Ctgb Tariffs Decree 2019

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

- By virtue of Article 74 Regulation (EC) 1107/2009, Article 10, first clause, *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);
- Taking into consideration that 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 according 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;
- By virtue of Article 80 of Regulation (EU) 528/2012, Article 10, first clause, *Wet Gewasbeschermingsmiddelen en biociden* (Plant Protection Products and Biocidal Products Act), and Section 17 of the *Kaderwet zelfstandige bestuursorganen* (Independent Administrative Bodies Framework Act);
- Taking into consideration that 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;
- Taking into consideration that the transitional provisions in Regulation (EU) 528/2012 also require that fees and charges continue to apply to applications for the authorisation of biocidal products that must be processed according to 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 6 November 2013 when it amended the Plant Protection Products and Biocides Act for the implementation of the Biocidal Products Regulation;

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

Chapter 1 - Definitions:

a. Regulation on Plant Protection Products: Regulation (EC) 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 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) 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. new active substance:
    i. (plant protection products)
        1. an active substance as specified in Article 30 of the Plant Protection Products Regulation
        2. an active substance which according to Implementing Regulation (EU) 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 products) active substance as referred to in Article 3 first clause under e of the Biocidal products Regulation
h. zonal applications: applications for amendment/authorisation of plant protection products, which are treated according to Article 33 of the Plant Protection Products Regulation by means of the zonal or interzonal assessment method described there
i. European applications: applications for approval or amendment of the approval of an active substance, as referred to in Article 7 of the Plant Protection Products Regulation.

Interim amendment of Ctgb Tariffs Decree;
The Ctgb Tariffs Decree may, if necessary, be amended in the interim.

Timely payment
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.
In cases involving a demonstrable error, the Ctgb may decide to accept a late payment.

Communication
From the moment that a biocidal product application is submitted, all correspondence regarding costs and payment will be conducted by placing the messages in the Register for Biocidal Products (R4BP3) and possibly notifying the applicant by email about this placement.

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* (Freedom of Information Act) accordingly.

2. Transitional regime
Applications that were pending on the date this Decree went into force are processed from that date according to the provisions in this Decree.

3. Withdrawal of previous Ctgb Tariffs Decree
The Ctgb Tariffs Decree 2018 is withdrawn.

4. Entry into force
This Decree shall take effect, retroactively to the extent necessary, on 1 January 2019, following approval by Our Minister and publication in the *Staatscourant*.

5. Official title
The official title of this Decree is "**Tarievenbesluit Ctgb 2019**" (Ctgb Tariffs Decree 2019).

Adopted by the Board for the Authorisation of Plant Protection Products and Biocidal Products
on 26 September 2018

On behalf of the Board for the Authorisation of Plant Protection Products and Biocidal Products,

the Chairman,

ir. J.F. de Leeuw

Chapter 3 - Explanation of the Tariffs Decree

General

Article 10: according to law, the costs incurred by the Ctgb in carrying out the duties assigned to it in Article 4 of the Act must be covered by the fees and charges to be set by the Board. The fees and charges are directly related to the costs incurred by the Ctgb during execution of its tasks and require the approval of the Ministers of Agriculture, Nature Management and Food Quality (LNV) and Infrastructure and Water Management (IenW).

The fees and charges are set by this Decree and relate mainly to the following:

- Applications for or related to authorisations (e.g. applications for authorisation, amendment or extension of the authorisation, applications for approval of an active substance of a plant protection product or for the inclusion of an active substance in a biocidal product on Annex I or Ia to Directive 38/8/EC)
- Annual fees, which are charged to authorisation holders by the Ctgb, are based on the provisions in Article 10, first clause, of the Act
- Requests for public disclosure by reference to the Tariffs Decree, Freedom of Information Act (Besluit tarieven openbaarheid van bestuur).
- Service Desk requests
- Exemption as referred to in Article 53 of the Plant Protection Products Regulation
- Other activities

For the evaluation of summaries of data and studies for plant protection products and biocidal products, the actual costs are payable, which are charged in **advance**.
With the exception of:

- zonal applications; (NL ZRMS),
- applications for an expanded authorisation in the Netherlands (non-zonal) with Minor Uses only
- National applications under the Biocidal Product Regulation (BPR) and Union applications;
- and European applications:

for these applications, an advance payment will first be required and then a final amount will be charged on the basis of subsequent costing and actual costs.

