Ctgb Tariffs Decree 2018

The Board for the Authorisation of Plant Protection Products and Biocidal Products,

- Having regard to Article 74 of Regulation (EC) 1107/2009, Section 10(1) of the *Wet Gewasbeschermingsmiddelen en biociden* (Plant Protection Products and Biocidal Products Act), as well as Section 17 of the *Kaderwet zelfstandige bestuursorganen* (Independent Administrative Bodies Framework Act);
- Whereas the transitional provisions in Regulation (EC) 1107/2009 require that fees and charges continue to apply to applications for the authorisation of plant protection products that must be processed in accordance with to the provisions in the now expired Directive (EEC) 91/414 and its implementation in the *Wet gewasbeschermingsmiddelen en biociden* (Plant Protection Products and Biocidal Products Act), as in force before 14 June 2011;
- Having regard to Article 80 of Regulation (EU) 528/2012, Article 10(1) of the *Wet Gewasbeschermingsmiddelen en biociden* (Plant Protection Products and Biocidal Products Act), and Article 17 of the *Kaderwet zelfstandige bestuursorganen* (Independent Administrative Bodies Framework Act);
- Whereas the implementation of Regulation (EU) No 528/2012 resulted in additional arrangements regarding the tariffs (fees and charges), invoicing and payment for the services and activities that the Ctgb provides under the Regulation;
- Whereas the transitional provisions in Regulation (EU) 528/2012 also require that fees and charges continue to apply to applications for the authorisation biocidal products that must be processed in accordance with the provisions in the now expired Directive (EC) 1998/98 or on the basis of the *Wet gewasbeschermingsmiddelen en biociden* (Plant Protection Products and Biocidal Products Act) as in force before the amendment to this Act to implement the Biocidal Products Regulation went into effect on 6 November 2013;

Decree to establish the tariffs for the performance of its statutory tasks and other services, as described in this decree:

Chapter 1 – Definitions

a. Plant Protection Products Regulation: Regulation (EC) No 1107/2009 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
b. Plant Protection Products Directive: Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market
c. Biocidal Products Regulation: Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012
d. Biocidal Products Directive: Directive 98/8/EC of the European Parliament and the Council of 16 February 1998 concerning the placing of biocidal products on the market
e. the Act: Plant Protection Products and Biocidal Products Act (Wgb)
f. the Regulation: Regulations on plant protection products and biocidal products (Rgb)
g. the Board: the Board for the Authorisation of Plant Protection Products and Biocidal Products (Ctgb) as referred to in Section 3 of the Act
h. Our Minister: the Minister referred to in Section 1 of the Act
i. new active substance:
    i. (plant protection products)
        1. an active substance as referred to in Article 30 of the Plant Protection Products Regulation, or
        2. an active substance which according to Implementing Regulation (EU) No 540/2011 was not approved and was not on the market on 15 July 1993 and was therefore not made equivalent pursuant to a community measure
    ii. (biocidal) active substance as referred to in Article 3(1)(e) of the Biocidal Products Regulation
j. zonal applications: applications for amendment/authorisation of plant protection products whereby these applications are processed in accordance with the (inter)zonal assessment method described in Article 33 of the Plant Protection Products Regulation
k. European applications: applications for the approval or amendment of the approval of an active substance, as referred to in Article 7 of the Plant Protection Products Regulation.

Chapter 2 – Other provisions

1. Requests for public disclosure
Regarding requests for public disclosure, the Ctgb applies the provisions in the *Besluit tarieven openbaarheid van bestuur* (Decree on open government fees and charges) accordingly.

2. Transitional regime
Applications that were pending on the date this Decree entered into force are processed from that date in accordance with the provisions in this Decree.

3. Withdrawal of previous Tariffs Decrees
The Ctgb Tariffs Decree 2017 is withdrawn.

4. Entry into force
This Decree shall take effect, retroactively to the extent necessary, on 1 January 2018, following approval by Our Minister and publication in the *Staatscourant*.

5. Official title
The official title of this Decree is "***Tarievenbesluit Ctgb 2018***" (Ctgb Tariffs Decree 2018).

Adopted by the Board for the Authorisation of Plant Protection Products and Biocidal Products
on 27 September 2017

The Board for the Authorisation of Plant Protection Products and Biocidal Products,
p.p.
the Chair,

J.F. de Leeuw

Chapter 3 – Notes to the Ctgb Tariffs Decree

General

Section 10(1) of the Plant Protection Products and Biocidal Products Act (hereinafter: the Act) stipulates that the costs incurred by the Ctgb during the implementation of activities for which it is responsible by virtue of Section 4 of the Act must be covered by the tariffs charged, which are to be set by the Board. The tariffs are related directly to the costs incurred by the Ctgb and require the approval of the Minister of Agriculture, Nature and Food Quality (LNV) and the Minister of Infrastructure and Water Management (I&W).

