

Ctgb Tariffs Decree 2021

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General

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

- 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 Article 17 *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 Article 17 *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 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 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 - Terms and definitions

- a. Plant Protection Regulation: 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 referred to in Article 30 of the Plant Protection Regulation, or
 - 2. an active substance which
 - a. according to Implementing Regulation (EU) 540/2011 was not approved and
 - b. was not yet on the market on 15 July 1993 and
 - c. 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 whereby these applications are processed according to the (inter)zonal assessment method described in Article 33 of the corresponding Regulation
- i. 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 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 went into force are processed from that date according to the provisions in this Decree.

3. Withdrawal of previous Tariffs Decrees

The "Rectification Ctgb Tariffs Decree 2020" is withdrawn.

4. Entry into force

This Decree shall take effect, retroactively to the extent necessary, on 1 January 2021, following approval by Our Minister and publication of this Decree in the Staatscourant.

5. Interim amendment of the Ctgb Tariffs Decree

The Tariff Decree may, if necessary, be amended in the interim.

6. Official title

The official title of this Decree is "**Tarievenbesluit Ctgb 2021**" (Ctgb Tariffs Decree 2021) .

Approved by the Board for the Authorisation of Plant Protection Products and Biocidal Products
on 23 September 2020

The Board for the Authorisation of Plant Protection Products and Biocidal Products,
on its behalf:
Chairman,

ir. J.F. de Leeuw

Chapter 3 - Explanation of the Tariffs Decree

General

The Act stipulates that the costs incurred by the Ctgb during the implementation of activities for which it is responsible 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 for Agriculture, Nature and Food Quality (LNV) and the Minister of Infrastructure and Environment (IenW).

Structure of fees and charges

The fees and charges of the Ctgb cover the internal costs of the organisation. Applicants pay fees and charges consisting of the various assessments that are required for their applications. Due to the size and complexity of an application and dossier (e.g. whether use is restricted to greenhouses or outdoors, whether it is an application for a single product or for a large biocidal product family) the costs can vary considerably.

The fees and charges for an application consist of the costs for the various phases and expertises involved in the assessment, such as project management, human toxicology, residues, ecotoxicology, behaviour and environmental fate, physicochemical properties and efficacy. The various phases are essentially stacked on top of each other. The costs depend on the required work, which differs per application.

The type of application also determines the costs. For example, a product that has already been authorised in another Member State can be placed on the market in the Netherlands by means of mutual recognition. The Ctgb will then use most of the assessment from the other EU Member State and will mainly look at aspects that are specific to the Netherlands. The costs for mutual recognition are considerably lower than for a complete assessment. However, if additional assessments are required for authorisation on the Dutch market, this can still increase the costs.

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

- *Applications for authorisation of an active substance for a plant protection product or authorisation of an active substance for a biocidal product.*
- *Applications for authorisation (e.g. applications for new products, amendments or renewals of existing authorisations) of a biocidal product or plant protection product and other fees and charges (for example, annual fees, which authorisation holders must pay to the Ctgb based on Article 10, first paragraph of the Wgb).*
- *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 the Plant Protection Products Regulation (EU) 1107/2009.*
- *Exemption as referred to in Article 55 of the Plant Protection Products Regulation (EU) 528/2012.*
- *Other activities.*

Fixed fees and charges, and fees and charges based on subsequent costing

Due to the differences between the various types of applications, the Ctgb applies two types of fees and charges:

1. Product applications based on subsequent costing. An advance payment is requested for this. The final settlement takes place at the end of the application process. Invoicing times: at submission of the application, at completion of the intake and at final settlement. If the advance payment is insufficient, interim invoicing is possible.
2. Applications based on a fixed fee. These fees and charges must be paid in advance. In principle, no final settlement takes place in this situation. Invoicing times: at submission of the application, at completion of the intake and when submitting additional questions. If the Board decides to request additional information, the costs for assessing this additional information will also be charged.

For work for which no fees and charges have been set in advance, the actual costs will be charged.

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 advance payment can be changed if justified by the estimated hours.

Explanation of "Actual costs"

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 (including the VAT paid to such third parties). More information about the working method and cooperating partners can be found on the website www.ctgb.nl.

Explanation “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.

Annual fee

For the registration of an authorised plant protection product and biocidal product, an annual fee is charged. The reference date for this annual fee is 1 February, which is also the date on which registration for the following year becomes payable if the registration is not withdrawn in advance in writing. 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.

Frame formulation

The applicant for an authorisation under transitional law 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.