If the Board decides to ask additional questions about applications based on fixed fees and charges and subsequent costing, the costs for evaluating summaries of data and the assessment costs are also charged.

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

For additional and/or other activities for which no fees have been determined, the actual costs incurred will be charged. 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 fee is 1 February. If the applicant does not pay the annual fee in full before this date, the applicant is legally in default according to Article 6:81 of the Netherlands Civil Code (Burgerlijk Wetboek) and the authorisation can be revoked.

Definitions

DTG list
The 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 the Plant Protection Products Regulation (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 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 about the method and cooperating partners can be found on the website www.ctgb.nl.

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

b. The Ctgb will send an invoice for the application or assessment costs due, with a payment term of 30 days. Non-payment or late payment may lead to non-admissibility of the application under Article 2.3 of the Administrative Regulations 2018.

c. If an advance payment has been made for the actual costs incurred, this payment is subtracted from the total amount due. If the actual costs incurred are less than the advance payment, the difference is refunded to the applicant within 30 days after the date of the final invoice. If the actual costs are higher than the advance payment, an additional invoice follows with a payment term of 30 days.

d. Notwithstanding the provisions in Article 4:87.1 Awb, for fees and charges other than those referred to under b), the applicant must pay the invoice within 30 days after the 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 advance payment can be adjusted if indicated by the estimated hours.

Timely payment
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 due has been transferred or deposited to the Ctgb before this deadline.

In cases involving a demonstrable error, the Ctgb may decide to accept a late payment.

Payment in instalments
Until 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.

Payment options
It is possible to have invoice payments automatically transferred to the Ctgb. More information can be found on the website www.ctgb.nl.

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

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.

Separate fees and charges

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, fees and charges for biocidal products will continue to exist for procedures under national law or under Directive 98/8/EC, in addition to the fees and charges for products and procedures covered by the Regulation.

Reduced fee 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 fee 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) 528/2012 it is possible to apply for authorisation of several products at once. For applications whereby the Ctbg acts as evaluating Member State, an advance payment is used. For mutual recognition of an authorisation for a biocidal product family by a different Member State, fixed fees are charged.

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. The Regulation also 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 fee. Member States that conduct the assessments must still cover their costs; this premise has remained unchanged.

