Regulations concerning the making available on the market and use of biocidal products							
Applications	**Legal references**		**Conditions**	**Timelines**	**Maximum validity**	**General and technical characteristics of the dossier**	**Comments**
	Law	**articles**					
Approval of an active substance							
Approval of an active substance	Regulation (EU) 528/2012	Chapter II and annexes II and III	Refer to art. 4 and 5 of R 528/2012 Approval of active substances is restricted to the product-types for which relevant data have been submitted	≈ 2 years: 2 months for fee payment and compliance check + 1 year of assessment by the referent Member State + 9 months of evaluation by ECHA with peer review	10 years	Substance dossier with at least : - a dossier for the active substance - a dossier for at least one biocidal product that contain the active substance For further information, R 528/2012, art 6 and annexes II and III	
Authorisation of biocidal products							
Application for a national authorisation of a biocidal product	Regulation (EU) 528/2012	Chapter VI	Refer to R 528/2012, art.19	≈ 14 months : 2 months for fee payment and compliance check + 1 year of evaluation	10 years	Product dossier with at least : -a dossier for the product -a summary of product characteristics in French - a dossier for each active substance in the product. Further information in R528/2012, art.20, 21 and annex III	Applicants have to submit project of summary of product characteristics in french at the beginning of the procedure. If additional data is needed, the deadline can be extended up to 9 months maximum.
Application for an authorisation through mutual recognition in parallel of a product or a product family	Regulation (EU) 528/2012	Chapter VII, art. 34	Refer to R 528/2012, art.19	≈ 18 month : 2 months for fee payment and compliance check + 1 year of evaluation by the RMS* + 3 months of evaluation by the CMS* +1 month for the implementation in all the CMS	10 years. The date of expiry is the same as the reference authorisation	The dossier is similar to the one for a national autorisation + the list of all the member states concerned	The applicant has to submit a proposal of the Summary of Product Characteristics translated in french 10 days after the RMS has submitted its draft SPC proposal. If additional data is needed, the deadline can be extended up to 9 months maximum.
Application for an authorisation through mutual recognition in sequence of a product or a product family	Regulation (EU) 528/2012	Chapter VII, art. 33		≈6 months : 2 months for fee payment and compliance check + 3 months of evaluation + 1 month for the implementation in all the member states concerned NB :foresee 6 more months if the concerned member states disagree	10 years. The expiry date is the same as the reference authorisation	At the beginning of the procedure, the applicant has to send to the competent authority a translation of the authorisation issued by the RMS	
Application for a Union autorisation of biocidal product (if FR = RMS*)	Regulation (EU) 528/2012	Chapter VIII	Refer to R 528/2012, art.42	≈ 21 months : 2 months for fee payment and compliance check + 1 year of evaluation + 6 months to find a european agreement + 1 month for implementation in all the member states		Similar to a dossier for biocidal product with some specific aspects : -a confirmation that the biocidal product would have similar conditions of use across the union - the name of the competent authority with a letter of agreement	If additional data is needed, the deadline can be extended up to 10 months maximum.