Chapter 4 - Invoicing, payment and subsequent costing/refund

1. Plant protection products and Biocidal products under transitional legislation in the Netherlands

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 which is due within 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 amount due. 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. If the actual costs are higher than the advance paid, an additional invoice follows with a payment term of 30 days.
- d) Notwithstanding the provisions in Article 4:87.1 of the *Algemene Wet Bestuursrecht* (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.

Payment in instalments

Until two weeks after the invoice date, the applicant may request the Board for permission to pay the costs of the application procedure at the Ctgb in instalments. This request will be granted if the costs of the application procedure are more than € 5,000.

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, Ctgb formally accepts the application and notifies the applicant of the date of this acceptance. If you would like to pay in instalments, please contact the Finance & Control office (finance@ctgb.nl).

Collection options

It is possible to have invoice payments automatically transferred to the Ctgb. You can find more information about this on the website www.ctgb.nl. You can also contact the Finance & Control office (finance@ctgb.nl).

2. Biocidal Products Regulation (BPR):

With regard to biocidal products, the Ctgb must abide by the provisions regarding fees and charges laid down in the Biocidal Products Regulation as a matter of priority. These are explained below.

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.

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);
- under the Regulation, all communication between the applicant and 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 cover their costs;
- where the Biocidal Products Regulation does not offer a solution, Chapter 4 of this Ctgb Tariffs Decree applies.

Communication

From the time an application is submitted, all correspondence on costs and payment is done in the Register for Biocidal Products (R4BP).

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 in R4BP.
- 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.

Reduced tariff for clustered applications

If multiple applications are submitted simultaneously, for which a cluster assessment involving one or more expertises can be made for multiple applications, at the request of the applicant(s) the Ctgb can charge a reduced rate for these expertises.

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.

Chapter 5 - Most important changes

General

Hourly rate 2021	The hourly rate for 2021 is €143 per hour and is indexed for inflation by 2% compared to the rate for 2020.
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Service desk

RFM / PSM	The Service Desk products RFM and PSM have been merged into a single product: the Pre-Submission Meeting (PSM). The PSM is intended for applicants who, while compiling the application and dossier, have questions about correct explanation and implementation of the requirements. The applicant determines the agenda and thus the expertises participating in the PSM. The Ctgb invoices the costs and hours incurred by the employees at an hourly rate, with an advance payment of €1,000 per expertise involved.
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Plant protection

General	Overall, the fixed fees and charges for applications for plant protection products have been adjusted as a result of the increase in the hourly rate indicated above.
Applications for plant protection products	<p>The application fee (advance payment) for applications based on subsequent costing is for the intake.</p> <p>After the intake, another advance payment will be charged for the entire application based on the dossier.</p> <p><i>Please note: this advance payment is based on the estimated costs for the first assessment of the dossier and on average costs for the subsequent phases. Depending on the magnitude of the phases of the application process that have not yet been estimated in relation to the average, it may be necessary to send an invoice for an additional advance payment.</i></p> <p>After completion of the application process, the final settlement takes place.</p> <p>In the following chapters, indications of the amounts of advance payments are given. Based on the intake, the amount of this advance payment can differ.</p>
NLWERGZ NLTG NLWTG NLWG MRL	From 2021, these application types will be invoiced on the basis of advance payment and subsequent costing. The reason for this is that the divergence in the costs of the applications within a single type of application is increasing and this divergence cannot be limited by the use of fixed fees and charges for add-on activities.
Annual fee (plant protection products)	The fees and charges for plant protection products have decreased by more than 5.5% compared to 2020. This is because the total number of plant protection products on the reference date of 1 February 2021 is expected to be slightly higher than in 2020 and the costs (hours) of activities for European substance advice for plant protection will be somewhat lower. Part of the income from 2020 can also be used to cover these costs.

Biocidal products

General	Overall, the fixed fees and charges for applications for biocidal products have been adjusted as a result of the increase in the hourly rate indicated above.
Applications biocidal products	<p>New in 2021 is that for applications based on subsequent costing, the application fee (advance payment) will be invoiced before carrying out the validation.</p> <p>After the validation, another advance payment is invoiced for the entire application based on the dossier.</p> <p><i>Please note: this advance payment is based on the estimated costs for the first assessment of the dossier and on average costs for the subsequent phases. Depending on the magnitude of the phases of the application process that have not yet been estimated in relation to the average, it may be necessary to invoice an additional advance payment.</i></p> <p>After completion of the application process, the final settlement takes place.</p> <p>In the following chapters, indications of the amounts of advance payments are given. Based on the validation, the amount of this advance payment can differ.</p>
TBL, TVB	This new application type (TBL) concerns a different procedure for biocidal products under Transitional legislation. Applications under Transitional legislation for authorisation of biocidal products or renewal or major amendment of these authorisations can qualify for a limited assessment under specific conditions. The conditions are published on the Ctgb website.

