Ctgb Tariffs Decree 2017

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 and the corresponding appendixes:

Chapter 1 - 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. the Board: the Board for the Authorisation of Plant Protection Products and Biocidal Products (Ctgb) as referred to in Article 3 of the Act
h. our Minister: the Minister referred to in Article 1 of the Act
i. new active substance:
    i. (plant protection products)
        1. an active substance as referred to in Article 30 of the Plant Protection Regulation, or
        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) active substance as referred to in Article 3 clause 1e of the Plant Protection Regulation
j. 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

k. European applications: applications for the approval or amendment of the approval of an active substance, as referred to in Article 7 of the Plant Protection 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 Ctgb Tariffs Decree Ctgb 2016 is withdrawn.

4. Entry into force
This Decree shall take effect, retroactively to the extent necessary, on 1 January 2017, following approval by Our Minister and publication in the *Staatscourant*.

5. Official title
The official title of this Decree is "**Tarievenbesluit Ctgb 2017**" (Ctgb Tariffs Decree 2017).

Approved by the Board for the Authorisation of Plant Protection Products and Biocidal Products on 28 September 2016,

the Chair,

ir. J.F. de Leeuw

Chapter 3 - Fees and charges, Service Desk

Requests	Description	Tariff 2017
Category		
1	Up to 4 hours	No fee charged
2	4 hours and more	Actual costs on the basis of subsequent costing
3	Request for meeting (RFM)	Actual costs on the basis of subsequent costing
4	Pre-submission meeting (PSM)	Actual costs incurred on the basis of subsequent costing, with an advance payment of € 10,000
5	Pre-application support process for applications B-TFN, B-UTN and B-UTFN	Actual costs incurred on the basis of subsequent costing, with an advance payment of € 5,000
6	Briefing/informational meeting (general)	€ 195
7	Workshop	For the record only

Chapter 4 - Plant Protection Products

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

Type of application	Description	Tariff 2017
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 fees	€ 12,500
	Summarisation and assessment (prepare DAR or RAR)	Actual costs incurred with advance payment of € 150,000
	Activities related to the completion of an approval or renewal of an application for an active substance (Peer review; European decision-making)	Actual costs incurred with advance payment of € 75,000
TGEURAPM, TGEURPRM	**Ctgb rapporteur for application for initial approval or renewal of an active substance based on micro-organisms, pheromones or a comparable active substance**	
	Application fees	€ 9,000
	Summarisation and assessment (prepare DAR or RAR)	Actual costs incurred with advance payment of € 40,000
	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 € 40,000
TGEUCORA	**Ctgb Co-rapporteur AIR substance dossier**	
	Fee for reviewing and commenting on substance assessment RMS	Actual costs incurred with advance payment of € 20,000
	Summarisation and assessment (prepare DAR or RAR) *(only if parts of the DAR/RAR must be prepared in consultation with the RMS)*	Actual costs incurred with advance payment of € 50,000
	Co-rapporteur (type AIR) activities to complete an approval or a renewal of the application for an active substance (peer review and European decision-making) *(only if parts of the DAR/RAR must be prepared in consultation with the RMS)*	Actual costs incurred with advance payment of € 25,000
TGEURPCD	**Ctgb rapporteur for the assessment of confirmatory data**	
	Assessment of confirmatory data	Actual costs incurred with advance payment of € 15,000

Fees and charges for plant protection applications, product applications

Product applications based on subsequent costing

Type of application	Description	Tariff 2017
Zonal applications for which the Ctgb is rapporteur (the Netherlands is zonal rapporteur Member State). • New application (ZTG) • Application to amend current authorisation (ZWTG) • Renewal (ZRG) • Voluntary zonal renewal (ZTHG)	*Processing and assessment (advance payment type 1)* Regular zonal applications	Actual costs incurred with advance payment of € 50,000 *
	Processing and assessment (advance payment type 2) Zonal applications based on a micro-organism, pheromone or plant extract (low risk). Zonal applications to amend current authorisation based on a recent dRR.	Actual costs incurred with advance payment of € 30,000 *
	Application costs ZRG applications (renewal of a product authorisation with the Netherlands as zRMS), for which postponement has been granted for submitting the dRR. *This amount will be deducted from advance payment type 1 and 2 after submitting the DRR.*	€ 10,000
NLKUG, NLKUGH	Application to extend an existing authorisation in the Netherlands (not zonally) with **Minor Uses** only	Actual costs incurred with advance payment of € 8,000 *

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

Application fees for product authorisations based on fixed tariffs

An application and assessment fee is charged for these applications.