Chapter 4 - Amendments to the Ctgb Tariffs Decree 2019

Hourly rate 2019	The hourly rate for 2019 is €136 per hour and is indexed for inflation by 3% compared to the rate for 2018. The increase is caused by, among other things, increased salaries in the collective labour agreement, an increase in the regular ICT costs, amortisation of ICT investments and a standard price indexation of the other operating costs.
Service Desk	The pre-application support process has expired because applicants did not use it. If applicants want to start a pre-application process, they can submit a Request for Meeting (RFM) or ask for a Pre-submission Meeting (PSM).
Annual fee (plant protection products)	The amount of the annual fee follows the indexation of the hourly rate and has been increased by approximately 3%.
Annual fee (biocidal products)	The amount of the annual fee follows the indexation of the hourly rate and has been increased by approximately 3%.
Application fee for plant protection products	Overall, no major changes in standard hours are needed. However, three matters require attention: 1. It has been noted that insufficient time is available for the project leader tasks (coordinating and supervising applications) within the European context. 2. Components of applications are frequently transferred to the Member State level. This means that additional assessment time is needed for something that should have been completed by the Zonal Rapporteur Member State in the core dossier. This was not taken into consideration in the rates for these types of applications. Therefore, add-ons have been included for several components. 3. The component on hormone disrupters is a new part of the assessment. An add-on is charged for applications involving this component.
Fee for plant protection products applications NLTG/NLRG	The application fee for these applications has been reduced because the standard hours for the commentary round and intake of these applications can be decreased.
Fee for plant protection products applications NLRG	In Europe, it is left to the discretion of the Member States whether combined toxicity will be evaluated for all active substances in the product during the assessment of a renewal (renewal after reassessment of the active substance under 1107/2009). The Board has determined that the combined toxicity of all active substances in a plant protection product must be at a safe level; therefore combined toxicity will be assessed when multiple active substances are present.
Fee for plant protection products applications NLWTG	The application fee for these applications has been reduced because the standard hours for the intake of these applications can be decreased.
Fee for plant protection products applications THG	The application fee for THG has expired.
Fee for plant protection products applications Aspect FCE	For the aspect FCE, the standard hours for short cyclical applications have been increased because the assessment took longer than previously thought.
Fee for plant protection products applications MRL	The fee for MRL applications has been raised because the standard hours for intake of these applications have been increased.
Fee for plant protection products applications MTR	The fee for MTL has been increased because the standard hours for intake of these applications have been increased.
Fee for biocidal product applications that require assessments (national and Union-applications)	In 2019, the advance payments will be increased for product applications under the BPR if an assessment is required (national and Union applications) In 2018, the advance payment was based on a standard application, whereas the actual advance payment was

	increased based on the scale and complexity of the application (e.g. multiple product types, multiple family members, comparative assessment). In 2019, the average advance payments have been included in the Ctgb Tariffs Decree based on the average characteristics of applications. The increased fees for BPR product applications can be explained by the following. • These dossiers turned out to be more complex than previously assumed. Often, large consortia are formed and/or biocidal product families are very extensive, and the content of dossiers is not always in accordance with the requirements. • The European approval process – with its consensus structure, referrals and a discrete IT system – has required much more time from scientific assessors and project leaders.
Pre-application support process for the application types B-TFN, B-UTN and B-UTFN (biocidal products)	The fee for the pre-application support process based on subsequent costing for the application types B-TFN, B-UTN and B-UTFN has expired due to lack of use.
Union authorisation: attendance of BPC meeting by the project leader (biocidal products)	The fee for the attendance of BPC meetings by the project leader as part of an application for Union authorisation has expired. From 2019 onward, these costs will be based on subsequent costing and are part of the advance payment of the application for Union authorisation.
Initial fee parallel mutual recognition (biocidal products)	From 2019 onward, the fee for mutual recognition will be divided into an initial fee and an evaluation fee.
Parallel and sequential mutual recognitions and other applications for which the Netherlands acts as concerned Member State (biocidal products)	Add-ons for each family member have been replaced with add-ons for each meta-SPC. The add-on for each additional user category has been cancelled.
Substance assessment (biocidal products)	The application fee has been increased due to a different allocation of hours in the phases of the process.
Mutual recognition and simplified authorisation (biocidal products)	Separate fees for single product and biocidal product family
Same biocidal product (biocidal products)	The fee has been reduced from €1,716 to €1,400 because the standard hours can be decreased. For a biocidal product family, an add-on will be charged for every 5 products.
Notification obligation (biocidal products and plant protection products)	Application fee has been established. The assessment costs are included in the regular fees.

Chapter 5 - Fees and charges, Service Desk

Requests	Description	Amount
Category		
1	Up to 4 hours	No fee charged
2	4 hours and more	Actual costs incurred on the basis of subsequent costing
3	Request for meeting (RFM)	Actual costs incurred on the basis of subsequent costing
4	Short request for meeting (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	Briefing/informational meeting (general)	€200
7	Workshop	For the record only

Chapter 6 - Fees and charges, Plant protection products

For evaluation of data summaries and studies for plant protection 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 and European substance 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 for applications based on fixed fees and charges, the related costs for evaluating summaries of data and assessment costs are also due.

In the context of certain types of applications, such as 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 associated assessment costs will also be charged.

