

Regulatory Affairs Directorate Provision of Services – Fees

Biocidal Products - MT as rMS

	Fee (€)
New National Authorization (single biocidal product)	37,000 ¹
New National Authorization (biocidal product family)	48,000 ¹
Renewal of National Authorization (single biocidal product)	37,000 ¹
Renewal of National Authorization (biocidal product family)	50,000 ²
Simplified Authorization Procedure (single biocidal product)	9,000 ¹
Simplified Authorization Procedure (biocidal product family)	9,000 ²
New Union Authorization (single biocidal product)	37,000 ¹
New Union Authorization (biocidal product family)	50,000 ²
Renewal of Union Authorization (single biocidal product)	42,000 ¹
Renewal of Union Authorization (biocidal product family)	54,000 ¹



Active Substances for Biocidal Products – MT as rMS	
Approval of an Active Substance	220,000 ³
Approval of an Active Substance for Annex I inclusion 528/2012	110,000 ³
Renewal of an Active Substance	220,000 ³
Renewal of an Active Substance for Annex I inclusion 528/2012	110,000 ³

Biocidal Products – MT as cMS	
	Fee (€)
Mutual Recognition	500
Mutual Recognition for product family	500 + 50 per product family member
Simplified Authorization Procedure Notification	350
Simplified Authorization Procedure Notification for product family	350 + 25 per product family member
Authorization of the same biocidal product	500
Union Authorizations	500 + 50 per product family member (one-time fee)
Administrative change *	80
Minor change *	200
Major change *	300



Biocidal Products – (Transitional Rules)	
	Fee (€)
Notification of Biocidal Product – valid for a	100
maximum of 3 years	
Renewal of the Notification of Biocidal Product	50

- Biocidal Product: Additional fees may apply. Fee based on the consideration of one active substance, one user category, one PT and no comparative assessment. Inclusion of additional active substances, user categories or product types may result in additional costs. Please contact us on <u>biocides@mccaa.org.mt</u> for a quote provided free of charge.
- 2. Biocidal Product Family. Additional fees may apply. Fee based on the consideration of one active substance, one user category and one PT. Inclusion of family member, active substances, user categories or product types may result in additional costs. Please contact us on biocides@mccaa.org.mt for a quote provided free of charge.
- 3. Biocidal active substance: Additional costs may apply. Fee base on the consideration of one PT and no comparative assessment. Please contact us on biocides@mccaa.org.mt for a quote provided free of charge.



Plant Protection Product	S
	Fee (€)
Evaluation of a dossier in conformity with Regulation 545/2011 as a zonal Rapporteur Member State (zRMS), of a Plant Protection Product as per Regulation (EC) 1107/2009	35,000
Evaluation of a dossier in conformity with Regulation 545/2011as a zonal Rapporteur Member State (zRMS), of a Plant Protection Product as per Regulation (EC) 1107/2009 FOR LOW RISK PRODUCTS	25,500
Evaluation of a dossier in conformity with Regulation 545/2011 as a zonal Rapporteur Member State (zRMS), of a Plant Protection Product as per Regulation (EC) 1107/2009: FOR LOW RISK PRODUCTS FOR ORNAMENTAL USE ONLY	13,500
Pre-submission meeting for evaluation of a Plant Protection Product	1,500
Evaluation of a dossier in conformity with Regulation 545/2011 as a Member State which is not the zRMS of a Plant Protection Product as per Regulation (EC) 1107/2009	3,000
Evaluation of dossier according to Article 43 to	24,000



Regulation (EC) 1107/2009	
Evaluation of dossier according to Article 34 to	6,000
Regulation 1107/2009	
Mutual Recognition of a Plant Protection Product	
already authorized in another Member State with	500
similar environmental conditions as in Malta	
Mutual Recognition of a Plant Protection Product	
already authorized in another Member State with	
similar environmental conditions as in Malta containing	350
low risk active substance according to Article 22 of	
Regulation 1107/2009	
Re-Registration of Plant Protection Products whose	200
registration through mutual recognition in Malta has	200
expired	
Authorization for an amendment of an authorized plant	100
protection product	100
Authorization for emergency use as per Article 53 of	150
Regulation (EC) 1107/2009.	130
Label correction (First label correction being included	25
in the Mutual Recognition Fee) or Incomplete	25
Documentation	
Parallel Imports: For Commercial Use (New	500
Authorization)	
For Commercial Use (Renewal)	200



For Personal Use	50
Trading in pesticides	25
Active Substances for Plant Protection Products	
Market Authorisation of an Active Substance (including	
one representative product)	140,000
Renewal of an Active Substance (including one	
representative product)	120,000
Market Authorisation of a low risk Active Substance	
(including one representative product)	105,000
Evaluation of a dossier regarding the technical	
equivalence for an active substance regulated under	
Regulation (EC) 1107/2009	15,000
Pre-submission meeting for the evaluation of an Active	
Substance	1,500



Food Product	Fee (€)
Application for notification	10
Non-Food Product	Fee (€)
Application for notification	40

NB: These fees have been kept to the minimum, are based on the fees charged by other EU Member States, cover only the administrative costs and, where applicable, any costs resulting from necessary analysis or use of experts outside MCCAA. The Authority shall not charge any fee until pertinent request, to be made by applicant in writing, is duly acknowledged by the Authority (also in writing) and where the exact fee payable shall be clearly indicated and agreed upon.