Type of application	Description	Application fee
NLTG, NLWTG, NLRG, NLTHG,	**CMS application** Zonal applications for which the Ctgb is not rapporteur (the Netherlands is CMS) • New application (NLTG) • Application to amend current authorisation (NLWTG) • Renewal (NLRG) • Voluntary zonal renewal (NLTHG)	€ 8,960
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	€ 4,096
THG	**Renewal,** non-zonal (Article 80 Regulation (EC) No 1107/2009)	€ 6,912
NLWG	**Application to amend current authorisation** National request for amendment (national addendum) of an authorisation	€ 2,560

Assessment fees for product authorisations based on fixed tariffs

The assessment fees for these types of applications are based on applications with 1 active substance, with up to 5 uses (GAP regulations) and 1 dRR zone. Additional fees are charged if a product contains multiple active substances, if there are more than 5 uses and/or if there is more than 1 dRR.

For the purpose of applications for mutual recognition and applications whereby only the national addendum is assessed
NLTG, NLWTG, NLRG, NLTHG, NLWERG, NLWERGZ, NLWG

Aspect	**Assessment fee 2017**
Efficacy	€ 1,024
Physicochemical properties of the product, each active substance present in the product, respectively	€ 640
Criteria with respect to public health	€ 512
Criteria with respect to the operator	€ 1,280
Environmental behaviour and environmental fate	€ 1,920
Ecotoxicology	€ 2,560
Final assessment of the authorisation aspects	€ 2,432
Total	**€ 10,368**

For the purpose of applications for mutual recognition and national addendum for products based on micro-organisms, pheromones or comparable active substances
NLTG, NLWTG, NLRG, NLTHG, NLWERG, NLWERGZ, NLWG,

Aspect	**Assessment fee 2017**
Efficacy	€ 1,536
Physicochemical properties of the product, each active substance present in the product, respectively	€ 640
Criteria with respect to public health and the operator	€ 1,024
Environmental behaviour, environmental fate and ecotoxicology	€ 1,280
Final assessment of the authorisation aspects	€ 2,432
Total	**€ 6,912**

Fees and charges for assessments, general
THG, TG, WYG, PWSG, MRL, MTR, IKV

Aspect	**Assessment fee 2017**
Efficacy	€ 1,536
Physicochemical properties of the product, each active substance present in the product, respectively	€ 1,024
Criteria with respect to public health	€ 2,560
Criteria with respect to the operator	€ 2,432
Environmental behaviour and environmental fate	€ 2,304
Ecotoxicology	€ 4,480
Final assessment of the authorisation aspects	€ 2,432
Total	**€ 16,768**

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

Activities	Tariff 2017
Each additional active substance	€ 1,792
1 to 5 additional uses	€ 768
Tankmix	€ 1,792
Additional dRR	€ 8,960
Restriction during the assessment (e.g. interim amendment WG/GAP, change in use, etc., without modifying assessment.)	€1,024
Evaluation of summaries and studies concerning physico-chemical properties, analytical methods, efficacy, human toxicology and environmental fate and ecotoxicology	Actual costs incurred based on the estimated hours
Application of Guidance Document on aquatic organisms	€ 1,024
Application of Guidance Document on birds and mammals	€ 1,536
Application of Guidance Document DEGT50 (EFSA, 2014)	€ 256
Application of FOCUS Guidance Document Groundwater (EFSA, 2014)	€ 2,048
Application of Guidance Document on honeybees and other pollinators	For the record only
Application of Guidance Document on protected cultivation	€ 512
Comparative Assessment according to Article 50 Regulation (EC) 1107/2009 CA 1: Intake Agronomic assessment CA 2: Risk assessment	 € 744 Per use€ 744 Actual costs incurred based on the estimated hours

