Ctgb Tariffs Decree 2016

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) 528/2012 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) 1991/414 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 528/2012/EC 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 I - 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 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 2015 is withdrawn.

4. Entry into force
This Decree shall take effect, retroactively to the extent necessary, on 1 January 2016, following approval by Our Minister and publication in the *Staatscourant*.

5. Official title
The official title of this Decree is "**Tarievenbesluit Ctgb 2016**" (Ctgb Tariffs Decree 2016).

Approved by the Board for the Authorisation of Plant Protection Products and Biocidal Products on 23 September 2015 (V2.0) and 31 October 2015 (V3.0).

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

the Chair,

ir. J.F. de Leeuw

Chapter 3 - Fees and charges, Service Desk

Requests	**Description**	**Tariff 2016**
Category		
1	Up to 1 hour	€ 124
2	Up to 2 hours	€ 248
3	Up to 4 hours	€ 496
4	Up to 6 hours	€ 744
5	Up to 8 hours	€ 992
6	Up to 10 hours	€ 1,240
7	Up to 12 hours	€ 1,488
8	12 hours and more	Actual costs on the basis of subsequent costing
9	Request for meeting (RFM)	Actual costs on the basis of subsequent costing
10	Pre-submission meeting (PSM)	Actual costs incurred with advance payment of €10,000
11	Pre-application support process for applications B-TFN, B-UTN and B-UTFN	Actual costs incurred with an advance payment of €5,000
12	Briefing/informational meeting (general)	€ 175
13	Workshop	for the record

Chapter 4 - Plant Protection Products

Fees and charges for applications, plant protection products

Type of application	**Description**	**Tariff 2016**
ZTG, ZVTG, ZWTG, ZWXTG, ZTHG, ZRG, ZETG, ZEVTG, ZERG, ZEWTG, ZETHG, ZOVTG, ZEOVTG	**Applications for which Ctgb is rapporteur (NL is ZRMS)**	
	Processing costs (advance payment Type 1)	Actual costs incurred with advance payment of €30,000
	Processing costs (advance payment Type 2)	Actual costs incurred with advance payment of €50,000
NLKUG, NLKUGH	Application to extend an existing authorisation in the Netherlands (not zonally) with minor uses only#	Werkelijke kosten met voorschot van € 8,000
NLTG, NLTHG, NLRG, NLVTG, NLWTG	Applications for which Ctgb is not rapporteur (**NL is CMS**) #	€ 8,680
NLWERGZ, NLWERG	Application for mutual recognition #	€ 3,968
THG, TGV, UGV	Application for re-registration/provisional authorisation (non-zonal) #	€ 6,696
NLWG	National request for amendment (national addendum) of an authorisation for a plant protection product#	€ 2,480
	# The assessment fees for these types of applications are based on applications with 1 active substance, up to 5	

	uses (and 1 dRR zone)	

Fees and charges for other applications, plant protection products

Type of application	Description	Tariff 2016
MRL	Application to derive Maximum Residue Limit	€ 806
AA-EQS/MAC-EQS (MTR)	Application to derive Maximum Permissible Risk	€ 806
AG, VAG, UAG, NLWERGV	Application for derived authorisation, renewal or extension of a derived authorisation, renewal of an authorisation obtained via mutual recognition	€ 806
PAG, VPAG, UPAG, BPAG	Application for parallel trade permit, renewal of parallel trade permit, extended scope of parallel trade permit or new batch for parallel import	€ 806
TT	Application for adjuvant	€ 806
PWSG	Application for equivalence assessment for a plant protection product and/or change of production process (including new/additional production location) and/or the production location of the active substance of a plant protection product	€ 806
WSGNW	Application for a minor change in the formulation	€ 806
NLWATG	Application for national amendment of an authorisation for a plant protection product (in which GAP is not changed and no risk assessment is required)	€ 992
WNT, WNAW, OT	Application for 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	€ 248
WYG	Application for change in packaging, change in labelling, administrative changes	€ 248
EXV	Export declaration	€ 248
PGN	Application for permit to use a plant protection product for trial purposes where the treated crops do **not** enter the food chain	€ 248
PGR	Application for permit for plant protection trial purposes where the treated crops enter the food chain, base amount	€ 310
PGR	Additional amount per 5 crops that will enter the food chain	€ 126
VIG	Request for information on animal testing	€ 494
-	Mediating the exchange of animal testing data	Actual costs incurred
WGH, WGF, WGI	**Conversion of WGGA to WG or update WG**	
	Authorisation holder provides WG and meets the conditions	€ 806
	Authorisation holder does not submit WG, or WG does not meet the conditions	€ 1,240
	Conversion of WGGA to, or an update of, WG for parallel trade permits or amended authorisations	€ 372
	Conversion of legal conditions for use (WGGA) to WG1.0 to WG2.0	€ 248
IKV	**Notification obligation**	
	Regulation (EC) No. 1107/2009 Article 56, first clause or fourth clause (substantive) (advance payment)*	€ 806
	Regulation (EC) No. 1107/2009 Article 56, fourth clause (administrative)	€ 248
JV	**Annual fee**	€ 1,300
	Comparative assessment of crop, see Regulation (EC) No. 1107/2009	Actual costs incurred

