee for assessment of each additional active substance. Applicable for biocidal products containing more than one active substance.
C	Additional fee for assessment of each additional product type. Applicable for biocidal products used in more than one product type.
D	Additional fee for assessment of each additional user category. Applicable for biocidal products used in more than one user category.
E	Additional fee for comparative assessment. Applicable for biocidal products containing an active substance that is a candidate for substitution.
F	Additional fee for evaluation of new, or partly new, dossier on active substance/micro-organism. Applicable when the applicant does not have the right to use the dossier that was evaluated in connection to the approval of the active substance/micro-organism.
G	Additional fee for assessment of each active substance that have not been assessed previously by KemI. Applicable for biocidal products that are evaluated according to Swedish rules.
H	Additional fee for assessment of each new active organism. Applicable for biocidal products containing active organisms that are not already included in an authorised pesticide.
Additional fee for amendment of on-going application. Applicable when there is a need for a new evaluation according to the uniform principles (e.g. change of use or dose). SLV: Additional fee for assessment of residues by the National Food Agency. Applicable for biocidal products that are used in a way that it might come into contact with food, fodder or drinking water or if it should be used in the vicinity of or directly on animals that can be used in food production.	