For additional and/or other activities for which no fees have been determined, the actual costs incurred will be charged. This takes place following consultation with the applicant.

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

Type of application	Description	Amount
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	€12,875
	Summarisation and assessment (preparing 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	€12,875
	Summarisation and assessment (preparing 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*
	Summarisation and assessment (preparing 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 €15,500*
* Advance payment is based on an average dossier. The advance payment can be changed if justified by the estimated hours. If the advance payment is insufficient, additional charges will apply.		

Fees and charges for plant protection applications, product applications

Product applications based on subsequent costing

Type of application	**Description**	**Amount**
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 a dRR. *This amount will be deducted from advance payment type 1 and 2 after submitting the DRR.*	€10,000
NLKUG,	Application to expand the scope of an existing authorisation in the Netherlands (non-zonal) with **Minor Uses** only	Actual costs incurred with advance payment of €6,000*
* Advance payment is based on an average dossier. The advance payment can be changed if justified by the estimated hours. If the advance payment is insufficient, additional charges will apply.		

Application fees for product authorisations based on fixed fees and charges;
Application fees and and assessment fees are charged for these applications.

Type of application	Description	Amount
NLTG, NLRG	**CMS application** Zonal applications for which the Ctgb is not rapporteur (the Netherlands is CMS) • New application (NLTG) • Renewal (NLRG)	€8,976
NLWTG	**Application to amend current authorisation NL=CMS**	€6,120
NLWG	**Application to amend current authorisation** National request for amendment (national addendum) of an authorisation	€2,720
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	€4,760

Assessment fees for product authorisations based on fixed fees and charges
The assessment fees for the following types of applications are based on applications with 1 active substance, with up to 5 uses (GAP regulations) and 1 dRR (field or greenhouse use) per zone.
Additional fees can be charged if a product contains multiple active substances, if there are more than 5 uses, if there is more than 1 dRR, or if other additional activities are required. The fees and charges for these activities can be found in the table for “additional” charges for activities not covered by the standard fee.

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

NLTG, NLRG, NLTHG

Assessment of aspect	Amount
Efficacy	€1,088
Physicochemical properties of the product, each active substance present in the product, respectively	€544
Criteria with respect to public health	€408
Criteria with respect to the operator	€816
Environmental behaviour and environmental fate	€1,768
Ecotoxicology	€2,176
Project supervision	€2,992
Final assessment of the authorisation aspects	€1,360

NLWERG, NLWERGZ

Assessment of aspect	Amount
Efficacy	€680
Physicochemical properties of the product, each active substance present in the product, respectively	€544
Criteria with respect to public health	-
Criteria with respect to the operator	€408
Environmental behaviour and environmental fate	€2,720
Ecotoxicology	€2,176
Project supervision	€2,584
Final assessment of the authorisation aspects	€1,360

NLWTG, NLWG

Assessment of aspect	Amount
Efficacy	€680
Physicochemical properties of the product, each active substance present in the product, respectively	€408
Criteria with respect to public health	€408
Criteria with respect to the operator	€408
Environmental behaviour and environmental fate	€952
Ecotoxicology	€1,088
Project supervision	€2,176
Final assessment of the authorisation aspects	€1,360

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

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

Assessment of aspect	Amount
Efficacy	€1,632
Physicochemical properties of the product, each active substance present in the product, respectively	€680
Criteria with respect to public health and the operator	€544
Environmental behaviour, environmental fate and ecotoxicology	€1,360
Project supervision	€1,904
Final assessment of the authorisation aspects	€1,360

Fees and charges for assessment, general

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

Assessment of aspect	Amount
Efficacy	€1,224
Physicochemical properties of the product, each active substance present in the product, respectively	€1,088
Criteria with respect to public health	€2,175
Criteria with respect to the operator	€1,904
Environmental behaviour and environmental fate	€2,448
Ecotoxicology	€4,760
Project supervision	€2,584
Final assessment of the authorisation aspects	€1,360