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

Type of application		Description	Tariff 2016
TGEURAP, TGEURAPR	**Application Costs**	Application for approval or renewal of an active substance	€ 12,500
TGEURAPM, TREURAPRM		Application for approval or extension of approval of an active substance consisting of micro-organisms, plant extracts, pheromones or a comparable substance	€ 9,000
TGEUCORA		Co-rapporteur (type AIR) activities *	€ 12,500
TGEURAP, TGEURAPR	**Summarisation and assessment (preparing monograph)**	Summarisation and assessment (application for approval or extension of approval period of an active substance) (**advance payment**)*	Actual costs incurred with advance payment of € 150,000
TGEURAPM, TREURAPRM		Summarisation and assessment (application for approval or renewal of the application for an active substance consisting of micro-organisms, pheromones or a comparable substance) (**advance payment**)	Actual costs incurred with advance payment of € 40,000
TGEURAPCD		Assessment of confirmatory data **(advance payment)***	Actual costs incurred with advance payment of € 15,000
TGEUCORA		Co-rapporteur (type AIR): summarisation and assessment **(advance payment)***	Actual costs incurred with advance payment of € 50,000
TGEURAP, TGEURAPR	**Other activities** **(supplementary report)**	Activities to complete an approval or a renewal of the application for an active substance (European decision-making) **(advance payment)***	Actual costs incurred with advance payment of € 75,000
		Activities to complete an approval or a renewal of the application for an active substance consisting of micro-organisms, pheromones or a comparable substance from European decision making (**advance payment)***	Actual costs incurred with advance payment of € 22,000
TGEUCORA		Co-rapporteur (type AIR) activities to complete an approval or a renewal of the application for an active substance (European decision-making) **(advance payment)***	Actual costs incurred with advance payment of € 25,000
		*** Subsequent costing**	Actual costs incurred

Fees and charges, assessment of plant protection products

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

Aspect	Tariff 2016
Efficacy	€ 992
Physico-chemical properties of the product, each active substance present in the product, respectively	€ 372
Criteria with respect to public health	€ 496
Criteria with respect to the operator	€ 1,984
Environmental behaviour and environmental fate	€ 1,860
Ecotoxicology	€ 2,480

Final assessment of the authorisation aspects	€ 1,860
Total	**€ 10,044**

For the purpose of applications for mutual recognition and national addendum for products based on microorganisms, plant extracts, pheromones or comparable substances
NLWERG, NLWERGZ, NLWTG, NLTG, NLTHG, NLRG, NLVTG,

Aspect	**Tariff 2016**
Efficacy	€ 1,488-
physico-chemical properties of the product, each active substance present in the product, respectively	€ 992-
Criteria with respect to public health	€ 1,240-
Criteria with respect to the operator	-
Environmental behaviour and environmental fate	€ 1,240-
Ecotoxicology	-
Final assessment of the authorisation aspects	€ 1,860-
Total	**€ 6,820-**