	In line with this limited assessment, the fee for renewal of authorisations under Transitional legislation (TVB) has been adjusted downwards.
WBA, WBK	These new types of applications under Transitional legislation for biocidal products concern applications for "administrative change biocidal product" (WBA) and "minor change biocidal product" (WBK). These replace the following types of applications: WWGGA, WNT, WNAW, OT, WYB and WSBNW, which are all related to administrative and minor changes. The distinction between administrative or minor change is based on Implementing Regulation (EU) 354/2013
ART 46	ART 46 regarding applications for exemption of biocidal products. The commencement date of this type of application will be announced in the course of 2021. The actual costs incurred will be invoiced. Note: applications for exemptions must be submitted to the Ministry of Infrastructure and Water Management (IenW).
Annual fee (biocidal products)	For biocidal products, a slight increase in the fees and charges (1.4%) is required; in 2020 this increase was 2.5%. Because the European substance consulting activities for biocidal products are increasing, the costs (hours) will be higher in 2021 than in 2020. However, because the total number of biocidal products on the reference date of 1 February 2021 is expected to be higher than in 2020, the rate increase will be limited to 1.4%.

Chapter 6 - Fees and charges, Service Desk

Requests	Description	Amount
Category		
1	Service desk questions, up to 4 hours	No fee charged
2	Service desk questions, 4 hours or more	Actual costs incurred
3	Pre-submission meeting (PSM) Meeting for questions (or sub-questions) about dossier preparation	Actual costs incurred with an advance payment of €1,000 per expertise to be involved in the meeting
4	Workshop Meeting to keep applicants informed of current developments in practice.	Actual costs incurred are determined for each workshop

Chapter 7a – Fees and charges Plant Protection Products - Subsequent costing

General

For applications for active substances and plant protection products, subsequent costing with an advance payment that is invoiced at various times will be used.

For these applications it is difficult to estimate in advance how many hours the assessment (and any additional questions and the commentary round) will take, and there is a wide variation in the required assessment time between applications. At the start of the application process the Ctgb invoices the application fee as an advance payment. To this end, the Ctgb performs the admissibility check (active substances) or the intake (plant protection products).

After the admissibility check/intake, the Ctgb sends an advance payment invoice for the continuation of the application process. This advance payment is based on the estimated assessment costs, which are based in turn on the dossier and the average costs of the phases after the assessment. The entire application – from intake to final decision – is ultimately invoiced according to the actual costs incurred.

An exception to this are applications that are withdrawn before the dossier is actually submitted. In that case, the application fees already paid will not be refunded.

1. Fees and charges for active substance dossiers
2. Fees and charges for plant protection applications

- a. Fees and charges, applications where Ctgb is zonal rapporteur (zRMS)
- b. Fees and charges, applications Ctgb as Concerned Member State (cMS) (NLTG en NLWTG, NLRG)
- c. Fees and charges, applications for mutual recognition (NLWERG and NLWERGZ)
- d. Derivation of Maximum Residue Limit (MRL)
- e. Fees and charges, applications authorisation extended with minor uses (NLKUG)
- f. Fees and charges, applications for national change (NLWG)

1. Fees and charges, applications with active substance dossiers

For these types of application the actual costs incurred will be charged. The above-mentioned advance payment amounts are an indication based on an average dossier. The advance payment that will be charged will be determined after the intake has been completed. If the advance payment is insufficient to cover all costs, additional costs will be charged.

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 low risk substances, micro-organisms or pheromones	
	Application fees	€ 20,000
	Summarisation and assessment (prepare DAR or RAR)	€ 150,000
	Activities related to the completion of an approval or renewal of an application for an active substance (Peer review; European decision-making)	€ 75,000
TGEURAPM, TGEURPRM	Ctgb rapporteur for application for initial approval or renewal of an active substance based on low risk substances, micro-organisms, pheromones or a comparable substance	
	Application fees	€ 12,875
	Summarisation and assessment (prepare DAR or RAR)	€ 50,000
	Activities related to the completion of an approval or renewal of an application for an active substance (Peer review; European decision-making)	€ 30,000
TGEUCORA	Ctgb Co-rapporteur substance dossier	
	Fee for reviewing and commenting on substance assessment RMS	€ 20,000
	Summarisation and assessment (prepare DAR or RAR) <i>(only if parts of the DAR/RAR must be prepared in consultation with the RMS)</i>	€ 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) <i>(only if parts of the DAR/RAR must be prepared in consultation with the RMS)</i>	€ 25,000
TGEURPCD	Ctgb rapporteur for the assessment of confirmatory data	
	Assessment of confirmatory data	€ 15,500
TGDM	Data matching of the active substance dossier Assessment of data matching for substance dossiers of non-notifiers of the EU authorisation of the active substance, including the determination of Category 4 data if applicable, as referred to in EU GD Art. 43 PPP renewals; SANCO/2010/13170 rev. 14 on 7 October 2016.	€ 10,000
TGDM-C4	Data matching of Cat. 4 If Category 4 data have been claimed and determined in the primary assessment for data matching, then the applicant must provide these data before the set deadline and it must be assessed whether the data provided are sufficient to fully explain the data matching.	€ 2,000