The tariffs are established by this Decree and relate mainly to the following:

- Applications for authorisation or related to authorisations (such as applications for amendment or extension of the authorisation, application for approval of an active substance in a plant protection product or for inclusion of an active substance in a biocidal product in Annex I or Ia of Directive 38/8/(EC))
- Annual fees, which are charged to authorisation holders by the Ctgb, are based on the provisions in Section 10(1) of the Act
- Requests for public disclosure by reference to the Tariffs Decree, Public Information Act (*Besluit tarieven openbaarheid van bestuur*).
- Service Desk requests
- Exemption as referred to in Article 53 of Regulation (EC) No 1107/2009
- Regulation on the Exception of Plant Protection Products (*Regeling uitzondering bestrijdingsmiddelen,* RUB)
- Other activities

For evaluation of data summaries and studies for plant protection products and biocidal products, the actual costs incurred are charged, which are invoiced in advance. Excluded are zonal applications (NL ZRMS), applications for extending the scope in the Netherlands (non-zonal) of an existing authorisation with minor uses only, BPR applications and European applications, for which the actual costs incurred will be charged based on advance payment and subsequent costing.

If the Board decides to ask additional questions, the corresponding costs for evaluating data summaries and the assessment costs are charged.

In the context of certain types of applications, such as (for plant protection products) the authorisation of an adjuvant or a parallel trade permit, a substantive scientific assessment may be required. In those cases, it is therefore possible that – in addition to the application fee – the costs of the assessment will also be charged.

Additional and/or other activities for which no fees have been set will be charged at cost. This takes place following consultation with the applicant.

For the registration of an authorised plant protection product and biocidal product, an annual fee is charged. The reference date for this is 1 February. If the applicant does not pay the annual fee in full before this date, the applicant is legally in default within the meaning of Article 6:81 of the Netherlands Civil Code and the authorisation can be withdrawn.

Definitions

DTG list
The so-called DTG list defines the scope of permitted use, as included in the Evaluation Manual (available on the website of the Ctgb) under the aspect of efficacy.

“technical grade active substance”
“Technical grade active substance” is defined as the active substance with the corresponding technical specifications and provisions as listed in Regulation (EC) 1107/2009 (for plant protection products) and in the Annex to Regulation (EU) 545/2011, or (for biocidal products) the Union list of Approved Active Substances with Regulation (EU) 528/2012 for the active substance. In more general terms, “active substance” refers to the pure active substance.

Subsequent costing
For various applications the costs are calculated based on subsequent costing of the actual costs incurred; if this is the case, this is expressly stated next to the corresponding application.

Actual costs incurred
Actual costs incurred are the internal costs incurred by the Ctgb (the established hourly rate, multiplied by the number of hours

spent by the Ctgb) and the actual costs of third parties hired by the Ctgb as part of processing the application (including the VAT paid to such third parties). More information on the procedure and cooperation partners can be found at www.ctgb.nl.

Invoicing, payment and subsequent costing/refund
a. The fee payable to the Ctgb is charged on the basis of the specified items and tariffs.

b. Based on the provisions in the Decree on rules of procedure on regulations to authorise plant protection products and biocidal products Ctgb 2007, application costs must be paid when the application is submitted to the Ctgb. An invoice will be issued for this purpose. The Ctgb also accepts – in anticipation of a possible amendment to this point in the Decree on rules of procedure on regulations to authorise plant protection products and biocidal products Ctgb 2007 – that the applicant pays in response to the invoice issued by the Ctgb.

c. If an advance payment has been made for the actual costs incurred, this payment is subtracted from the amount owed. If the actual costs incurred are less than the advance payment, the difference is refunded to the applicant within 30 days after date of the final invoice.

d. Notwithstanding the provisions in Article 4:87.1 Awb, for fees or charges other than those referred to under b), the applicant must pay the invoice within 30 days after date of the invoice, stating the invoice number.

Adjustment of the advance payment
Preceding the submission of an application, the prospective applicant can request the Ctgb to make an estimate of the actual costs of that application and adjust the advance payment accordingly; this estimate is based on information provided by the prospective applicant. The amount of the advance payment can be changed if justified by the estimated hours.

Timely payment
Insofar as the provisions of Article 4:97 Awb apply, this shall not affect the administrative consequences of non-payment or late payment, which are included in the prevailing Decree rules of procedure on regulations to authorise plant protection products and biocidal products. Timely payment means that the payment is received by the Ctgb before the payment deadline on the invoice or if it is shown that the amount to be paid has been transferred or deposited to the Ctgb before this deadline.

Payment in instalments
Up to two weeks after the invoice date, the applicant may request the Board for permission to pay the costs of the procedure at the Ctgb in instalments.

- This request will be granted if the costs of the procedure are more than €5,000.
- If the costs for the procedure are no more than €30,000, this amount may be paid in up to three monthly instalments of one-third of the total sum.
- If the costs for the procedure are more than €30,000, this amount may be paid in up to four monthly instalments of one-fourth of the total sum.

The first instalment must be paid within 30 days after the date of the original invoice.
If payment is made in instalments, following timely payment of the first instalment, the Board formally accepts the application and notifies the applicant of the date of this acceptance.

Direct debit payments
Invoices can be paid automatically by direct debit. You can find more information about this at www.ctgb.nl.

Interim amendment of the Tariffs Decree
The Tariffs Decree may be temporarily amended if necessary.

In addition to, and partly in deviation from the above, the following provisions apply to the activities conducted by the Ctgb to implement the Biocidal Products Regulation.