Fees and charges for assessments, general
THG, TGV, MRL, AA-EQS/MAC-EQS (MTR), IKV, TG, UG, UGV, and other applications

Aspect	**Tariff 2016**
Efficacy	€ 1,488
physico-chemical properties of the product, each active substance present in the product, respectively	€ 992
Criteria with respect to public health	€ 2,480
Criteria with respect to the operator	€ 2,356
Environmental behaviour and environmental fate	€ 2,232
Ecotoxicology	€ 4,340
Final assessment of the authorisation aspects	€ 1,860
Total	**€ 15,748**

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

Aspect	Tariff 2016
Each additional active substance	€ 1,736-
1 to 5 additional uses	€ 744-
Tankmix	€ 1,736-
Additional dRR	€ 8,680-
Restriction during the assessment (e.g. interim amendment WG/GAP, change in use, etc., without modifying assessment.)	€ 992-
Application of Guidance Document on aquatic organisms	€ 992-
Application of Guidance Document on birds and mammals	€ 1448-
Application of Guidance Document DEGT50 (EFSA, 2014)	€ 248-
Application of FOCUS Guidance Document Groundwater (EFSA, 2014)	€ 1,984-
Application of Guidance on honeybees and other pollinators	PM
Application of Guidance on protected cultivation	€ 496-
Comparative Assessment	for the record

Fees and charges for other assessments

Aspect	Tariff 2016
Assessment criteria with respect to the welfare of the animals that are to be controlled	**Actual costs incurred**
EU MRL assessments based on Article 12 (assessment costs)	€ 620

Fees and charges for summarising and evaluating studies regarding product data

Aspect	OECD code	Description	Tariff 2016/Price per study
wzh	3-3.9 and 6	the efficacy of the plant protection product	Actual costs incurred
tox	7.1.1 / 7.1.2 / 7.1.3 / 7.1.14 / 7.1.5 / 7.1.6	determining acute oral toxicity; percutaneous toxicity; inhalation toxicity; skin irritation; eye irritation; skin sensitisation	€ 124
tox	7.1.7	study of combinations of products	actual costs incurred
tox	7.3.1 t/m 7.5.4	data on exposure	€ 1,379
tox	7.6.1 / 7.6.2	in vivo/in vitro study of dermal absorption	€ 1,379
res	8.1.1	Data on storage stability (per study, per matrix)	€ 690
res	8.2	Metabolism and kinetics (per study, per crop group)	€ 1,379
res	8.2	metabolism and kinetics with chicken, goat, cow, pig or other animals (per study, per animal)	€ 1,379
res	8.3	Residue tests (per test)	€ 2,069
res	8.4.1 / 8.4.2 / 8.4.3 / 8.4.	feeding study with chicken, goat, cow, pig or other animals (per study)	€ 1,379
res	8.5.2	pulp and balance study/follow-up study (per study)	€ 690
res	8.5.1	characteristics of the residue during processing	€ 690
res	8.6	determination of residues in succeeding crops (per study)	€ 1,379
res	8.7	number of crop groups to derive MRL (per MRL/group MRL)	€ 345
fat	9.1.1 / 9.1.2	aerobic degradation rate study/aerobic degradation rate study, per study, including kinetic evaluation	€ 1,379
fat	9.10	Monitoring data/additional research	actual costs incurred