Additional charges for activities not covered by the standard fee

Activities	Amount
Each additional active substance	€2,040
For each 1 to 5 additional uses	€952
Tankmix	€2,040
Additional dRR	€9,792
Evaluation of summaries and studies concerning physico-chemical properties, analytical methods, efficacy, human toxicology and environmental fate and ecotoxicology	Actual costs incurred
Use of Guidance on honeybees and other pollinators	€3,808
Use of Guidance on protected cultivation (per 5 crops)	€544
B10 (non-relevance of metabolites), per metabolite	€952
GAP restriction during application	€1,088
Assessment bridging study	€544
Additional assessments:	
* Birds & Mammals	€1,632
* Aquatic	€1,224
* Combined toxicity	€1,088
* Non-target organisms	€1,088
Use of GD hormone disruption	€4,624
Comparative assessment according to Article 50 Regulation (EC) 1107/2009 CA 1: Intake Agronomic assessment CA 2: Risk assessment	 For the record only Per use for the record only Actual costs incurred

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

Type of application	Description	Amount
Administrative changes		
WNT, WNAW, OT	Change of name authorised product, Change of name, address and/or city of the authorisation holder Transfer of authorised product to a different company	€272
INTR	Withdrawal of an authorisation of a plant protection product	No fee charged
Minor changes		
WSGNW	Minor change in the formulation	€884
Add or change product manufacturer, change production location	Change product production process (transitional legislation)	No fee charged
NLWATG	Minor change of WG-GA/WG including restricting scope of permitted use. (for which GAP is not changed and no risk assessment is required)	€272
Other types of authorisations		
AG, VAG, UAG, NLWERGV	**Derived applications** New derived authorisation Renewal of derived authorisation Expansion of derived authorisation Administrative extension of an authorisation obtained by mutual recognition	€884
PAG, VPAG, UPAG,	**Parallel trade applications** Parallel trade permit Renewal of parallel trade permit Expansion of parallel trade permit	€884
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	€272
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	€340
PGR	**Exemption for trial purposes** Supplemental charge for each 5 crops/uses the applicant wants to enter the food chain (regulations in the table)	€136
VIG	Request for **information on animal testing**	€544
	Mediating the exchange of animal testing data	Actual costs incurred
TT	Application for adjuvant	€884
TT-W	Application to change adjuvants	€272
EXV	Export declaration	€272
	Exemption as referred to in Article 53 of Regulation (EC) 1107/2009:	
	Activities up to 30 hours; Fee:	€4,080
	Activities 30 - 45 hours; Fee	€6,120
	Activities 45 - 60 hours; Fee:	€8,160
	Activities 60 - 75 hours; Fee:	€10,200

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

Type of application	Description	Amount
WYG	Changes to packaging, shelf life or labelling	€408
PWSG	Change in production process of active substance and/or additional production location of the active substance. Equivalence of assessment through Tier I not yet assessed in another Member State	€1,768
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	€272
MRL	Derivation of Maximum Residue Limit (MRL)	€2,584
MTR	Applications to derive norm as part of the Water Framework Directive (derived from AA-EQS/MAC-EQS)	€2,040
Notification obligation		
IKV	Regulation (EC) No. 1107/2009 Article 56, fourth clause (administrative)	€272

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

Type of application	Description	Amount
All applications	Evaluation of summaries and studies concerning physico-chemical properties, analytical methods, efficacy, human toxicology and environmental fate and ecotoxicology	Actual costs incurred

Annual fee plant protection product

	Annual fee	Amount
AF	Annual fee plant protection product	€1,615

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

Chapter 7 – Fees and charges for biocidal products

For the evaluation of summaries of data and studies for biocidal products, the actual costs are payable that are charged in advance. Excluded are national applications and applications for Union authorisation under the BPR 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.

For certain types of applications, such as a minor change, 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.

For additional and/or other activities for which no fees have been determined, the actual costs incurred will be charged. This takes place following consultation with the applicant. Examples include national applications and applications for Union authorisation under the BPR, submitted before 2018, for which the estimated application costs are insufficient because a second assessment and/or peer review is necessary.