2. Fees and charges for plant protection applications

a. Ctgb as zonal rapporteur Member State (zRMS)

For these types of application the actual costs incurred will be charged. The above-mentioned advance payment amounts are an indication based on an average dossier. The advance payment that will be charged will be

determined after the intake has been completed. If the advance payment is insufficient to cover all costs, additional costs will be charged.

Type of application	Description	Amount
ZTG, ZTG-LR	Zonal application for new authorisation NL = zRMS The suffix –LR indicates a product application in which the low-risk substance procedure is followed.	
	Application fees	€ 10,000
	Assessment costs	€ 70,000
ZWTG, ZWTG-LR	Application to amend current authorisation The suffix –LR indicates a product application in which the low-risk substance procedure is followed.	
	Application fees	€ 10,000
	Assessment costs	€ 60,000
ZRG	ZRG applications (renewal of a product authorisation with the Netherlands as zRMS),	
	Application fees	€ 10,000
	Assessment costs	€ 75,000

Explanation:

During the intake, the Ctgb determines whether the dossier is of sufficient quality to start the assessment. In addition, it is determined how much time the various expertises need to complete the first assessment. During the intake it is not yet possible to determine for the dossier in question how much time is needed to assess additional data after the stop-the-clock and to process the comments of other Member States. However, estimates are available for average dossiers. After the intake, you will receive an invoice for an advance payment based on the estimate of the required assessment time for your dossier plus the average time required for the additional questions phase and the commentary round. Depending on the actual magnitude of the additional questions phase and the commentary round, this advance payment may be too high or too low. If the advance payment is too low, you will receive an invoice for an additional advance payment during the application process. If the first advance payment is too high, the Ctgb will refund the remaining amount at the end of the application process.

b. Fees and charges, applications Ctgb as Concerned Member State (CMS) (NLTG and NLWTG, NLRG)

An NLTG is an application for a new authorisation with the Netherlands as the Concerned Member State. An NLRG is a application for a renewal with the Netherlands as the Concerned Member State.

An NLWTG is an application to amend the current authorisation in which the Netherlands is a concerned Member State.

For these types of application the actual costs incurred will be charged. The above-mentioned advance payment amounts are an indication based on an average dossier. The advance payment that will be charged will be determined after the intake has been completed. If the advance payment is insufficient to cover all costs, additional costs will be charged.

Type of application	Description	Amount
NLTG, NLRG	Zonal application for new authorisation/renewal of authorisation where the Netherlands is CMS	
	Application fee for new authorisation (NLTG) and Renewal (NLRG)	€ 10,000
	Assessment costs	€ 12,000
NLWTG	Application to amend current authorisation, the Netherlands is CMS	
	Application fees	€ 6,500
	Assessment costs	€ 6,500

Explanation

During the intake, the Ctgb checks whether the dossier (national addendum) is of sufficient quality to start the assessment. In addition, it is determined how much time the various expertises need to complete the first assessment. During the intake, it is not yet possible to determine how much time is needed for possible assessment of additional data in the corresponding dossier after the initial assessment. However, estimates are available for average dossiers. After the intake you will receive an invoice for an advance payment based on the estimated time for the first assessment of your dossier plus the average time required for the second assessment. Depending on the actual scope of the second assessment, this advance payment may be too high or too low. If the advance payment is too low, you will receive an invoice for an additional advance payment during the application process. If the first advance payment is too high, the Ctgb will refund the remaining amount at the end of the application process.

c. Mutual recognition of plant protection products (NLWERG and NLWERGZ)

Mutual recognition can be based on a zonal dossier (NLWERGZ) or on an authorisation under Directive 91/414/EEC (NLWERG) from another Member State

For these types of application the actual costs incurred will be charged. The above-mentioned advance payment amounts are an indication based on an average dossier. The advance payment that will be charged will be determined after the intake has been completed. If the advance payment is insufficient to cover all costs, additional costs will be charged.