fat	9.2.2	Soil residue study	€ 690
fat	9.2.3	Soil accumulation study	€ 1,379
fat	9.2.1	Soil dissipation study	€ 1,724
fat	9.3.1	Leaching from columns	€ 690
fat	9.3.2 / 9.3.3	Lysimetry study/field leaching study, per study	€ 2,069
fat	9.3.3	lysimetry standardisation study/leaching, per study	€ 2,069
fat	- / 9.9	kinetic evaluation (general); degradation rate and route (in the atmosphere), per study	€ 690
eco	10.6.2	acute toxicity earthworms	€ 517
eco	10.1.6	acute oral toxicity for birds	€ 517
eco	10.1.8 / 10.3.2.2.	determination of acceptance of bait, granules or treated seed, per study	€ 1,724
eco	10.1.9 / 10.3.2.3.	determination of effects of secondary poisoning, per study	€ 2,758
eco	10.1.7 / 10.3.3.	studies under field conditions, per study	€ 4,482
eco	10.2.2.1 / 10.2.2.2 / 10.2.2.3	acute toxicity for fish/aquatic invertebrates; effects on algae growth, per study	€ 517
eco	10.2.5.1 / 10.2.5.2 / 10.2.5.3	chronic exposure fish; supplementary study aquatic organisms (Early Life Stage); idem (Fish Life Cycle Test), per study	€ 690
eco	10.2.6.1a	chronic toxicity *daphnia* 21-day study	€ 690
eco	10.2.3	microcosm/mesocosm study	€ 6,034
eco	10.2.6-7 / 10.7.2 / 10.8 / 10.9	supplementary research concerning effects (laboratory data, field studies etc.) on non-target organisms (including soil organisms), per study	actual costs incurred
eco	10.4.3	residue test with bees	€ 690
eco	10.4.2.1 and 10.4.2.2 together	acute toxicity for bees	€ 690
eco	10.4.4 / 10.4.5 / 10.4.7	cage studies/field studies/tunnel studies with bees, per study	€ 2,069
eco	10.5.1 / 10.5.2	studies at standard/larger laboratory scale, per study	€ 690
eco	10.5.2	studies at larger laboratory scale (aged residue), per study	€ 690
eco	10.5.3 / 10.5.4 / 10.8.1.4.	studies under semi-field conditions; field studies (single species); field studies (single species) of terrestrial plants, per study	€ 2,069
eco	10.5.4 / 10.8.1.4.	field tests, field studies (multispecies) (including terrestrial plants), per study	€ 690
eco	10.6.3 / 10.6.5	sublethal effects/bioconcentration (residue) on earthworms, per study	€ 690
eco	10.6.6	effects on other nontarget macro-organisms in the soil, per study	€ 690
eco	10.6.7	litter-bag study	€ 1,379
eco	10.6.4	field study with earthworms	€ 2,758
eco	10.7.1	nitrogen fixation and carbon mineralisation, per study	€ 690
eco	10.8.2	laboratory data about effects on aquatic plants, e.g. *Lemna*, per study	€ 517
eco	10.8.1	laboratory data about effects on non-target plants	€ 690
tox	-	other data on toxicology	actual costs incurred
res	-	other data on residues	actual costs incurred
fce, tox, res, ecotox, fate, wkzh		other activities	actual costs incurred
fce, tox, res, ecotox, fate, wkzh		evaluation of summarised studies	actual costs incurred