Basic assumptions and premises
The Biocidal Products Regulation requires Member States to take a number of matters into account:

- the partial reimbursement of the fee if the applicant fails to submit the requested information within the deadline (Article 80(3)(b));
- where appropriate, the specific needs of SMEs, including the possibility of splitting payments into several instalments and phases (Article 80(3)(c));
- in the structure and amount of the fees, the circumstance of whether the information is submitted jointly or separately (Article 80(3)(d));
- in duly justified cases, provided that the agency or the competent authority agrees, all or part of the fee may be waived (Article 80(3)(e)).

Communication
From the time an application is submitted, all correspondence on costs and payment is done by placing the notice in the Register for Biocidal Products (R4BP3) and possibly notifying the applicant of this placement by e-mail.

Invoicing, payment and subsequent costing/refund (biocidal products)

- After receiving the application, the Ctgb calculates the fee that is payable on the basis of the specified items and tariffs. The invoice is sent as soon as possible following receipt of the application.
- The Biocidal Products Regulation provides that the costs of an application procedure must be paid within 30 days after the invoice date. Additional time for payment cannot be provided.
- If payment is late, the application is rejected.
- If the invoiced amount concerns an advance payment, the actual costs incurred are charged after the completion of the procedure by means of subsequent costing. If the actual costs incurred are less than the advance payment, the difference is refunded to the applicant within four weeks after date of the final invoice.
- If the applicant does not pay in full before this date, the applicant is legally in default within the meaning of Article 6:81 of the Netherlands Civil Code.

Separate tariffs
Since it is anticipated that the approval of the existing and identified active substances will continue until after 2024, all authorised biocidal products in the Netherlands are expected to fall under the regime of the Biocidal Products Regulation in 2027. Until then, tariffs for biocidal products will continue to exist for procedures under national law or under Directive 98/8/EC, in addition to the tariffs for products and procedures covered by the Regulation.

Reduced tariff for clustered applications
If multiple applications are submitted simultaneously, for which a cluster assessment can be made on one or more aspects of multiple applications, at the request of the applicant the Ctgb can charge a reduced tariff for these aspects.
If there are multiple applicants, each applicant is jointly and severally liable for paying the entire amount to the Ctgb. The Ctgb does not become involved with the mutual payment arrangements between applicants.

Application for biocidal product families
Under Regulation (EU) No 528/2012 it is possible to apply for authorisation for multiple products simultaneously. For applications for w the Ctgb acts as an evaluating Member State, an advance payment is charged depending on the number of family members. For mutu recognition of an authorisation of a biocidal product family by another Member State, fixed application costs are charged with an add the fact that this concerns a family with a certain number of family members.

Frame formulation
The applicant for an authorisation of a biocidal product can request the Ctgb to ascertain that the corresponding biocidal product qualifies as a frame formulation. The frame formulation offers the authorisation holder the possibility of obtaining a very similar authorisation (for example in different colours) more easily and at lower cost. The determination of the frame formulation results in additional application costs, which are added to the standard application costs.

Entry into force of Regulation (EU) No 528/2012
On 1 September 2013, Regulation (EU) No 528/2012 entered into force. This Regulation applies to all biocidal products and active substances in biocidal products (and applications for such products and substances) which, according to transitional legislation, do not fall under the operation of national law or Directive 98/8/EC. The Regulation contains rules about the amounts Member States may charge for the services they provide related to the procedures in the Regulation.

Miscellaneous
Under the Regulation, all communication between the applicant and the Ctgb shall take place digitally. Moreover, the Regulation introduces new types of applications and new types of authorisations, new obligations with respect to amounts charged, invoicing and payment, and the possibility of charging a modified tariff. Member States that conduct the assessments must still cover their costs; this premise has remained unchanged.