Type of application	Description	Amount
NLWERGZ, NLWERG	Application fees	€ 5,000
	Assessment costs	€ 12,000

Explanation

During the intake, the Ctgb checks whether the dossier (national addendum) is of sufficient quality to start the assessment. In addition, it is determined how much time the various expertises need to complete the first assessment. During the intake, it is not yet possible to determine how much time is needed for possible assessment of additional data in the corresponding dossier after the initial assessment. However, estimates are available for average dossiers. After the intake you will receive an invoice for an advance payment based on the estimated time for the first assessment of your dossier plus the average time required for the second assessment. Depending on the actual scope of the second assessment, this advance payment may be too high or too low. If the advance payment is too low, you will receive an invoice for an additional advance payment during the application process. If the first advance payment is too high, the Ctgb will refund the remaining amount at the end of the application process.

d. Derivation maximal residue limit (MRL)

For these types of application the actual costs incurred will be charged. The above-mentioned advance payment amounts are an indication based on an average dossier. The advance payment that will be charged will be determined after the intake has been completed. If the advance payment is insufficient to cover all costs, additional costs will be charged.

Type of application	Description	Amount
MRL	Derivation of Maximum Residue Limit (MRL)	
	Application fees	€ 3,000
	Assessment costs	€ 7,000

Explanation

During the intake, the Ctgb determines whether the dossier is of sufficient quality to start the assessment. In addition, it is determined how much time is needed to complete the first assessment. During the intake, it is not yet possible to determine how much time is needed for possible assessment of additional data in the corresponding dossier after the initial assessment. However, estimates are available for average dossiers. After the intake you will receive an invoice for an advance payment based on the estimated time for the first assessment of your dossier plus the average time required for the second assessment. Depending on the actual scope of the second assessment, this advance payment may be too high or too low. If the advance payment is too low, you will receive an invoice for an additional advance payment during the application process. If the first advance payment is too high, the Ctgb will refund the remaining amount at the end of the application process.

e. Fees and charges, applications national authorisation extended with minor uses (NLKUG)

For these types of application the actual costs incurred will be charged. The above-mentioned advance payment amounts are an indication based on an average dossier. The advance payment that will be charged will be

determined after the intake has been completed. If the advance payment is insufficient to cover all costs, additional costs will be charged.

Type of application	Description	Amount
NLKUG	Application to extend an existing authorisation in the Netherlands (not zonally) with Minor Uses only	€ 6,000
	Assessment costs	€ 8,000

Explanation

During the intake, the Ctgb determines whether the requested extended authorisation fits within risk envelope of the currently authorised uses. If this is the case, no assessment is necessary and decision-making can take place. If not all requested extensions fall entirely within the risk envelope, an assessment is required. During the intake it is determined which expertises are required for the assessment and how much time these expertises need to complete the first assessment. During the intake, it is not yet possible to determine how much time is needed for possible assessment of additional data in the corresponding dossier after the initial assessment. However, estimates are available for average dossiers. If an assessment is required, you will receive an invoice for an advance payment based on the estimated time for the first assessment of your dossier plus the average time required for the second assessment. Depending on the actual scope of the second assessment, this advance payment may be too high or too low. If the advance payment is too low, you will receive an invoice for an additional advance payment during the application process. If the first advance payment is too high, the Ctgb will refund the remaining amount at the end of the application process.

f. National application to amend the current authorisation (NLWG)

An NLWG is an application to amend the current authorisation for which only the national addendum needs to be assessed as to whether the requested change falls within the risk envelope of the existing core assessment.

For these types of application the actual costs incurred will be charged. The above-mentioned advance payment amounts are an indication based on an average dossier. The advance payment that will be charged will be determined after the intake has been completed. If the advance payment is insufficient to cover all costs, additional costs will be charged.

Type of application	Description	Amount
NLWG	National request for amendment (national addendum) of an authorisation	
	Application fees	€ 3,500
	Assessment costs	€ 3,500

Explanation

During the intake, the Ctgb determines whether the requested change relates to the national addendum or the core RR. If the requested change to the core RR fits within the risk envelope of the currently authorised uses, no assessment is necessary and decision-making can take place. If the requested changes relate to the national addendum, it is determined which expertises are required for the assessment and how much time these expertises need to complete the first assessment. During the intake, it is not yet possible to determine how much time is needed for possible assessment of additional data in the corresponding dossier after the initial assessment. However, estimates are available for average dossiers. If an assessment is required, you will receive an invoice for an advance payment based on the estimated time for the first assessment of your dossier plus the average time required for the second assessment. Depending on the actual scope of the second assessment, this advance payment may be too high or too low. If the advance payment is too low, you will receive an invoice for an additional advance payment during the application process. If the first advance payment is too high, the Ctgb will refund the remaining amount at the end of the application process.