Fees and charges for summarising and evaluating studies regarding substance data

Aspect	OECD code	Description	Tariff 2016/Price per study
fce	1 and 4.2	the identity of the active substance and corresponding analysis methods	€ 690
fce	2	the physico-chemical properties of a substance	€ 690
wzh	3-3.6	the efficacy of the plant protection product	Actual costs incurred
fce	4.4 / 4.5 / 4.7 / 4.8 / 4.3	the residue analysis methods for the active substance, to determine residues in the soil/in drinking and surface water/in the atmosphere/in bodily fluids and tissues/on plants, plant products, food and feed, per study	€ 124
tox	5.1.	metabolism and kinetics in experimental animals	€ 345
tox	5.2.1 / 5.2.2 / 5.2.4 / 5.2.5	the toxicity of the active substance in experimental animals: determination of acute oral/percutaneous toxicity; skin/eye irritation, per study	€ 345
tox	5.2.6	acute toxicity: determination of skin sensitisation	€ 690
tox	5.2.3	toxicity in experimental animals: determination of acute inhalation toxicity	€ 862
tox	5.3.5	short-term toxicity studies, 28-day inhalation dose study	€ 1,034
tox	5.3.1 / 5.3.2 / 5.3.3 / 5.3.4 / 5.3.7	short-term toxicity studies, 28/90-day oral dose (including rat, 2nd domestic animal species); 1-2 years dog ; 28-day dermal dose study, per study	€ 1,379
tox	5.3.6 / 5.3.8	short-term toxicity study 90-day inhaled dose/dermal dose, per study	€ 1724
tox	5.4.1	genotoxicity studies in vitro: *Salmonella typhimurium* reverse mutation test; *Escherichia coli* reverse mutation test; *Saccharomyces cerevisiae* gene mutation test; *Saccharomyces cerevisiae* mitotic recombination assay, per study	€ 345
tox	5.4.2 / 5.4.3	in vitro mammalian cytogenetic test; in vitro sister chromatid exchange assay in mammalian cells; gene mutation test in mammalian cells; DNA damage and repair; unscheduled DNA synthesis in mammalian cells, per study	€ 517
tox	5.4.4 / 5.4.5 / 5.4.6	gentoxicity studies in vivo (somatic cells): micronucleus test; mammalian bone marrow cytogenetic test; mouse spot test; unscheduled DNA synthesis test with mammalian liver cells; mouse heritable translocation assay; sex-linked recessive lethal test in *Drosophila melanogaster;* rodent (gametes) dominant lethal test; mammalian (gametes) spermatogonial chromosome aberration test, per study	€ 862
tox	5.5.1 / 5.6.1	genotoxicity in vivo, toxicity with long-term exposure and carcinogenicity; in vivo, multi-generation study, per study	€ 2,069
tox	5.6.10	developmental toxicity study (rat)/(2nd species, usually rabbit), per study	€ 1,379
tox	5.7.1.	acute neurotoxicity in rats	€ 1,034
tox	5.7.2	delayed neurotoxicity study (rat)	€ 1,379
tox	5.8/ 5.9/ 5.10	other toxicity or medical data	actual costs incurred
res	6.1/ 6.1.1/ 6.1.2	Data on storage stability (per study, per matrix)	€ 690
res	6.2.1	Metabolism and kinetics (per study, per crop group)	€ 1,379
res	6.2.2 / 6.2.3 / 6.2.4 / 6.2.5	metabolism and kinetics with chicken, goat, cow, pig or other animals (per study, per animal)	€ 1,379
res	6.3	number of crop groups for which residue studies have been submitted, per study	€ 179
res	6.4.1 / 6.4.2 / 6.4.2 / 6.4.3	feeding study with chicken, goat, cow, pig or other animals (per study)	€ 1,379
res	6.5.2	pulp and balance studies/follow-up study (per study)	€ 690
res	6.5.1	characteristics of the residue during processing	€ 1,034
res	6.6.1 / 6.6.2	determination of residues in succeeding crops (per study)	€ 1,379
res	6.7	number of crop groups to derive MRL (per MRL/group MRL)	€ 345
fat	7.1.1 / 7.1.2 / 7.1.3	aerobic degradation pathway study; anaerobic degradation pathway study; soil photolysis, per y, including kinetic evaluation	€ 1,379