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

Type of application	Description	Tariff 2017
Administrative amendment		
WNT, WNAW, OT	Amendment of name authorised product, Amendment of name, address and/or city of the authorisation holder Transfer of authorised product to a different company	€ 256
INTR	Withdrawal of an authorisation of a plant protection product	No fee charged
Minor changes		
WSGNW	Minor change in the formulation	€ 832
Add or change product manufacturer, change production location	Change product production process (transitional legislation)	No fee charged
NLWATG	Minor amendment of WG-GA/WG including restricting scope of permitted use. (for which GAP is not changed and no risk assessment is required)	€ 256
Other types of authorisations		
AG, VAG, UAG, NLWERGV	**Derived applications** New derived authorisation Renewal of derived authorisation Extension of derived authorisation Administrative renewal of an authorisation obtained by mutual recognition	€ 832
	Parallel trade applications	

PAG, VPAG, UPAG, BPAG	Parallel trade permit Renewal of parallel trade permit Extension of parallel trade permit New batch for parallel import	€ 832
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	€ 256
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	€ 320
PGR	**Exemption for trial purposes** Supplement for use on 5 crops uses the applicant wants to enter the food chain (regulations in the table)	€ 128
VIG	Request for **information on animal testing**	€ 512
	Mediating the exchange of animal testing data	Actual costs incurred
TT	Application for adjuvant	€ 832
EXV	Export declaration	€ 256
	EU MRL assessment in accordance with Article 12 of 396/2005 (preparing Evaluation Report)	€ 640
WGF, WGI	**Conversion of WGGA to WG or update WG**	
	Authorisation holder provides WG and meets the conditions	€ 832
	Authorisation holder does not provide WG or WG does not meet conditions for up to 5 uses	€ 1,280
	Supplement for each group of 5 uses if authorisation holder does not supply WG or WG does not meet conditions	€ 256
	Conversion of WGGA to, or an update of, WG for parallel trade permits or amended authorisations	€ 384
	Conversion of legal conditions for use (WGGA) to WG1.0 to WG2.0	€ 256
	Exemption as referred to in Article 53 of Regulation (EC) 1107/2009	*fees and charges, see Rgb Staatscourant no. 63105, 30 November 2016*

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

Type of application	**Description**	**Tariff 2017**
WYG	Changes to packaging, shelf life or labelling	€ 384
PWSG	Change in production process of active substance and/or additional production location of the active substance. Equivalence through Tier I not yet assessed in another Member State	€ 1,280
	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	€ 256
MRL	Derivation of Maximum Residue Limit (MRL)	€ 832
MTR	Applications to derive norm as part of the Water Framework Directive	€ 832
	Notification obligation	
IKV	Regulation (EC) No. 1107/2009 Article 56, first clause or fourth clause (substantive)	€ 832
IKV	Regulation (EC) No. 1107/2009 Article 56, fourth clause (administrative)	€ 256

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

Type of application	Description	Tariff 2017
All applications	Evaluation of summaries and studies concerning physico-chemical properties, analytical methods, efficacy, human toxicology, environmental fate and ecotoxicology	Actual costs incurred based on the estimated hours