Chapter 7b – Fees and charges, Plant protection products, other applications - Fixed fees and charges

This concerns applications and assessments based on a fixed fee.

1. Fees and charges, other applications for plant protection products where there is no assessment
2. Fees and charges for other plant protection product applications for which additional assessment costs (in addition to the application fee) can be charged if necessary.

1. Fees and charges, other applications for plant protection products where there is no assessment

Type of application	Description	Amount
	Administrative amendment	
WNT	Amendment of name authorised product	€ 285
WNAW	Amendment of name, address and/or city of the authorisation holder	€ 285
WYG-AG	Change to the labelling of derived and parallel trade permits	€ 285
OT	Transfer of authorised product to a different company	€ 285
INTR	Withdrawal of an authorisation of a plant protection product	no fee charged
	Minor changes	
WSGNW	Minor change in the formulation	€ 930
Add or change product manufacturer, change production location	Change product production process (transitional legislation)	no fee charged
NLWATG	Administrative change WGGG/WG (legal conditions for use/instructions for use) linguistic changes and restrictions on scope of permitted use	€ 285
	Other types of authorisations	
	Derived applications	
AG	New derived authorisation	€ 930
VAG	Renewal of derived authorisation	€ 930
UAG	Expansion of derived authorisation	€ 930
	Parallel trade applications	
PAG	Parallel trade permit	€ 930
VPAG	Renewal of parallel trade permit	€ 930
UPAG	Expansion of parallel trade permit	€ 930
	Exemption for trial purposes	
PGN	Permit for trial purposes plant protection product, where the treated crops will not be introduced into the food chain	€ 285
PGR	Exemption to use a plant protection product for trial purposes where the treated crops enter the food chain, basic fee	€ 360
PGR	Additional amount per 5 crop uses where the treated crop is introduced into the food chain (regulations in the table)	€ 145
VIG	Request for information on animal testing	€ 575
TT	Application for approval of an adjuvant	€ 930
TT-W	Application for changing an adjuvant	€ 285
EXV	Export declaration	€ 285

2. Fees and charges for other plant protection product applications for which additional assessment costs (in addition to the application fee) can be charged if necessary

Type of application	Description	Amount
WYG	Changes to packaging, shelf life or labelling	€ 430
PWSG	Change in production process of <u>active substance</u> and/or additional production location of the active substance. Equivalence through Tier I not yet assessed in another Member State	€ 1,860
PWSGC	Change in production process of <u>active substance</u> and/or additional production location of the active substance. Equivalence is assessed by another Member State and published on CircaBC	€ 285
MTR	Application to derive standard under the Water Framework Directive (derived from AA-EQS/MAC-EQS)	€ 2,145
IKV	Notification obligation Regulation (EC) No. 1107/2009 Article 56, clause 4	€ 285
ART38	Exemption as referred to in Article 53 of Regulation (EC) 1107/2009:	Actual costs incurred

*If an assessment is required, the actual costs incurred will be charged.

Chapter 7c - Annual fee plant protection products

	Annual fee	Amount
AF	Annual fee plant protection product	€ 1,545

Chapter 8a – Fees and charges Biocidal products (BPR)

General

Applications for approval of active substances, applications for Union authorisation, applications for simplified authorisation and applications for national authorisation under Regulation (EU) 528/2012 (BPR), in which the Ctgb acts as the evaluating Member State, are invoiced on the basis of subsequent costing with an advance payment that is invoiced at various times.

During the validation, the Ctgb determines whether the dossier is of sufficient quality to start the assessment. In addition, it is determined how much time is needed to complete the first assessment. During the validation, it is not yet possible to determine how much time is needed for possible assessment of additional data in the corresponding dossier after the initial assessment. However, estimates are available for average dossiers. After validation you will receive an invoice for an advance payment based on the estimated time for the first assessment of your dossier plus the average time required for the second assessment. Depending on the actual scope of the second assessment, this advance payment may be too high or too low. If the advance payment is too low, you will receive an invoice for an additional advance payment during the application process. If the first advance payment is too high, the Ctgb will refund the remaining amount at the end of the application process.

A fixed fee is charged for applications that the Ctgb accepts as a concerned Member State (CMS), applications for Same Biocidal Product, and administrative and minor changes to authorisations.

For additional and/or other services and activities for which no fee has been set, the actual costs incurred will be charged.