Chapter 4 – Amendments to the Tariffs Decree 2018

Hourly rate 2018	€132 per hour
Service Desk: Short RFM (request for meeting)	It will be possible for applicants to request a short RFM after the biocidal products workshops. The short RFM is an opportunity to discuss the implications of the workshop subject for their own product or product application. The short RFM is offered in units of thirty minutes per aspect, with two Ctgb employees always present. Applicants may submit related questions in advance.
Annual fee (plant protection products)	The tariff for the annual fee includes a surcharge for the advisory activities for the EU plant protection substance assessment. These costs must be paid in full by the authorisation holder from 2018 onwards. As a result, the tariff has been increased by 10.7%.
Annual fee (biocidal products)	The tariff for the annual fee for biocidal products is virtually unchanged compared with the 2017 tariff. For a "biocidal product family", a separate annual fee is charged; in addition, a limited fee is charged for each "family member". The total fee for a biocidal product family including the family members is subject to a maximum of €4,900. The fees will not increase relative to 2017.
Assessment costs (general) for plant protection products and biocidal products	A comprehensive analysis of standard hours was carried out in 2017, leading to the fees for 2018. The fixed assessment fees have therefore been revised.
"Project management" fee for plant protection products and biocidal products	The fee for "project management" is new. In the assessment costs, a distinction has been made between aspect-based activities and project management activities. Conversely, the fee for the final assessment has been reduced.
Fee for final assessment of plant protection products and biocidal products	The fee for the final assessment has been reduced to €1,320.
Assessment costs for applications for mutual recognition and national addendum (plant protection products)	Based on the analysis of standard hours, from 2018 onwards a distinction will be made between the fees for the assessment of applications for mutual recognition and the assessment of applications for national addendum (cMS). These assessment fees have been revised and adjusted.
Additional fees and charges (plant protection products)	Activities relating to Application of the Guidance Document on aquatic organisms, birds and mammals are included in the standard assessment fees. The additional fees for this are being dropped.
Active substance applications (plant protection products)	The advance fee for the assessment of a substance based on a micro-organism has been increased. The advance fee for the final phase (peer review) has been reduced.
Minor Uses (plant protection)	The advance fee has been reduced to €6,000.
ZTG-LR and ZWTG-LR (plant protection)	There are new application codes for zonal applications of low-risk products. Article 47 applies to these applications.
Application to amend current authorisation NL = CMS NLWTG (plant protection)	The application fee for the NLWTG has been reduced to €4,488.
Notifications under the Regulation on the Exception of Plant Protection Products RUBMLD	The fee for notifications under the Regulation on the Exception of Plant Protection Products (RUBMLD) is new: €660.
Fee for applications for biocidal products requiring assessment	The fixed rates for resource applications which need to be assessed will in 2018 will be replaced by; subsequent costing based on the actual costs whereby an advance fee will now be charged instead of the fixed application costs.
Fee for mutual recognition B-TWER (biocidal products)	The fee for an extension by way of mutual recognition of biocidal products (without a family) is new. This is an all-in-one fee.
Fee for summarising and evaluating studies regarding product data (biocidal products)	A fixed fee is no longer charged for the aspect of efficacy; instead, the actual costs are invoiced on the basis of the estimated hours.

Chapter 5 – Fees and charges, Service Desk

Requests	Description	Tariff 2018
Category		
1	Up to 4 hours	No fee charged
2	4 hours and more	Actual costs on the basis of subsequent costing
3	Request for meeting (RFM)	Actual costs on the basis of subsequent costing
4	Short RFM	0.5 hours preparation + hours on the basis of subsequent costing
5	Pre-submission meeting (PSM)	Actual costs incurred on the basis of subsequent costing, with an advance payment of €10,000
6	Pre-application support process for applications B-TFN, B-UTN and B-UTFN	Actual costs incurred on the basis of subsequent costing, with an advance payment of €5,000
7	Briefing/informational meeting (general)	€195
8	Workshop	For the record only

Chapter 6 – Fees and charges, plant protection products

For evaluation of data summaries and studies for plant protection products and biocidal products, the actual costs incurred are charged, which are invoiced in advance. Excluded are zonal applications (NL ZRMS), applications for extending the scope in the Netherlands (non-zonal) of an existing authorisation with minor uses only, BPR applications and European applications, for which the actual costs incurred will be charged based on advance payment and subsequent costing.

If the Board decides to ask additional questions, the corresponding costs for evaluating data summaries and the assessment costs are charged.

In the context of certain types of applications, such as (for plant protection products) the authorisation of an adjuvant or a parallel trade permit, a substantive scientific assessment may be required. In those cases, it is therefore possible that – in addition to the application fee – the costs of the assessment will also be charged.

Additional and/or other activities for which no fees have been set will be charged at cost. This takes place following consultation with the applicant.

Fees and charges, applications for approval of active substances, plant protection products

Type of application	**Description**	**Tariff 2018**
TGEURAP, TGEURAPR	**Ctgb rapporteur for application for initial approval or renewal of an active substance, *excluding an active substance based on micro-organisms or pheromones***	
	Application costs	€12,500
	Summary and assessment (prepare DAR or RAR)	Actual costs incurred with advance payment of €150,000 *
	Activities related to the completion of an approval or renewal of an application for an active substance (Peer review; European decision-making)	Actual costs incurred with advance payment of €75,000 *
TGEURAPM, TGEURPRM	**Ctgb rapporteur for application for initial approval or renewal of an active substance based on micro-organisms, pheromones or a comparable active substance**	
	Application costs	€12,500
	Summary and assessment (prepare DAR or RAR)	Actual costs incurred with advance payment of €50,000 *
	Activities related to the completion of an approval or renewal of an application for an active substance (Peer review; European decision-making)	Actual costs incurred with advance payment of €30,000 *
TGEUCORA	**Ctgb Co-rapporteur substance dossier**	
	Fee for reviewing and commenting on substance assessment RMS	Actual costs incurred with advance payment of €20,000 *
	Summary and assessment (prepare DAR or RAR) *(only if parts of the DAR/RAR must be prepared in consultation with the RMS)*	Actual costs incurred with advance payment of €50,000 *

	Co-rapporteur activities to complete an approval or a renewal of the application for an active substance (peer review and European decision-making) *(only if parts of the DAR/RAR must be prepared in consultation with the RMS)*	Actual costs incurred with advance payment of €25,000*
TGEURPCD	**Ctgb rapporteur for the assessment of confirmatory data**	
	Assessment of confirmatory data	Actual costs incurred with advance payment of €15,000 *

* This advance payment can be changed if justified by the estimated hours. If the advance payment is found to be insufficient, the additional amount will be invoiced. This advance payment is based on an average dossier.