Annual fee plant protection product

	Annual fee	
JV	Annual fee plant protection product	€ 1,419

Chapter 5 - Biocidal Products

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

Type of application	Application type R4BP 3	Description	Tariff 2017
		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)	
B-UTFN, B-UTFH	UA-APP	Union Authorisation for a biocidal product family where the Netherlands is the evaluating competent authority (new product or re-registration)	
B-TN, B-TH	NA-APP	National authorisation of biocidal product (new product or re-registration)	
B-TFN, B-TFH	NA-APP	National authorisation of biocidal product family (new product or re-registration)	
B-TPR, B-TPRF		Provisional authorisation (biocidal product or family)	
B-TR, B-TRF	NA-RNL	Renewing an authorisation (biocidal product or family)	
B-GW, B-GWF	NA-AAT, NA-MAC	Major change of an authorisation (biocidal product or family) for which the Netherlands is the evaluating competent authority	
		Standard tariff	
		Application fees	€ 6,912
		Assessment costs, physico-chemical properties and analysis methods	€ 1,536
		Assessment costs, efficacy	€ 4,608
		Assessment costs, human toxicology	€ 4,608
		Assessment costs, environmental aspects	€ 4,992
		Final assessment	€ 2,432
		Total costs for a 'standard' application	**€ 25,088**
		The standard tariff for biocidal product applications is based on a national application (not a Union authorisation), 1 user category, 1 PT, 1 active substance, no Substance of Concern, no comparative assessment and no confidentiality request	
		The tariff for a biocidal product family has the same basis as an application for a biocidal product	
		Additional fees and charges for activities not covered by the standard tariff:	
		Comparative assessment	€ 11,392
		Family (basic fee)	€ 11,392
		Family (per family member)	€ 1,280
		Extra user category	€ 1,792
		Extra PT	€ 1,792
		Extra active substance	€ 1,792
		Substance of concern (per substance)	€ 1,792
		Union authorisation (NL is evaluating competent authority)	€ 4,352
		Confidentiality request (per item)	€ 128
		Summarising and/or evaluating studies on physico-chemical properties, analytical methods, efficacy, human toxicology and environmental aspects	actual costs incurred based on the estimated hours
		Applications for mutual recognition (NL is concerned Member State)	

B-TWENP B-TWEHP	NA-MRP	All-in-one tariff for mutual recognition (in parallel) of a single product (not a family)	€ 7,296
B-TWENS B-TWEHS	NA-MRS	All-in-one tariff for mutual recognition (in sequence) of a single product (not a family)	€ 7,296
B-GWC, B-GWFC	NA-AAT NA-MAC	All-in-one tariff for major amendment of an authorisation (biocidal product or family) for which the Netherlands is the concerned Member State.	€ 7,296
		The standard tariff for mutual recognition of a family has the same basis as an application for mutual recognition of a regular authorisation.	
		Additional fees and charges for activities not covered by the standard tariff:	
		Comparative assessment	€ 1,240
		Family (per family member)	€ 896
		Extra user category	€ 896
		Extra PT	€ 896
		Extra active substance	€ 896
When submitting an application for mutual recognition in parallel, the fees and charges in force at that time are invoiced. If the fees and charges have changed when the mutual recognition in parallel can actually be implemented, an additional invoice will be issued to settle the difference.			
		Simplified authorisation	
B-ET, B-ETF	SA-APP	Simplified authorisation	€ 7,296
B-ETN, B-ETFN	SA-APP	Renewal of a simplified authorisation (single product or family)	€ 896
		The standard tariff for biocidal product applications is based on 1 user category, 1 PT, 1 active substance and no confidentiality request.	
		The tariff for a biocidal product family has the same basis as an application for a biocidal product	
		Additional fees and charges for activities not covered by the standard tariff:	
		Family (basic tariff)	€ 896
		Family (per family member)	€ 896
		Extra PT	€ 896
		Extra active substance	€ 896
		Confidentiality request (per item)	€ 128
		Summarising and/or evaluating studies on physico-chemical properties, analytical methods, efficacy, human toxicology and environmental aspects	actual costs incurred based on the estimated hours
		Simplified authorisation notification	
B-EM	SN-NOT	Notification of simplified authorisation, authorised in another Member State	€ 1,536
		Authorisation according to the procedure of 'the same biocidal product'	
B-ST	NA-BBS, NA-BBP	All-in-one tariff for same biocidal product, single product (not a family)	€ 1,664
		The standard tariff for 'same biocidal product' applications is based on a national application without simultaneous administrative changes.	
		The standard tariff for 'same biocidal product family' has the same basis as an application for a regular authorisation of a 'same biocidal product'.	
		Additional fees and charges for activities not covered by the standard tariff:	
		Family (per family member)	€ 256

