

FEE STRUCTURE

In accordance with Article 80 of Regulation (EU) No. 528/2012 of the European Parliament and of the Council and Regulation 25 of S.I. No. 427 of 2013, the following fees shall apply from **15th November 2023**

Fees relating to Biocidal Products¹

Description	Fee
<u>Notification</u>	
National Notification of a biocidal product	€300
Trivial amendment	€300
Notification under the BPR (Article 17.6 [#] and Article 27 [‡])	€300
<u>Biocidal Product Authorisation</u>	
National Authorisation (single product) – rMS	€20,000
National Authorisation (product family) – rMS	€40,000
Mutual recognition (single product) – cMS***	€2,500
Mutual recognition (product family) – cMS***	€5,000
Simplified Authorisation procedure (single product) - rMS	€5,000
Simplified Authorisation procedure (product family) - rMS	€10,000
Same biocidal product (single product)- rMS	€300
Same biocidal product (product family)- rMS	€1,300
Provisional Authorisation (single product) – rMS	€20,000
Provisional (product family) – rMS	€40,000
Renewal of a National Authorisation (single product) – rMS	€20,000**
Renewal of a National Authorisation (product family) – rMS	€40,000**
Additional product-type (in addition to the cost of product authorisation/family authorisation) - rMS	€20,000
Renewal of a Simplified Authorisation Procedure (single product) – rMS	€5,000**
Renewal of a Simplified Authorisation Procedure (product family) – rMS	€10,000**
Comparative Assessment	€2,000
Endocrine assessment	€2,000
<u>Changes to Authorised Products</u>	
Administrative changes	€300
Transfer of product authorisation	€300
Minor change	€1,500
Major change (National Authorisation – single product) – rMS	€5,000
Major change (National Authorisation – product family) – rMS	€10,000
Major change (Simplified Authorisation Procedure – single product) - rMS	€2,500
Major change (Simplified Authorisation Procedure – product family) - rMS	€5,000
Major change (National Authorisation – product and family) - cMS	€2,000
Major change (Simplified Authorisation Procedure – product and family) - cMS	€1,000
<u>Permits for Trials</u>	
Parallel trade permit	€500
Amendment to parallel trade permit	€300
Notification of experiment or test - trial permit (‘once off’ experiment)	€300
Change to a trial permit (‘once off’ experiment)	€100
Notification of experiment or test - trials permit (experimental/trial programme)	€2,000
Change to a trial permit (experimental/trial programme)	€300
Renewal of trials permit (experimental/trial programme)	€300
Emergency use permit	€1,000
Renewal of an emergency use permit	€300
<u>Annual Registration Fees</u>	
ARF (professional product)	€225*
ARF (non-professional product)	€125*
Re-instating product on the Register/Late ARF (professional product)	€425*
Re-instating a product on the Register/Late ARF (non-professional product)	€225*

Certificate of Inclusion on the Register (Certificate of Free Sale)	€150
<u>Fees for work on behalf of the European Union (Biocidal Active Substances)¹</u>	
Description	Fee
<u>Active substance evaluation (includes micro-organisms/biologicals)</u>	
Pre-submission consultations/meetings****	€1,000
Dossier receipt, registry and validation check	€4,000
Project co-ordination of the evaluation and CAR	€10,000
Examination/peer review of physical and chemical properties and analytical methods	€30,000
Examination/peer review of residues profile	€30,000
Examination/peer review of efficacy profile	€10,000
Examination/peer review of toxicology profile	€65,000
Examination/peer review of environmental fate and behaviour	€85,000
Examination/peer review of ecotoxicology profile	€70,000
Endocrine assessment	€10,000
Total (single dossier – active substance + one product-type)	€315,000
Additional product-type	€80,000
<u>Article 28 active substance evaluation (Amendment of Annex I)</u>	
Pre-submission consultations/meetings	€2,000
Dossier receipt, registry and validation check	
Project co-ordination of the evaluation and CAR	€6,000
Examination/peer review of physical and chemical properties and analytical methods	€7,000
Examination/peer review of residues profile	€6,000
Examination/peer review of efficacy profile	€7,000
Examination/peer review of toxicology profile	€7,000
Examination/peer review of environmental fate and behaviour	€8,000
Examination/peer review of ecotoxicology profile	€7,000
Endocrine assessment	€5,000
Total (single dossier – active substance + one representative product)	€55,000
<u>Other Fees relating to substance evaluations</u>	
Co-Rapporteur/eCA fee (for evaluation or peer review)	€50,000
Post-approval submission of confirmatory information/data	€10,000
Renewal of a substance approval – (Single Dossier + one product type)	€185,000 **
Additional product-type	€47,000 **
<u>Product evaluation for Union Authorisation (where Ireland is the evaluating Competent Authority (eCA))</u>	
Union Authorisation (single product)	€75,000
Union Authorisation (Biocidal product family)	€150,000
Additional product-type (In addition to the cost of Union authorisation)	€20,000
Major change (Union authorisation – single product) – rMS	€40,000
Major change (Union authorisation – product family) – rMS	€75,000
Renewal of a Union Authorisation (single product)	€75,000 **
Renewal of a Union Authorisation (product family)	€150,000 **
Union Authorisation (the same biocidal product – authorised & pending)	€300

¹A reduced fee may be applied, where appropriate.

* €25 will be transferred to the Poisons Information Centre to cover the cost of maintaining the Poisons database

** The final fee will be determined based on the proportion of expert evaluation required

*** Fee will be payable for mutual recognition and renewal of mutual recognition product authorisations

**** Fee must be paid before the pre-submission meeting/consultation. Fee will be deductible from total the fee for evaluation.

Notification of an additional product that falls under an authorised biocidal product family

‡ Notification of a product authorised under simplified procedures in another Member State

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