The following categories are distinguished for applications submitted under the BPR:

1. Fees and charges for applications for approval of active substances
2. Fees and charges for applications for the authorisation of a product or for the change or renewal of a product authorisation, where Ctgb is the evaluating competent authority (eCA).
3. Fees and charges for applications for the authorisation of a product or for the amendment or renewal of a product authorisation, where the Netherlands is a concerned Member State
4. Fees and charges for other applications or administrative requests

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

For these types of application the actual costs incurred will be charged. The above-mentioned advance payment amounts are an indication based on an average dossier. The advance payment that will be invoiced is determined after completion of the validation. If the advance payment is insufficient to cover all costs, additional costs will be charged.

Type of application	Application type R4BP	Description		Amount
EU-B, TB3EURAP, TB4EURAP	AS-APP, AS-RNL, AS-EVA, AN-APP	Application fees	One product type (PT)	€ 20,000
			Additional fee per PT when approval for multiple PTs is applied for	€ 5,000
		Assessment costs	Simple dossier or a dossier for an application for inclusion in Annex I of Regulation (EU) 528/2012	€100,000
			Average dossier	€200,000
			Complex dossier	€250,000
		Costs for activities related to European decision-making		€ 75,000

2. Fees and charges for applications for the authorisation of a product or for the amendment or renewal of a product authorisation, where the Ctgb is the evaluating competent authority (eCA) – Subsequent

costing

For these types of application the actual costs incurred will be charged. The above-mentioned advance payment amounts are an indication based on an average dossier. The advance payment that will be invoiced is determined after completion of the validation. If the advance payment is insufficient to cover all costs, additional costs will be charged.

Type of application	Application type R4BP	Description	Amount single product	Amount product family
Union application:				
B-UTN, B-UTH B-UTFN, B-UTFH	UA-APP	Application fees	€ 10,000	€ 15,000
		Assessment costs	€ 60,000	€ 85,000
National application:				
B-TN, B-TH, B-TFN, B-TFH	NA-APP	Application fees	€ 10,000	€ 15,000
		Assessment costs	€ 35,000	€ 60,000
Simplified application:				
B-ET, B-ETF	SA-APP	Application fees	€ 2,500	€ 5,000
		Assessment costs	€ 7,500	€ 12,000
Renewal of an authorisation:				
B-TR, B-TRF	NA-RNL	Application fees	€ 10,000	€ 15,000
		Assessment costs	€ 35,000	€ 60,000
Major change to an authorisation:				
B-GW, B-GWF	NA-MAC, SA-MAC, UA-MAC	Application fees	€ 10,000	€ 15,000
		Assessment costs	€ 35,000	€ 60,000

3. Fees and charges for applications for the authorisation of a product or for the amendment or renewal of a product authorisation, where the Netherlands is Concerned Member State (CMS) - Fixed fees and charges

Type of application	Type R4BP	Description	Amount single product	Amount product family
Mutual recognition in parallel:				
B-TWENP B-TWEHP B-TWEFNP B-TWEFHP	NA-MRP	Application fees	€ 3,860	€ 5,435
		Evaluation costs	€ 7,725	€ 9,580
		Additional costs:		
		Comparative assessment	€ 1,430	€ 1,430
		Additional active substance	€ 715	€ 715
		Extra PT	€ 1,000	€ 1,000
		For more than 5 meta-SPCs, an add-on fee is charged for each additional meta-SPC	n/a	€ 1,000

Type of application	Type R4BP	Description	Amount single product	Amount biocidal product family
Mutual recognition in sequence:				
B-TWENS B-TWEFNS	NA-MRS	Costs (application + evaluation)	€ 11,585	€ 14,875
		Additional costs:		
		Comparative assessment	€ 1,430	€ 1,430
		Additional active substance	€ 715	€ 715
		Extra PT	€ 1,000	€ 1,000
				For more than 5 meta-SPCs, an add-on fee is charged for each additional meta-SPC

Type of application	Type R4BP	Description	Amount single product	Amount product family
Renewal of an authorisation:				
B-TWER, B-TWERF	NA-RNL	Application fees	€ 3,860	€ 5,435
		Evaluation costs	€ 7,725	€ 9,580
		Additional costs:		
		Comparative assessment	€ 1,430	€ 1,430
		Additional active substance	€ 715	€ 715
		Extra PT	€ 1,000	€ 1,000
		For more than 5 meta-SPCs, an add-on fee is charged for each additional meta-SPC	n/a	€ 1,000

Type of application	Type R4BP	Description	Amount single product	Amount product family
Major change to an authorisation:				
B-GWC, B-GWFC	NA-MAC	Application fees	€ 3,860	€ 5,435
		Evaluation costs	€ 7,725	€ 9,580