		Simultaneous administrative change	€ 256
		Other tariffs biocidal products	
If necessary, assessment costs can be charged for the applications listed below. These costs are determined in advance based on an estimate of the actual costs incurred.			
B-FL	NA-NPF	Adding a product to a biocidal family	€ 1,280
B-AW	NA-ADC	Amendment of authorisation: administrative amendment	€ 256
B-KW	NA-MIC	Amendment of authorisation: minor change, conversion of WG/GA to SPC at the request of the authorisation holder	€ 1,536
PB	ET-NOT	Notification of experiment or trial	€ 512
		Parallel trade permit	
PAB,VPAB, UPAB,BPAB	PP-APP	All-in-one tariff	€ 832

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

Type of application	**Description**	**Tariff 2017**
	Application costs	
TB, TBE, UB, WSB	Application costs for authorisation, extended authorisation, amendment	€ 5,120
KB	Determination of frame formulation	€ 2,560
TVB	Extension of approval period	€ 2.816
TB, TBE, UB, WSB, WYB, TVB	**Assessment costs**	
	Efficacy	€ 1,280
	Physicochemical properties of the product, each active substance present in the product, respectively	€ 1,536
	Criteria with respect to the operator and public health	€ 2,304
	Environmental behaviour and environmental fate	€ 2,304
	Final assessment of the authorisation aspects	€ 2,432
	Total assessment costs for a 'standard' application; the application costs are charged separately	**€ 9,856**
TB, UB, TBE	If comparative assessment is used (tariff per aspect)	€ 896
	Application costs and assessment costs combined	
DVB	Complete assessment urgently needed biocidal product	€ 11,008
	Other applications	
	If necessary, assessment costs can be charged for the applications listed below. These costs are determined in advance based on an estimate of the actual costs incurred.	
AB, VAB, UAB	Authorisation, extension of approval periods or extension of range of uses of derived biocidal product	€ 832
WWGGA	Amendment WGGA (editorial)	€ 256
WSBNW	Application for a minor change in the biocide formulation	€ 832
PAB, VPAB, BPAB, UPAB	Parallel authorisation biocidal product, extension of parallel authorisation of biocidal product, other applications concerning parallel authorisation of a biocidal product	€ 832
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	€ 256
WYB	Amend packaging or labelling of a biocide, other amendments (editorial)	€ 384
EXV	Export declaration	€ 256
VIB	Request for information on animal testing of biocidal product	€ 512
	Mediating the exchange of animal testing data	Actual costs

		incurred
Change of production location of product under transitional legislation		No fee charged

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

Type of application	Application type R4BP 3	Description	Tariff 2017
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	€ 12,500
		Summarising, evaluating and assessing	
EU-B, TB2EURAP, TB3EURAP, TB4EURAP	AS-APP, AS-RNL, AS-EVA	Extra evaluation and extra assessments	Actual costs incurred with advance payment of €250,000
EU-B, TB2EURAP, TB3EURAP, TB4EURAP	AS-APP, AS-RNL, AS-EVA	Average evaluation	Actual costs incurred with advance payment of €200,000
EU-B, TB2EURAP, 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, TB2EURAP, 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

Fees and charges for summarising and evaluating studies regarding product data

Type of application	Aspect	Description	Tariff 2017
TB, TBE, UB, WSB, WYB, TVB	efficacy	The efficacy of the pesticide (per application)	€ 1,497
All applications	other aspects	Studies on physico-chemical properties, analytical methods, efficacy, human toxicology and environmental aspects, to be summarised and/or evaluated	actual costs incurred based on the estimated hours

Fees and charges for summarising and evaluating studies regarding substance data

Type of application	Aspect	Description	Tariff 2017
All applications	other aspects	studies on physico-chemical properties, analytical methods, efficacy, human toxicology and environmental aspects, to be summarised and/or evaluated	actual costs incurred based on the estimated hours

Annual fee biocidal product

AF	**Annual fee**	
	Authorisation biocidal product (National)	€ 1,175
	Authorisation biocidal family	€ 1,000
	Additional charge per family member	€ 195
	The maximum tariff that is charged for a family is € 4,900 per year.	
	For placing biocidal products from a product family on the Dutch market, a fee will be charged for both the family and the individual members.	

