

## 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 1<sup>st</sup> September 2021

### Fees relating to Biocidal Products<sup>1</sup>

Description	Fee
<b><u>Notification</u></b>	
National Notification of a biocidal product	€300
Trivial amendment	€300
Notification under the BPR (Article 17.6 <sup>#</sup> and Article 27 <sup>*</sup> )	€300
<b><u>Biocidal Product Authorisation</u></b>	
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
<b><u>Changes to Authorised Products</u></b>	
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
<b><u>Permits for Trials</u></b>	
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
<b><u>Annual Registration Fees</u></b>	
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

## Fees for work on behalf of the European Union (Biocidal Active Substances)<sup>1</sup>

Description	Fee
<b><u>Active substance evaluation (includes micro-organisms/biologicals)</u></b>	
Pre-submission consultations/meetings Dossier receipt, registry and validation check	€5,000
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
<b>Total (single dossier – active substance + one product-type)</b>	<b>€315,000</b>
<b>Additional product-type</b>	<b>€80,000</b>
<b><u>Article 28 active substance evaluation (Amendment of Annex I)</u></b>	
Pre-submission consultations/meetings Dossier receipt, registry and validation check	€2,000
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
<b>Total (single dossier – active substance + one representative product)</b>	<b>€55,000</b>
<b><u>Other Fees relating to substance evaluations</u></b>	
Co-Rapporteur/eCA fee (for evaluation or peer review)	<b>€50,000</b>
Post-approval submission of confirmatory information/data	<b>€10,000</b>
Renewal of a substance approval	<b>€185,000 **</b>
<b><u>Product evaluation for Union Authorisation (where Ireland is the evaluating Competent Authority (eCA))</u></b>	
Union Authorisation (single product)	<b>€75,000</b>
Union Authorisation (Biocidal product family)	<b>€150,000</b>
Additional product-type (In addition to the cost of Union authorisation)	<b>€20,000</b>
Major change (Union authorisation – single product) – rMS	<b>€40,000</b>
Major change (Union authorisation – product family) – rMS	<b>€75,000</b>
Renewal of a Union Authorisation (single product)	<b>€75,000 **</b>
Renewal of a Union Authorisation (product family)	<b>€150,000 **</b>
Union Authorisation (the same biocidal product – authorised & pending)	<b>€300</b>

<sup>1</sup>A 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

# 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