Fees and charges for plant protection applications, product applications

Product applications based on subsequent costing

Type of application	**Description**	**Tariff 2018**
Zonal applications for which the Ctgb is rapporteur (the Netherlands is zonal rapporteur Member State). • New application (ZTG, ZTG-LR) • Application to amend current authorisation (ZWTG, ZWTG-LR) • Renewal (ZRG) • Voluntary zonal renewal (ZTHG)	*Processing and assessment (advance payment type 1)* Regular zonal applications	Actual costs incurred with advance payment of €50,000 *
	Processing and assessment (advance payment type 2) Zonal applications based on a micro-organism, pheromone or plant extract (low risk). Zonal applications to amend current authorisation based on a recent dRR.	Actual costs incurred with advance payment of €30,000 *
	Application costs ZRG applications (renewal of a product authorisation with the Netherlands as zRMS), for which postponement has been granted for submitting the dRR. *This amount will be deducted from advance payment type 1 and 2 after submitting the DRR.*	€10,000
NLKUG,	Application to extend an existing authorisation in the Netherlands (not zonally) with **Minor Uses** only	Actual costs incurred with advance payment of €6,000 *
* This advance payment can be changed if justified by the estimated hours. If the advance payment is found to be insufficient, the additional amount will be invoiced. This advance payment is based on an average dossier.		

Application fees for product applications based on fixed tariffs

Application and assessment fees are charged for these applications.

Type of application	**Description**	**Application fee**
NLTG, NLRG, NLTHG,	**CMS application** Zonal applications for which the Ctgb is not	€9,108

	rapporteur (the Netherlands is CMS) • New application (NLTG) • Renewal (NLRG) • Voluntary zonal renewal (NLTHG)	
NLWTG	**Application to amend current authorisation NL = CMS**	€6,336
NLWERGZ, NLWERG	**Mutual recognition** Mutual recognition can be based on a zonal dossier (NLWERGZ) or on an authorisation under Directive 91/414/EEC (NLWERG) from another Member State	€4,488
THG	**Renewal,** non-zonal (Article 80 Regulation (EC) No 1107/2009) *This application type expires in 2018*	*€4,992*
NLWG	**Application to amend current authorisation** National request for amendment (national addendum) of an authorisation	€2,640

Assessment fees for product applications based on fixed tariffs

The assessment fees for the types of applications set out below are based on applications with one active substance, with up to 5 uses (GAP regulations) and one dRR zone.
Additional costs will be charged in certain cases, e.g. if a product contains multiple active substances, if there are more than five uses, if there is more than one dRR, or if other additional activities have to be carried out.

For the purpose of applications for mutual recognition and applications whereby only the national addendum is assessed

NLTG, NLRG, NLTHG,

Aspect	**Assessment fee 2018**
Efficacy	€1,056
Physicochemical properties of the product, each active substance present in the product, respectively	€132
Criteria with respect to public health	€396
Criteria with respect to the operator	€792
Environmental behaviour and environmental fate	€1,716
Ecotoxicology	€2,112
Project support	€2,904
Final assessment of the authorisation aspects	€1,320

NLWERG, NLWERGZ,

Aspect	**Assessment fee 2018**
Efficacy	€660
Physicochemical properties of the product, each active substance present in the product, respectively	€396
Criteria with respect to public health	-
Criteria with respect to the operator	€396
Environmental behaviour and environmental fate	€2,508

Ecotoxicology	€2,112
Project support	€2,508
Final assessment of the authorisation aspects	€1,320

NLWTG, NLWG

Aspect	**Assessment fee 2018**
Efficacy	€660
Physicochemical properties of the product, each active substance present in the product, respectively	€132
Criteria with respect to public health	€396
Criteria with respect to the operator	€396
Environmental behaviour and environmental fate	€792
Ecotoxicology	€1,056
Project support	€2,112
Final assessment of the authorisation aspects	€1,320

For the purpose of applications for mutual recognition and national addendum for products based on micro-organisms or pheromones or comparable active substances (including low-risk products)

NLTG, NLWTG, NLRG, NLTHG, NLWERG, NLWERGZ, NLWG

Aspect	**Assessment fee 2018**
Efficacy	€1,584
Physicochemical properties of the product, each active substance present in the product, respectively	€132
Criteria with respect to public health and the operator	€528
Environmental behaviour, environmental fate and ecotoxicology	€1,320
Project support	€1,848
Final assessment of the authorisation aspects	€1,320

Fees and charges for assessments, general

THG, WYG, PWSG, MRL, MTR, IKV and other applications

Aspect	**Assessment fee 2018**
Efficacy	€1,188
Physicochemical properties of the product, each active substance present in the product, respectively	€1,056
Criteria with respect to public health	€2,112
Criteria with respect to the operator	€1,848
Environmental behaviour and environmental fate	€2,376
Ecotoxicology	€4,620
Project support	€2,508