Explanation Ctgb Tariffs Decree 2017

General

Article 10, first clause of the Plant protection products and biocidal products Act (hereinafter: the Act) stipulates that the costs incurred by the Ctgb during the implementation of activities for which it is responsible according to Article 4 of the Act must be covered by the tariffs charged, which are to be set by the Board. The tariffs are related directly to the costs incurred by the Ctgb and require the approval of the Minister of Economic Affairs and the Minister of Infrastructure and Environment.

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

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

For evaluation of data summaries and studies for plant protection products and biocidal product, 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 applications, for which the actual costs incurred will be charged based on advance payment and subsequent costing.

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

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

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

Actual costs incurred
Actual costs incurred are the internal costs incurred by the Ctgb (the established hourly rate, multiplied by the number of hours spent by the Ctgb) and the actual costs of third parties hired by the Ctgb as part of processing the application (including the VAT paid to such third parties).

Invoicing, payment and subsequent costing/refund
a. The fee payable to the Ctgb is calculated based on the specified items and tariffs.
b. Based on the provisions in the Decree rules of procedure on regulations to authorise plant protection products and biocidal products Ctgb 2007, application costs must be paid when the application is submitted to the Ctgb. An invoice will be issued for this purpose. The Ctgb also accepts – in anticipation of a possible amendment to this point in the Decree rules of procedure on regulations to authorise plant protection products and biocidal products Ctgb 2007 – that the applicant pays in response to the invoice issued by the Ctgb. If an advance payment has been made for the actual costs incurred, this payment is subtracted from the amount owed. If the actual costs incurred are less than the advance payment, the difference is refunded to the applicant within 30 days after date of the final invoice.
d. Notwithstanding the provisions in Article 4:87.1 Awb, for fees or charges other than those referred to under b), the applicant must pay the invoice within 30 days after date of the invoice, stating the invoice number.

Adjustment of the advance payment
Preceding the submission of an application, the prospective applicant can request the Ctgb to make an estimate of the actual costs of that application and adjust the advance payment accordingly; this estimate is based on information provided by the prospective applicant. In that case, in consultation with the applicant an advance payment for the application is determined based specifically on the dossier to be submitted. By doing so, the Ctgb hopes to encourage the submission of complete and adequate dossiers, which saves time and therefore results in a lower advance payment and lower final invoice.

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

Payment in instalments
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 no more than € 30,000, this amount may be paid in up to three 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.

Basic assumptions and premises
The Biocidal Products Regulation requires Member States to take a number of matters into account, some of which are new for the Ctgb:

- 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)

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

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

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.

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

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

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

Reduced tariff for clustered applications
If multiple applications are submitted simultaneously, for which a cluster assessment can be made on one or more aspects

of multiple applications, at the request of the applicant the Ctgb can charge a reduced tariff for these aspects.

If there are multiple applicants, each applicant is jointly and severally liable for paying the entire amount to the Ctgb. The Ctgb does not become involved with the mutual payment arrangements between applicants.

Frame formulation
The applicant for an authorisation of a biocide can request the Ctgb to ascertain that the corresponding biocide 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.

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

Other fees and charges
Regarding activities for which a fixed fee or charge cannot yet be determined, the cost price (actual costs incurred) will be charged. This takes place following consultation with the applicant.

Changes in 2017

Hourly rate 2017
The hourly rate charged by the Ctgb has been indexed and will increase by 3% in 2017 to € 128 per hour.

Annual fees, general
For the registration of an authorised plant protection product and biocidal product, an annual fee is charged.