4. Fees and charges for other applications or administrative requests biocidal products* – Fixed fees and charges

Type of application	Type R4BP	Description	Amount
Administrative change to an authorisation:			
B-AW, B-AWF	NA-ADC, NA-TRS, NA-CCL, NA-MRG, SA-ADC, SA-TRS, UA-ADC, UA-TRS	Application for administrative change for a single product or biocidal product family in accordance with Implementing Regulation (EU) 354/2013	€ 285
Minor change to an authorisation:			
B-KW, B-KWF	NA-MIC, SA-MIC, UA-MIC	Application for minor change for a single product or biocidal product family in accordance with Implementing Regulation (EU) 354/2013	€ 1,290
Same Biocidal Product:			
B-ST, B-STF, B-STR en B-STFR	NA-BBS, NA-BBP, SA-BBP, NA-RNL	Application for authorisation or renewal of a product or a biocidal product family using the procedure in Implementing Regulation (EU) 414/2013 and (EU) 1802/2016 (Same biocidal product)	€ 1,430
		Additional costs for families (per 5 products)	€ 645
		Additional costs for simultaneous administrative change	€ 285
Other applications:			
B-FL	NA-NPF, SA-NPF, UA-NPF	Application to add a product to a biocidal product family	€ 1,430
PB	ET-NOT	Notification of experiment or trial	€ 575
PAB, VPAB, UPAB,	PP-APP	Application for parallel trade permit	€ 860
IKV-B	UE-NOT NE-NOT SE-NOT	Application fee for Obligatory Notification biocidal products (reporting new information)	€ 285
B-EM	SN-NOT	Notification of simplified authorisation, authorised in another Member State	€ 285

*If an assessment is required, the actual costs incurred will be charged.

Chapter 8b - Fees and charges Biocidal products (Transitional legislation) – Fixed fees and charges

General

If one or more active substances for the specified Product Types is not yet included on the Union list of approved substances or Annex I of Regulation (EU) No. 528/2012, then Transitional legislation is in force.

Fixed fees and charges will be invoiced for applications under Transitional legislation. Reduced fees and charges will be invoiced if a comparison can be made in the assessment with a currently authorised product.

For additional and/or other services and activities for which no fee has been set, the actual costs incurred will be invoiced.

The following categories are distinguished for applications under Transitional legislation:

1. 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
2. Fees and charges for renewal of an authorised product
3. Changes and other applications

1. 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 for authorisation, or major change to an authorisation	
TB, TBL, UB, WB	Application costs	€ 5,150
TB	Assessment costs for a complete assessment	
	Efficacy	€ 2,145
	Physicochemical properties of the product	€ 1,000
	Criteria with respect to public health and operator	€ 1,575
	Environmental behaviour and environmental fate	€ 2,145
	Project supervision	€ 2,575
	Evaluation of summaries and studies concerning physicochemical properties, analytical methods, efficacy, human toxicology and environmental fate	Actual costs incurred
TBL, UB, WB	Assessment costs for a limited assessment	
	Efficacy	€ 575
	Physicochemical properties of the product	€ 285
	Criteria with respect to public health and operator	€ 575
	Environmental behaviour and environmental fate	€ 575
	Project supervision	€ 1,715
KB	Application for establishing frame formulation	€ 2,860

2. Fee for renewal of an authorised product

Type of application	Description	Amount
TVB*	Renewal of an authorised product	€ 5,150

*If an assessment is required, the actual costs incurred will be charged.

3. Changes and other applications

Type of application	Description	Amount
WBA	Administrative change biocidal product This concerns an administrative change according to Implementing Regulation (EU) 354/2013	€ 286
WBK	Minor change biocidal product This concerns a minor change according to Implementing Regulation (EU) 354/201	€ 858
Change of production location of product		No fee charged

Other applications*		
AB, VAB, UAB	Application for authorisation, renewal or extended authorisation of a derived biocidal product	€ 858
PAB, VPAB, UPAB	Parallel trade permit for a biocidal product, renewal of parallel trade permit for a biocidal product, other applications concerning parallel trade permits for biocidal products	€ 858
EXV	Export declaration	€ 286
VIB	Request for information on animal testing of biocidal product	€ 572
ART46**	Exemptions of biocidal products in accordance with Regulation (EU) 528/2012 art. 55	Actual costs incurred

*If an assessment is required, the actual costs incurred will be charged.

** The commencement date of this application type will be announced in the course of 2021

Chapter 8c - Annual fee plant biocidal products

Annual fee biocidal product

AF	Annual fee	Amount
	<i>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.</i>	
	Authorisation of a biocidal product	€ 1,270
	Authorisation biocidal family	€ 1,075
	Additional charge per family member	€ 205
	The maximum fee that will be charged for a family is € 5,050 per year.	