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

Type of application	Application type R4BP3	Description	Amount
		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 €70,000*
B-UTFN, B-UFTH	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 €100,000*
B-TN, B-TH	NA-APP	National authorisation of biocidal product (new product or re-registration)	Actual costs incurred with advance payment of €45,000*
B-TFN, B-TFH	NA-APP	National authorisation of biocidal product family (new product or re-registration)	Actual costs incurred with advance payment of €75,000*
B-TPR		Provisional authorisation (biocidal product)	Actual costs incurred with advance payment of €45,000*
B-TPRF		Provisional authorisation (family)	Actual costs incurred

			with advance payment of €75,000*
B-TR,	NA-RNL	Renewal of an authorisation (biocidal product)	Actual costs incurred with advance payment of €45,000*
B-TRF	NA-RNL	Renewal of an authorisation (family)	Actual costs incurred with advance payment of € 75,000*
B-GW,	NA-MAC, SA-MAC, UA-MAC	Major change of an authorisation (biocidal product) for which the Netherlands is the evaluating competent authority	Actual costs incurred with advance payment of €45,000*
B-GWF	NA-MAC, SA-MAC, UA-MAC	Major change of an authorisation (family) for which the Netherlands is the evaluating competent authority	Actual costs incurred with advance payment of €75,000*

* Advance payment is based on an average dossier.
The advance payment can be changed if justified by the estimated hours.
If the advance payment is insufficient, additional charges will apply.

Type of application	**Application type R4BP3**	**Applications for mutual recognition (NL is concerned Member State)**	**Amount**
B-TWENP B-TWEHP	NA-MRP	Initial fee for mutual recognition in parallel with a single product (not a family)	€3,500
B-TWENP B-TWEHP	NA-MRP	Evaluation fee for mutual recognition in parallel with a single product (not a family)	€4,524
B-TWEFNP	NA-MRP	Initial fee for mutual recognition in parallel with a biocidal product family	€4,500
B-TWEFNP	NA-MRP	Evaluation fee for mutual recognition in parallel with a biocidal product family	€7,060
B-TWENS	NA-MRS	All-in fee for sequential mutual recognition of a single product (no family)	€8,024
B-TWEFNS	NA-MRS	All-in fee for sequential mutual recognition of a biocidal product family	€11,560
B-TWER	NA-RNL	Initial fee for renewal of the authorisation of a single product for which the Netherlands is the Member State concerned.	€3,500
B-TWER	NA-RNL	Evaluation fee for renewal of the authorisation of a single product for which the Netherlands is the Member State concerned.	€4,524
B-TWEFR	NA-RNL	Initial fee for renewal of the authorisation of a biocidal product family for which the Netherlands is the Member State concerned.	€4,500
B-TWEFR	NA-RNL	Evaluation fee for renewal of the authorisation biocidal product family for which the Netherlands is the Member State concerned.	€7,060
B-GWC,		Initial fee for a major change to an authorisation (biocidal	€3,500

B-GWFC	NA-MAC	product or family) for which the Netherlands is the Member State concerned.	
B-GWC, B-GWFC	NA-MAC, SA-MAC, UA-MAC	Evaluation fee for a major change to an authorisation (biocidal product or family) for which the Netherlands is the Member State concerned.	€4,524
		Additional fees and charges for activities involving applications for which the Netherlands is the Member State concerned if the activities are not covered by the standard fee.	
		Comparative assessment	€1,360
		Additional active substance	€952
		For more than 5 meta-SPCs an add-on fee is charged for each additional meta-SCP	€952
		Additional PT	€952
		Simplified authorisation	
B-ET	SA-APP	Simplified authorisation	€7,480
B-ETF		Simplified authorisation of a family	€10,608
B-ETN, B-ETFN	SA-APP	Renewal of a simplified authorisation (single product or family)	€952
		Additional fees and charges for activities not covered by the standard fee:	
		Additional active substance (per 5 scenarios)	€680
		Additional user category	€544
		Additional scenario (per scenario)	€544
		Additional use	€272
		Additional study	€952
		Substance of Concern	€680
		MRL	€272
		Additional meta-SPC	€952
		Registration of product families (per 5 products)	€612
		>5 co-formulants	€204
		Summarising and/or evaluating studies on physico-chemical 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	€272
		Authorisation according to the procedure of 'the same biocidal product'	
B-ST, B-STF	NA-BBS, NA-BBP, SA-BBP	Fee for same biocidal product, single product or family	€1,400
		The standard fee for 'same biocidal product' applications is based on a national application without a simultaneous administrative change.	
		Registration product families (per 5 products)	€612
		Additional fees and charges for activities not covered by the standard fee:	
		Simultaneous administrative change	€272
		Other fees and charges, 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	€1,360
B-AW, B-AWF	NA-ADC, NA-	Amendment of authorisation: administrative change	€340