fat	7.12/ 7.13	monitoring data/supplementary research on environmental fate	Actual costs incurred
fat	7.2.1 / 7.2.3 / 7.2.2	aerobic degradation rate study 20°C; aerobic degradation rate study 10°C, per study	€ 1,034
fat	7.2.4 / 7.2.5	anaerobic degradation rate study	€ 1,034
fat	7.3.3	soil accumulation study	€ 1,379
fat	7.3.1	Soil dissipation study	€ 1,724
fat	7.4.1 / 7.4.2	adsorption; adsorption to silt particles, per study	€ 1,034
fat	7.4.3 / 7.4.4 / 7.6	leaching from columns; photochemical degradation in water, per study	€ 1,034
fat	7.4.5	column studies with aged residue	€ 1,379
fat	7.4.7 / 7.4.8	Lysimetry study/field leaching study, per study	€ 2,069
fat	7.4.7 / 7.4.8	(standardisation study with) lysimetry study; field leaching study, per study	€ 2,069
fat	7.5 / 7.10	hydrolytic degradation in water; degradation rate and pathway in the atmosphere; kinetic evaluation (general), per study	€ 690
fat	7.7	Ready biodegradability in water	€ 345
fat	7.8	degradation rate and pathway in water/sediment systems	€ 1,379
fat	7.9	research in the saturated zone	€ 2,069
eco	8.1.1 / 8.2.1 / 8.3.1 / 8.4.a / 8.5	acute oral toxicity for birds/fish/aquatic invertebrates; effects on algae growth; effects on sediment organisms, per study	€ 517
eco	8.1.2 / 8.1.3	diet study for birds (quail or mallard duck)/second bird species, per study	€ 690
eco	8.10	nitrogen and carbon mineralisation	€ 690
eco	8.1.4	subchronic and reproductive toxicity with birds	€ 1,034
eco	8.15	effect on biological wastewater purification methods	€ 690
eco	8.16.1	laboratory data about effects on other non-target organisms	Actual costs incurred
eco	8.16.2	field studies about effects on other non-target organisms	Actual costs incurred
eco	8.2.2-8.2.5 / 8.2.6	chronic toxicity for fish; bioconcentration in fish, per study	€ 690
fat	7.3.2	Soil residue study	€ 690
eco	8.3.2	chronic toxicity aquatic invertebrates	€ 690
eco	8.6a	determination of effects on aquatic plants	€ 690
eco	8.7.4	feeding test with bee brood	€ 690
eco	8.7.1/ 8.7.2 together	acute toxicity for bees	€ 862
eco	8.9.1	acute toxicity earthworms	€ 345
eco	8.9.2	sublethal effects on earthworms	€ 675
eco	-	request to derive an MTR outside the framework of an application	€ 862
eco	-	laboratory data about effects on non-target plants	€ 1,034
eco	-	Update AA-EQS/MAC-EQS (MTR) soil	€ 3,448
eco	-	update AA-EQS/MAC-EQS (MTR) water	€ 3,448
eco	-	derive AA-EQS/MAC-EQS (MTR) soil	€ 345
eco	-	derive AA-EQS/MAC-EQS (MTR) water	€ 10,516
res	-	other data on residues	Actual costs incurred

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 R4BP3	Description	Tariff 2016
		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)	
		Standard tariff	
		Application costs	€ 6,696
		Assessment costs physico-chemical properties and analysis methods	€ 1,488
		Assessment costs, efficacy	€ 4,464
		Assessment costs, human toxicology	€ 4,464
		Assessment costs, environmental aspects	€ 4,464
		Final assessment	€ 1,860
		Total costs for a 'standard' application	**€ 23,436**
		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	€ 11,036
		Family (basic tariff)	€ 11,036
		Family (per family member)	€ 1,240
		Extra user category	€ 1,736
		Extra PT	€ 1,736
		Extra active substance	€ 1,736
		Substance of concern (per substance)	€ 1,736
		Union authorisation (NL is evaluating competent authority)	€ 4,216
		Confidentiality request (per item)	€ 124
		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)	€ 7,068
B-TWENS B-TWEHS	NA-MRS	All-in-one tariff for mutual recognition (in sequence) of a single product (not a family)	€ 7,068
B-GW, B-GWF	NA-AAT NA-MAC	All-in-one tariff for major change of an authorisation (in which NL is concerned Member State)	€ 7,068
		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:	
		Family (per family member)	€ 868
		Extra user category	€ 868
		Extra PT	€ 868
		Extra active substance	€ 868
		Simplified authorisation (NL = ECA)	
B-ET, B-ETF	SA-APP	Simplified authorisation	€ 7,068
B-ETN, B-ETFN	SA-APP	Renewal of a simplified authorisation (single product or family)	€ 868
		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)	€ 868
		Family (per family member)	€ 868
		Extra PT	€ 868
		Extra active substance	€ 868
		Confidentiality request (per item)	€ 124
		Simplified authorisation notification	
B-EM	SN-NOT	Notification of simplified authorisation, authorised in another Member State	€ 1,488
		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)	€ 1,612
		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)	€ 248
		Simultaneous administrative change	€ 248
		Other tariffs biocidal products	
B-FL	NA-NPF	Adding a product to a biocidal family	€ 1,240
B-AW	NA-ADC	Amendment of authorisation: administrative amendment	€ 248
B-KW	NA-MIC	Amendment of authorisation: minor change, conversion of WG/GA to SPC at the request of the authorisation holder	€ 1,488
PB	ET-NOT	Notification of experiment or trial	€ 496
		If necessary, assessment costs can be charged for processing a notification of an experiment or trial.	
		Parallel trade permit	
PAB,VPAB, UPAB,BPAB	PP-APP	All-in-one tariff	€ 806