Final assessment ofthe authorisation aspects	€1,320

Additional fees and charges for activities not covered by the standard tariff

Activities	**Tariff 2018**
Each additional active substance	€1,980
1 to 5 additional uses	€924
Tankmix	€1,980
Additional dRR	€9,240
Evaluation of summaries and studies concerning physicochemical properties, analytical methods, efficacy, human toxicology and environmental fate and ecotoxicology	Actual costs incurred
Application of Guidance Document DEGT50 (EFSA, 2014)	€264
Application of FOCUS Guidance Document Groundwater (EFSA, 2014)	€2,112
Application of Guidance Document on honeybees and other pollinators	€3,696
Application of Guidance Document on protected cultivation	€528
B10 (non-relevance metabolites) – per metabolite	€924
Comparative Assessment in accordance with Article 50 Regulation (EC) 1107/2009 CA 1: Intake Agronomic assessment CA 2: Risk assessment	 €766 Per number of uses €766 Actual costs incurred

Fees and charges for other plant protection applications without additional assessment costs

Type of application	**Description**	**Tariff 2018**
Administrative amendment		
WNT, WNAW, OT	Amendment of name authorised product, Amendment of name, address and/or city of the authorisation holder Transfer of authorised product to a different company	€264
INTR	Withdrawal of an authorisation of a plant protection product	No fee charged
Minor changes		
WSGNW	Minor change in the formulation	€858
Add or change product manufacturer, change production location	Change product production process (transitional legislation)	No fee charged
NLWATG	Minor amendment of WG-GA/WG including restricting scope of permitted use. (for which GAP is not changed and no risk assessment is required)	€264
Other types of authorisations		

AG, VAG, UAG, NLWERGV	**Derived applications** New derived authorisation Renewal of derived authorisation Extension of derived authorisation Administrative renewal of an authorisation obtained by mutual recognition	€858
PAG, VPAG, UPAG,	**Parallel trade applications** Parallel trade permit Renewal of parallel trade permit Extension of parallel trade permit	€858
PGN	**Exemption for trial purposes** Exemption to use a plant protection product for trial purposes where the treated crops do **not** enter the food chain	€264
PGR	**Exemption for trial purposes** Exemption to use a plant protection product for trial purposes, where the treated crops enter the food chain, base amount	€330
PGR	**Exemption for trial purposes** Supplement for use on 5 crops uses the applicant wants to enter the food chain (regulations in the table)	€132
VIG	Request for **information on animal testing**	€528
	Mediating the exchange of animal testing data	Actual costs incurred
TT	Application for adjuvant	€858
TT-W	Application for modification of adjuvants	€264
EXV	Export declaration	€264
WGF, WGI	**Conversion of WGGA to WG or update WG**	
	Authorisation holder provides WG and meets the conditions	€858
	Authorisation holder does not provide WG or WG does not meet conditions for up to 5 uses	€1,320
	Supplement for each group of 5 uses if authorisation holder does not supply WG or WG does not meet conditions	€264
	Conversion of WGGA to, or an update of, WG for parallel trade permits or amended authorisations	€396
RUBMLD	Notifications under the Regulation on the Exception of Plant Protection Products	€660
	Exemption as referred to in Article 53 of Regulation (EC) No 1107/2009:	
	Activities up to 30 hours; fee:	€3,960
	Activities 30-45 hours; fee:	€5,940
	Activities 45-60 hours; fee:	€7,920
	Activities 60-75 hours; fee:	€9,900

Fees and charges for other plant protection product applications for which additional assessment costs can be charged

Type of application	**Description**	**Tariff 2018**
WYG	Changes to packaging, shelf life or labelling	€396
PWSG	Change in production process of active substance and/or additional production location of the active substance. Equivalence through Tier I not yet assessed in another Member State	€1,320
PWSGC	Change in production process of active substance and/or additional production location of the active substance. Equivalence is assessed by another Member State and published on CircaBC	€264
MRL	Derivation of Maximum Residue Limit (MRL)	€858

MTR	Applications to derive norm as part of the Water Framework Directive	€858
Notification obligation		
IKV	Regulation (EC) No 1107/2009, Article 56(4) (administrative)	€264

Fees and charges for summaries and studies to be evaluated regarding product data

Type of application	**Description**	**Tariff 2018**
All applications	Evaluation of summaries and studies concerning physicochemical properties, analytical methods, efficacy, human toxicology and environmental fate and ecotoxicology	actual costs incurred

Annual fee for plant protection product

	Annual fee	**Tariff 2018**
AF	Annual fee for plant protection product	€1,571

For the registration of an authorised plant protection product and biocidal product, an annual fee is charged. The reference date for this is 1 February. If the applicant does not pay the annual fee in full before this date, the applicant is legally in default within the meaning of Article 6:81 of the Netherlands Civil Code and the authorisation can be withdrawn.

Chapter 7 – Fees and charges, Biocidal Products

For evaluation of data summaries and studies for plant protection products and biocidal products, the actual costs incurred are charged, which are invoiced in advance. Excluded are zonal applications (NL ZRMS), applications for extending the scope in the Netherlands (non-zonal) of an existing authorisation with minor uses only, BPR applications and European applications, for which the actual costs incurred will be charged based on advance payment and subsequent costing.

If the Board decides to ask additional questions, the corresponding costs for evaluating data summaries and the assessment costs are charged.