	TRS, NA-CCL, NA-MRG, SA-ADC, SA-TRS, US-TDC, UA-TRS		
B-KW, B-KWF	NA-MIC, SA-MIC, UA-MIC	Amendment of authorisation: minor change	€1,224
PB	ET-NOT	Notification of experiment or trial	€544
PAB, VPAB, UPAB,	PP-APP	**Parallel trade permit** Fee	€816
IKV-B		Application fee for Obligatory Notification biocidal products	€272

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	Amount
	Application costs	
TB, UB, WSB, TVB	Application costs for authorisation, extended authorisation, amendment	€3,128
KB	Determination of frame formulation	€2,720
TVB	Renewal	€2,992
TB, UB, WSB, WYB, TVB	**Assessment costs**	
	Efficacy	€2,176
	Physicochemical properties of the product, each active substance present in the product, respectively	€952
	Criteria with respect to the operator and public health	€1,496
	Environmental behaviour and environmental fate	€2,040
	Project supervision	€2,720
	Final assessment of the authorisation aspects	€1,360
TB, UB, TBE	If comparative assessment is used (fee per aspect)	€1,360
	Application fees and assessment fees combined	
DVB	Assessment of urgently needed biocidal product	€11,696
	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, renewal or extending the scope of use of a derived biocidal product	€816
WWGGA	Amendment WGGA (editorial)	€272
WSBNW	Application for a minor change in the formulation of the biocidal product	€816
PAB, VPAB, UPAB	Parallel authorisation biocidal product, renewal of parallel authorisation of biocidal product, other applications concerning parallel authorisation of a biocidal product	€816
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	€272
WYB	Change packaging or labelling of a biocide, other changes (editorial)	€408
EXV	Export declaration	€272
VIB	Request for information on animal testing of biocidal product	€544
	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 R4BP3	Description	Amount
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 is for a single product type (PT)	€15,000*
		If the approval of the same substance for multiple PTs is applied for, an additional fee is charged for each PT	€5,000*
		Summarising, evaluating and assessing	
EU-B, TB3EURAP, TB4EURAP	AS-APP, AS-RNL, AS-EVA	Additional evaluation and additional assessments	Actual costs incurred with advance payment of €250,000*
EU-B, TB3EURAP, TB4EURAP	AS-APP, AS-RNL, AS-EVA	Average evaluation	Actual costs 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*

* Advance payment is based on an average dossier.
The advance payment can be changed if justified by the estimated hours.
If the advance payment is insufficient to cover all costs, additional fees will be charged.

Fees and charges for summarising and evaluating studies regarding product data

Type of application	Description	Amount
All applications	Studies on physico-chemical 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	Amount
All applications	Studies on physico-chemical 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	Amount
	Authorisation biocidal product (National)	€1,220
	Authorisation of biocidal product family (National)	€1,030
	Additional fee per family member	€200

	The maximum fee that is charged for one family is €5,050 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 fee is 1 February. If the applicant does not pay the annual fee in full before this date, the applicant is legally in default according to Article 6:81 of the Netherlands Civil Code (Burgerlijk Wetboek) and the authorisation can be revoked.