Fees and charges for product applications and other activities, for which 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 2016
	Application costs	
TB, TBE, UB, WSB	Application costs for authorisation, extended authorisation, amendment	€ 4,960
KB	Determination of frame formulation	€ 2,480
TVB	Extension of approval period	€2,728
TB, TBE, UB, WSB,	**Assessment costs**	
WYB, TVB	Efficacy	€ 1,240
	Physico-chemical properties of the product, each active substance present in the product, respectively	€ 1,488
	Criteria with respect to the operator and public health	€ 2,232
	Environmental behaviour and environmental fate	€ 2,232
	Final assessment of the authorisation aspects	€ 1,860
	Total assessment costs for a 'standard' application; the application costs are charged separately	**€ 9,052**
TB, UB, TBE	If comparative assessment is used (tariff per aspect)	€ 868
	Application costs and assessment costs combined	
DVB	Complete assessment urgently needed biocide	€ 10,664
	Other applications	
	If necessary, the above-mentioned assessment costs can be charged extra.	
AB, VAB, UAB	Authorisation, extension of approval periods or extension of range of uses of derived biocidal product	€ 806
WWGGA	Amendment WGGA (editorial)	€ 806
WSBNW	Application for a minor change in the biocide formulation	€ 806
PAB, VPAB, BPAB, UPAB	Parallel authorisation biocidal product, extension of parallel authorisation of biocidal product, other applications concerning parallel authorisation of a biocidal product	€ 806
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	€ 248
WYB	Amend packaging or labelling of a biocide, other amendments (editorial)	€ 248
EXV	Export declaration	€ 248
PWSB	Change in production process (including new/additional production location) and/or the location where the active substance is produced	€ 992
VIB	Request for information on animal testing biocide	€ 496
PB	Permit for trial purposes biocide	€ 496
	Mediating the exchange of animal testing data	Actual costs incurred
JV	**Annual fee**	
	Authorisation of Biocide	€ 1,170
	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.	

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

Type of application	Type of applicationR4 BP3	Description	Tariff 2016
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 528/2012	€ 12,500
		Summarising, evaluating and assessing	
EU-B, TB2EURAP, TB3EURAP, TB4EURAP	AS-APP, AS-RNL, AS-EVA	Additional evaluation and additional assessments **(advance payment)***	Actual costs incurred with advance payment of €250,000
EU-B, TB2EURAP, TB3EURAP, TB4EURAP		Subsequent costing	Actual costs incurred
EU-B, TB2EURAP, TB3EURAP, TB4EURAP	AS-APP, AS-RNL, AS-EVA	Average evaluation **(advance payment)***	Actual costs incurred with advance payment of €200,000
EU-B, TB2EURAP, TB3EURAP, TB4EURAP		* Subsequent costing	**Actual costs incurred**
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 528/2012 **(advance payment)***	Actual costs incurred with advance payment of €100,000
EU-B, TB2EURAP, TB3EURAP, TB4EURAP		* Subsequent costing	Actual costs incurred
		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 528/2012 (European decision making) **(advance payment)***	Actual costs incurred with advance payment of €75,000
EU-B, TB2EURAP, TB3EURAP, TB4EURAP		* Subsequent costing	Actual costs incurred

Fees and charges for summarising and evaluating studies regarding product data

Type of application	Aspect	Description	Tariff 2016
TB, TBE, UB, WSB, WYB, TVB	efficacy	the efficacy of the pesticide (per application)	€ 1,450
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

Fees and charges for summarising and evaluating studies regarding substance data

Type of application	Aspect	Description	Tariff 2016
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

Explanation Ctgb Tariffs Decree 2016

General aspects

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 applications 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

If the Board decides to ask additional questions, costs are also charged for summarisation/evaluation, in addition to the assessment costs. For summarising and evaluating data and studies for plant protection products and microbiological products, costs are charged as listed in this Decree, with the exception of zonal applications (NL ZRMS), applications for extended authorisation 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.