Annual fees (plant protection products)
The annual fee for plant protection products is not indexed in the same way as the hourly rate, but will increase by € 119 relative to 2016, and is set at: € 1,419. This increase is the result of activities for which the Ctgb is obligated to charge beginning in 2017 via the annual fee based on the provisions in Article 44 of Regulation (EC) No. 1107/2009 *(Letter: Ministry of Economic Affairs, dated 12 December 2016 DGAN-PAV/16183632).*

Annual fees (biocidal products)
The annual fee for biocidal products in 2017 is not indexed in the same way as the hourly rate, but will increase by € 5 (0.4%) relative to the fee in 2016. The fee has not been indexed with 3% and can remain virtually the same because the number of authorised biocidal products on 1 February 2017 (the reference date) is expected to be higher than that in 2016.

For a biocidal product family, a separate annual fee is charged; in addition, a limited fee is charged for each family member. The total fee for a biocidal product family including the family members is subject to a maximum. The fees will not increase relative to 2016.

Fee for final assessment plant protection products and biocidal products
The fee for the final assessment has been increased. The administrative burden has become greater because dossier data and decisions must be entered and recorded in multiple European systems.

Additional fees and charges (general)
As a supplement to the standard assessment costs for plant protection products and biocidal products, there are additional fees and charges. These fees and charges apply to activities that are not covered by the standard assessment costs.

Changing the packaging for plant protection products and biocidal products
This fee will increase from € 248 to € 372.

Additional fees and charges (plant protection products):
Product applications that involve a tankmix are given an additional assessment. An additional fee for this assessment is charged. Moreover, due to new guidances, an additional fee is charged for a number of uses.

Active substance applications, plant protection products
The advance payment for active substance applications for the final phase of an active substance assessment based on a micro-organism has been increased. During this phase there is intensive contact with the EFSA.
The same applies to the fee for Co-rapporteur of active substances covered by AIR. This advance payment has also been increased.

Comparative Assessment (plant protection products)
A new item is the Comparative Assessment fee. It has been agreed that this fee will be invoiced in two instalments: firstly, the intake and the agronomic assessment, and secondly the risk assessment, which will be invoiced on the basis of actual costs incurred.

Renewal (ZRG)
An additional fee has been introduced for ZRG applications (renewal of a product authorisation with the Netherlands as zRMS), for which postponement has been granted for submitting the dRR. When a definitive dRR is submitted, this amount will be deducted from the actual costs incurred.

Fees and charges for summarising and evaluating studies (plant protection products).
The list of fees for evaluating and summarising studies has lapsed. The actual costs incurred will now be charged.

Assessment costs for mutual recognition and applications for which only the national addendum will be assessed (plant protection products)
A distinction has been made between chemical dossiers, dossiers for products based on micro-organisms and assessments of renewals.
During the assessment of chemical dossiers, a shift has taken place between the items in favour of the fees and charges for FCE and the final assessment. The final phase of a decision requires more and more time (publication on Circa the website, sanitising).

Assessment costs for applications for mutual recognition and national addendum for products based on micro-organisms,

pheromones or comparable active substances
The assessment costs at the aspect level have been reduced; the fee for the final assessment has also been increased for these applications.

Plant protection products, minor change NLWATG
The fee for minor changes to the WG-GA/WG, including restrictions on the scope of permitted use, has been reduced from € 806 to € 248

Conversion of WGGA to WG or update WG
A graduated fee scale has been implemented for the WGGA conversion; as a result, the fees for applications with many crops now cover the actual costs incurred.

Biocidal product applications for mutual recognition (NL is concerned Member State)
A fee for comparative assessment involving mutual recognition has been implemented. This fee is lower than when we perform the comparative assessment ourselves; the Ctgb only checks whether the specific conditions in the Netherlands have been correctly taken into account in the comparative assessment.

Biocidal products, amending the WWGGA
The fee for amending the WWGGA has been reduced from € 806 to € 256.

Exemption for trials with biocidal products
The fee for granting an exemption for trials under transitional legislation has expired; all exemptions now fall under the BPR.

Changing the production process of active substance in biocidal products
The fee for changing the production process of the active substance has expired; this has been reported to ECHA *(all active substances must be listed in Article 95).*

Service desk
As of 1 January 2017, the categories have changed:
- No fee is charged for questions requiring *up to* 4 hours;
- The standard hourly rate is charged after 4 hours.