In the context of certain types of applications, such as (for plant protection products) the authorisation of an adjuvant or a parallel trade permit, a substantive scientific assessment may be required. In those cases, it is therefore possible that – in addition to the application fee – the costs of the assessment will also be charged.

Additional and/or other activities for which no fees have been set will be charged at cost. This takes place following consultation with the applicant.

Fees and charges for applications for biocidal products and other activities under Regulation (EU) 528/2012

Type of application	Application type R4BP 3	Description	Tariff 2018
		Applications for which a complete assessment is required	
B-UTN, B-UTH	UA-APP	Union Authorisation for a biocidal product where the Netherlands is the evaluating competent authority (new product or re-registration)	Actual costs incurred with advance payment of €35,000 *
B-UTFN, B-UTFH	UA-APP	Union Authorisation for a biocidal product family where the Netherlands is the evaluating competent authority (new product or re-registration)	Actual costs incurred with advance payment of €45,000 *
B-TN, B-TH	NA-APP	National authorisation of biocidal product (new product or re-registration)	Actual costs incurred with advance payment of €35,000 *
B-TFN, B-TFH	NA-APP	National authorisation of biocidal product family (new product or re-registration)	Actual costs incurred with advance payment of €45,000 *
B-TPR,		Provisional authorisation (biocidal product)	Actual costs incurred with advance payment of €35,000 *
B-TPRF		Provisional authorisation (family)	Actual costs incurred with advance payment of €45,000 *
B-TR,	NA-RNL	Renewing an authorisation (biocidal product)	Actual costs

			incurred with advance payment of €35,000 *
B-TRF	NA-RNL	Renewing an authorisation (family)	Actual costs incurred with advance payment of €45,000 *
B-GW,	NA-AAT, NA-MAC	Major change of an authorisation (biocidal product) for which the Netherlands is the evaluating competent authority	Actual costs incurred with advance payment of €35,000 *
B-GWF	NA-AAT, NA-MAC	Major change of an authorisation (family) for which the Netherlands is the evaluating competent authority	Actual costs incurred with advance payment of €45,000 *
		Union authorisation: attendance of BPC meeting by project leader	€3,168

* This advance payment can be changed if justified by the estimated hours. If the advance payment is found to be insufficient, the additional amount will be invoiced. This advance payment is based on an "average" dossier without comparative assessment, extra user category, PT or multiple active substances.

		Applications for mutual recognition (NL is concerned Member State)	
B-TWENP B-TWEHP	NA-MRP	Tariff for mutual recognition (in parallel) of a single product (not a family)	€7,392
B-TWENS B-TWEHS	NA-MRS	Tariff for mutual recognition (in sequence) of a single product (not a family)	€7,392
B-TWER		Fee for an extension by way of mutual recognition (without a family)	€7,392
B-GWC, B-GWFC	NA-AAT NA-MAC	Tariff for major amendment of an authorisation (biocidal product or family) for which the Netherlands is the Member State concerned.	€7,392
		The standard tariff for mutual recognition of a family has the same basis as an application for mutual recognition of a regular authorisation.	
		Additional fees and charges for activities not covered by the standard tariff:	
		Comparative assessment	€1,320
		Family (per family member)	€924
		Extra user category	€924
		Extra PT	€924
		Extra active substance	€924
When submitting an application for mutual recognition in parallel, the fees and charges in force at that time are invoiced. If the fees and charges have changed when the mutual recognition in parallel can actually be implemented, an additional invoice will be issued to settle the difference.			
		Simplified authorisation	
B-ET, B-ETF	SA-APP	Simplified authorisation	€7,128
B-ETN, B-ETFN	SA-APP	Renewal of a simplified authorisation (single product or family)	€924

		The standard tariff for biocidal product applications is based on 1 user category, 1 PT, 1 active substance and no confidentiality request.	
		The tariff for a biocidal product family has the same basis as an application for a biocidal product	
		Additional fees and charges for activities not covered by the standard tariff:	
		Family (basic fee)	€924
		Family (per family member)	€924
		Extra PT	€924
		Extra active substance	€924
		Confidentiality request (per item)	€132
		Summarising and/or evaluating studies on physicochemical properties, analytical methods, efficacy, human toxicology and environmental aspects	actual costs incurred
		Simplified authorisation notification	
B-EM	SN-NOT	Notification of simplified authorisation, authorised in another Member State	€264
		Authorisation in accordance with the procedure of "the same biocidal product"	
B-ST	NA-BBS, NA-BBP	Tariff for same biocidal product, single product (not a family)	€1,716
		The standard tariff for "same biocidal product" applications is based on a national application without simultaneous administrative changes.	
		The standard tariff for "same biocidal product family" has the same basis as an application for a regular authorisation of a "same biocidal product".	
		Additional fees and charges for activities not covered by the standard tariff:	
		Simultaneous administrative change	€264
		Other tariffs for biocidal products	
		If necessary, assessment costs can be charged for the applications listed below. These costs are estimated in advance.	Actual costs incurred
B-FL	NA-NPF, SA-NPF, UA-NPF	Adding a product to a biocidal product family	€1,320
B-AW	NA-ADC, NA-TRS	Amendment of authorisation: administrative amendment	€264
B-KW	NA-MIC	Amendment of authorisation: minor change, conversion of WG/GA to SPC at the request of the authorisation holder	€1,188
PB	ET-NOT	Notification of experiment or trial	€528
		Parallel trade permit	
PAB, VPAB, UPAB,	PP-APP	Tariff	€792