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

Subsequent costing
For various articles 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 article.

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.
c. If an advance payment has been made on 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 modify 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 less than €30,000, this amount may be paid in up to three monthly instalments of one-third of the total sum.
- If the costs for the procedure are more than €30,000, this amount may be paid in up to four monthly instalments of one-fourth of the total sum.

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

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 active 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 the established date, the applicant is legally in default according to Article 6:81 of the Netherlands Civil Code.

Separate sets of 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 a frame formulation. The frame formulation offers the authorisation holder the possibility of obtaining a very similar authoris (for example in different colours) more easily and at lower cost. The determination of the frame formulation results in additional costs, which are charged in addition 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 concerning 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 2016

Hourly rate 2016
The hourly rate charged by the Ctgb has been indexed and will increase by 5% in 2016: €124 per hour. This increase is mainly due to indexation of public sector wages and a periodic cost increase. The external fees and charges for summarising and evaluating will increase by 2%. The fees and charges have been indexed with the above-mentioned percentages.

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)
Despite the increased hourly rate, the annual fee for plant protection products in 2016 will not be raised relative to the fee in 2015. The fee is not indexed because the number of authorised plant protection products on 1 February 2016 (the reference date) is expected to be higher than that in 2015; as a result, the fee can stay the same.

Annual fees (biocidal products)
Despite the increased hourly rate, the annual fee for biocidal products in 2016 will not be raised relative to the fee in 2015, but will be reduced. This reduction is because the number of authorised biocidal products on 1 February 2016 (the reference date) is expected to be higher than that in 2015 and because it is expected that the implementation of EU Substance Advice on biocidal products will take less time.

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.

Applications to extend an existing authorisation in the Netherlands (non-zonal) with minor uses only (NLKUG) (plant protection product).
Because there are major differences between the various NLKUG applications, it has been decided to invoice this group of applications on the basis of advance payment and subsequent costing. In this way, the actual costs are taken into account and arbitrary higher costs can be avoided in case of minor extensions that fall within the risk envelope.

MTR (plant protection products)
The nomenclature of MTR has been changed to AA-EQS/MAC-EQS.

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

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.

Fees and charges for summarising and evaluating studies (plant protection products).
A number of descriptions of studies have been modified. In addition, for 4 types of studies, the fees have been corrected relative to 2015.

Applications for mutual recognition (NL is concerned Member State – biocidal products)
One application type with corresponding fee has been added to the all-in-one fees and charges for mutual recognitions. This concerns an application for a major change.

Tariff WYB (change packaging, change labelling of a biocidal product, other editorial changes – biocidal products)
This tariff has been reduced.

Service desk
For questions during the pre-application phase, you can contact the Service Desk. For information provision, the Service Desk has three types of instruments available:
1. Separate questions are answered by e-mail or telephone;
2. Meetings during which submitted questions are discussed with members of staff of the Ctgb;
3. Meetings for which applicants can register.

A Request for Meeting (**RFM**) is a meeting during the pre-application phase for a product or substance application. In addition, there is the Pre-submission Meeting (**PSM**), which is intended for discussion and/or addressing specific constraints preceding submission of the substance dossier. These are standard with a zonal application (NL ZRMS) for a plant protection product.

Besides the existing RFM and PSM meetings, a new category has been added in 2016. This concerns a pre-application

support process for the Union authorisations of biocidal products (applications B-TFN, B-UTN and B-UTFN). These meetings are intended to assist applicants with the application process for Union authorisations.

Service Desk requests with a labour input of less than 12 hours are classified into categories with fixed costs. Service Desk requests with a labour input of more than 12 hours are invoiced based on subsequent costing. The PSM, RFM and pre-application support process are invoiced based on advance payment and subsequent costing. Meetings are invoiced based on a predetermined fee for participation.