Regulations concerning the making available on the market and use of biocidal products							
Applications	**Legal references**		**Conditions**	**Timelines**	**Maximum validity**	**General and technical characteristics of the dossier**	**Comments**
	Law	**articles**					
Application for an authorisation according to the simplified procedure	Regulation (EU) 528/2012	Chapter V, art. 25 to 27	Refer to R 528/2012, art.25	4 months : 1 month for fee payment + 3 months of evaluation	10 years	- the applicant has to prove that the biocidal product meets the conditions listed in art. 25 of R 528/2012 - the applicant has to give to the european agency a confirmation from the competent authority that it agrees to carry out the evaluation	If additional data is needed, the deadline can be extended up to 3 months maximum. The making available on the market in other member states is possible through a simple notification (a mutual recognition procedure is not required)
Application for a same product or a same product family	Implementating regulation (EU) 414/2013		For 2 products with the same properties. The reference product has to be avalaible on the market (or being evaluated) Further information : R 414/2013	4 months : 2 months for fee payment and compliance check+ 2 months for authorisation	10 years. The expiry date is the same as the reference authorisation	Dossier for a same product : - number of the autorisation of the reference product - an information about the differences between the reference product and the same product - a letter of access - a SPC proposal in French	
Application for a provisional authorisation	Regulation (EU) 528/2012	Chapter XII, art. 55 §2	- the new active substance(s) contained in the product is(are) being evaluated -the competent authority has submitted a recommandation for approval of the new active substance		3 years		If the active substance is not eventually approved, the autorisation granted by the competent authority is cancelled
Application for the authorisation of a product family	Regulation (EU) 528/2012	Chapter I, art.3 §1 s) and art. 19 §6	Refer to art.19 §6	the deadline is equivalent to the procedure for a national authorisation of a product	10 years		The addition of a product within the family product is allowed after a simple notification (administrative change process)
Application for a parallel trade permit	Regulation (EU) 528/2012	Chapter X, art. 53	The biocidal product has to be made available on the market in another member state and has to be identical to a product already authorised in the Member State of introduction		the validity of this authorisation is the same as the authorisation of the reference product	All the required information is listed in §4 of art.53	If the authorisation is withdrawn in the Member State of origin for safety of efficacy reason, the Member State of introduction may withdraw the parallel trade permit
Application for an authorisation of a product or a product family for a research and development activity	Regulation (EU) 528/2012	Art. 56 §3	A previous application is needed if the experiments could have harmful effects or any unacceptable adverse effect, whether immediate or delayed, on humans, on animals or on environment				

Regulations concerning the making available on the market and use of biocidal products							
Applications	**Legal references**		**Conditions**	**Timelines**	**Maximum validity**	**General and technical characteristics of the dossier**	**Comments**
	Law	**articles**					
Renewal of an active substance approval or a product authorisation							
Renewal of the approval of an active substance	Regulation (EU) 528/2012	Chapter III, art.14 and 15	Refer to art.12 : the renewal is possible if the active substance still meets the conditions mentioned in art.4 or 5. The application for the renewal of the approval of an active substance has to be made at least 550 days before the expiry date (or the earliest expiry date for the multi-PT active substances)	Between 12 and 25 months : the time of evaluation depends on whether a full evaluation is necessary or not	15 years	the dossier includes at least : - all relevant data required that has been generated since the initial approval - an assessment of whether the conclusions of the previous evaluation remain valid - the choice of the competent authority and a letter of agreement	
Renewal of the authorisation of a product or a product family	Regulation (EU) 528/2012	Chapter VI, art. 31	The product shall still fulfill the conditions mentioned in art. 19	Between 7 and 16 month : the time of evaluation depends on whether a full evaluation is necessary or not		the dossier includes at least : -all relevant date required that has been generated since initial authorisation - an assessment of whether the conclusions of the previous evaluation of the product remain valid - the choice of the competent authority and a letter of agreement	
Changes of authorised biocidal products							
application for an administrative change of a biocidal product or a product family	Implementing regulation 354/2013	Chapter II, art.6		30 days after the fees have been paid			The change shall be notified one year at the latest after it was implemented except for the changes listed in section 1 of the title I of the annex: these changes have to be notified before their implementation
Application for a minor change of a biocidal product or a family product (if FR=RMS)	Implementing regulation 354/2013	Chapter II, art. 7		≈ 7 months ½ : 2 months for fee payment and compliance check + 3 months of evaluation + 1 month½ to reach an agreement with the member states+ 1 month for implementation in all the CMS			If additional data is needed, the deadline can be extended up to 4 months maximum.
Application for a major change of a biocidal product or a product family (if FR=RMS)	Implementing regulation 354/2013	Chapter II, art.8		≈ 12 months : 2 months for payment and compliance check + 6 months of evaluation + 3 months to reach an agreement with the member states + 1 month of implementation in all the CMS			If additional data is needed, the deadline can be extended up to 7 months maximum.
Application for a major or minor change of a product or a product family (France = CMS)	Implementing regulation (EU) 354/2013	Chapter II, art. 9 and 9a		2 months½ for a minor change 5 months for a major change			If additional data is needed, the deadline can be extended up to 3 months maximum.

*RMS : Referent Member State

** CMS : Concerned Member States