Fees and charges for product applications and other activities, where one or more existing active substances are not yet included for the specified Product Types on the Union list of approved substances or Annex I of Regulation (EU) No. 528/2012

Type of application	**Description**	**Tariff 2018**
	Application costs	
TB, TBE, UB, WSB	Application costs for authorisation, extended authorisation, amendment	€3,036

KB	Determination of frame formulation	€2,640
TVB	Extension of approval period	€2,904
TB, TBE, UB, WSB, WYB, TVB	**Assessment costs**	
	Efficacy	€1,980
	Physicochemical properties of the product, each active substance present in the product, respectively	€924
	Criteria with respect to the operator and public health	€1,452
	Environmental behaviour and environmental fate	€1,980
	Final assessment of the authorisation aspects	€2,640
	Project support	€1,320
TB, UB, TBE	If comparative assessment is used (tariff per aspect)	€1,320
	Application costs and assessment costs combined	
DVB	Assessment urgently needed, biocidal product	€11,352
	Other applications	
	If necessary, assessment costs can be charged for the applications listed below. These costs are estimated in advance.	Actual costs incurred
AB, VAB, UAB	Authorisation, extension of approval periods or extension of range of uses of derived biocidal product	€792
WWGGA	Amendment WGGA (editorial)	€264
WSBNW	Application for a minor change in the biocidal product formulation	€792
PAB, VPAB, UPAB	Parallel authorisation biocidal product, extension of parallel authorisation of biocidal product, other applications concerning parallel authorisation of a biocidal product	€792
WNT, WNAW, OT	Change of name of authorised product, change of name, address and/or city of the authorisation holder, or transfer of authorised product to a different company	€264
WYB	Amend packaging or labelling of a biocidal product, other amendments (editorial)	€396
EXV	Export declaration	€264
VIB	Request for information on animal testing of biocidal product	€528
	Evaluation of additional efficacy data	Actual costs incurred
	Mediating the exchange of animal testing data	Actual costs incurred
Change of production location of product under transitional legislation		No fee charged

Fees and charges for applications for approval and renewal of active substances as well as inclusion on Annex I (of Regulation (EU) 528/2012)

Type of application	Application type R4BP 3	Description	Tariff 2018
EU-B	AS-APP, AS-RNL, AS-EVA, AN-APP	Application for approval of an active substance (existing or new) or inclusion of an active substance on Annex I of Regulation (EU) 528/2012 This application fee applies to one product type (PT)	€12,500 *
		If approval of the same substance is applied for for multiple PTs, additional fee per PT	€4,500 *
		Summarising, evaluating and assessing	
EU-B, , TB3EURAP, TB4EURAP	AS-APP, AS-RNL, AS-EVA	Extra evaluation and extra assessments	Actual costs incurred with advance payment of €250,000 *
EU-B, , TB3EURAP,	AS-APP, AS-RNL,	Average evaluation	Actual costs

TB4EURAP	AS-EVA		incurred with advance payment of €200,000 *
EU-B, , TB3EURAP, TB4EURAP	AS-APP, AS-RNL, AS-EVA, AN-APP	Evaluation based on simple dossier or dossier for application for inclusion of active substance in Annex I of Regulation (EU) 528/2012	Actual costs incurred with advance payment of €100,000 *
		Other activities	
EU-B, , TB3EURAP, TB4EURAP	AS-APP, AS-RNL, AS-EVA, AN-APP	Activities to complete the application for an active substance or inclusion of an active substance in Annex I of Regulation (EU) 528/2012 (European decision making)	Actual costs incurred with advance payment of €75,000 *

* this advance payment can be changed if justified by the estimated hours. If the advance payment appears to be insufficient, the additional amount will be invoiced.

Fees and charges for summarising and evaluating studies regarding product data

Type of application	**Description**	**Tariff 2018**
All applications	Studies on physicochemical properties, analytical methods, efficacy, human toxicology and environmental aspects, to be summarised and/or evaluated	actual costs incurred

Fees and charges for summarising and evaluating studies regarding substance data

Type of application	**Description**	**Tariff 2018**
All applications	Studies on physicochemical properties, analytical methods, efficacy, human toxicology and environmental aspects, to be summarised and/or evaluated	actual costs incurred

Annual fee biocidal product

AF	**Annual fee**	
	Authorisation for biocidal product (National)	€1,178
	Authorisation for biocidal product family	€1,000
	Additional charge per family member	€195
	The maximum fee that is charged for one family is €4,900 per year.	
	For placing biocidal products from a product family on the Dutch market, a fee will be charged for both the family and the individual members.	

For the registration of an authorised plant protection product and biocidal product, an annual fee is charged. The reference date for this is 1 February. If the applicant does not pay the annual fee in full before this date, the applicant is legally in default within the meaning of Article 6:81 of the Netherlands Civil Code and the authorisation can be withdrawn.