

Oversigt over grundgebyrer og tillægsgebyrer for behandling af ansøgninger om godkendelse af plantebeskyttelsesmidler
Overview of basic fees and additional fees for processing of applications for approval of plant protection products

Alle gebyrer er angivet i danske kroner (DKK)
All fees in Danish Kroner (DKK)

<p>I. Godkendelse af aktivstoffer, jf. § 47, stk. 2, i bekæmpelsesmiddelbekendtgørelsen Behandling af en anmeldelse efter plantebeskyttelsesmiddelforordningen eller kommissionsforordning (EU) Nr. 1141/2010 af et aktivstof til vurdering med henblik på optagelse på listen over godkendte aktivstoffer til plantebeskyttelsesmiddelforordningen.</p> <p>I. Approval of active substance, cf. Section 47, subsection 2 of the Statutory Order on Pesticides Processing of a notification according to Plant Protection Regulation or Commission Regulation (EU) No. 1141/2010 of an active substance for evaluation with a view to inclusion on the list of approved active substances for Plant Protection Regulation.</p> <p>Processing of application for equivalence assessment of active substances Behandling af ansøgning om ækvivalensvurdering af aktivstoffer</p>	<p>Maks. Not exceeding 2.002.000</p> <p>157.000</p>
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II. Godkendelse af kemiske plantebeskyttelsesmidler Authorisation of Chemical Plant Protection Products Godkendelsestype Type of application	Basic fee Grundgebyr	Tillægsgebyrer Additional fees						
		A <i>Se note 1</i>	B	C <i>Se note 2</i>	F <i>Se note 3</i>	Amendment I	Amendment II	Amendment III
		Assessment of residues and MRL (per AS) Vurdering pr. aktiv stof (FVST/DTU)	Assessment of Efficacy (Agro)	Assessment pr. active substance Vurdering af aktiv stof pr. AS (MST)	Assessment of co-formulants Vurdering af hjælpestoffer	of on-going application (MST)	of on-going application (FVST/DTU)	of on-going application (Agro)
<p>9202. DK is the examining member state (ZRMS) (new active substance in DK, me-too or renewal of authorisation) DK som ZMRS foretager vurdering (nyt AS i DK, me-too, fornyelse af tidligere godkendelser)</p>	269.000	42.800	50.300	83.500	11.700	32.200	9.110	10.300
<p>9203. Other examining member state than DK. DK (CMS) (new active substance in DK, me-too or renewal of authorisation) DK som CMS foretager vurdering på baggrund af andet lands RR (nyt AS i DK, me-too, fornyelse af tidligere godkendelser)</p>	177.000	36.600	29.700	46.100	11.700	16.200	7.500	5.360
<p>9204. DK is the examining member state (IRMS) for an Inter Zonal assessment (new AS in DK, me too or renewal of authorisation) <i>Evaluation for all zones (i.e. use in greenhouses, post harvest treatment, treatment of empty rooms or containers used for storing plants or plant products, and for seed treatment)</i> DK foretager vurdering (IRMS) for hele EU (nyt AS i DK, me too og fornyelse af tidligere godkendelser). <i>Evaluering for alle zoner (til brug i væksthuse, behandling af afgrøder efter høst, behandling af tomme lagerrum eller til bejdsning)</i></p>	292.000	42.800	50.300	79.100	11.700	32.200	9.110	10.300
<p>9205. DK is the examining member state (ZRMS) for a Plant Protection Product containing a <u>low risk</u> AS (new AS in DK, me-too or renewal of authorisation). DK foretager vurdering (ZRMS) for produkter med <u>lavrisikoaktivstof</u> (nyt AS i DK, me-too, fornyelse af tidligere godkendelser)</p>	155.000	21.400	50.300	37.600	11.700	32.200	4.280	10.300
<p>9206. DK - CMS assessment on the basis of another country's RR- Plant protection product containing a <u>low risk</u> AS. DK foretager vurdering (ZCMS) på baggrund af andet lands RR for <u>lavrisikoaktivstof</u></p>	88.000	18.400	25.900	31.100	11.700	16.200	4.280	5.360

Gælder fra 15. januar 2020
With effect from 15th of January 2020

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		A Se note 1	B	C Se note 2	F Se note 3	Amendment I	Amendment II	Amendment III
		Assessment of residues and MRL (per AS) Vurdering pr. aktiv stof (FVST/DTU)	Assessment of Efficacy (Agro)	Assessment pr. active substance Vurdering af aktiv stof pr. AS (MST)	Assessment of co-formulants Vurdering af hjælpestoffer	of on-going application (MST)	of on-going application (FVST/DTU)	of on-going application (Agro)
<p>9240. DK is the examining member state (IRMS) for an Inter Zonal assessment for a Plant Protection product containing a <u>low risk</u> AS (new AS in Dk, me too or renewal of authorisation). <i>Evaluation for all zones (i.e. use in greenhouses, post harvest treatment, treatment of empty rooms or containers used for storing plants or plant products, and for seed treatment)</i> DK foretager vurdering (IRMS) for produkter med lavrisikoaktivstof for hele EU (nyt AS i DK, me too og fornyelse af tidligere godkendelser). <i>Evaluering for alle zoner (til brug i væksthuse, behandling af afgrøder efter høst, behandling af tomme lagerrum eller til bejdsning)</i></p>	176.000	21.400	50.300	37.600	11.700	32.200	4.320	10.200
<p>9207. Provisional authorisation (based on a DAR) Provisorisk godkendelse (Kræver at der er en DAR)</p>	246.000	18.400	50.300	124.000	11.700	32.200	4.280	5.360
<p>9208. Mutual recognition (N-zone, EU - Reg. 1107) <i>The reference member state belongs to the northern zone or have evaluated for all zones (i.e. use in greenhouses, post harvest treatment, treatment of empty rooms or containers used for storing plants or plant products, and for seed treatment)</i> Gensidig anerkendelse (N-zone, EU - Reg. 1107) <i>Ansøgning på baggrund af en godkendelse givet i et andet land i samme zone eller for EU-lande til produkter til væksthuse, behandling af afgrøder efter høst, til tomme lagerrum eller bejdsning.</i></p>	95.600	17.200	13.000	46.100	11.700			
<p>9209. Mutual recognition (Other zone - Reg. 1107) <i>The reference member state belongs to a different zone than the northern zone or have evaluated for all zones (i.e. use in greenhouses, post harvest treatment, treatment of empty rooms or containers used for storing plants or plant products, and for seed treatment)</i> Gensidig anerkendelse (Anden zone - Reg. 1107) <i>Ansøgning på baggrund af en godkendelse givet i et land udenfor Nordzonen (f.eks. nabolande) eller for EU-lande til produkter til væksthuse, behandling af afgrøder efter høst, til tomme lagerrum eller bejdsning.</i></p>	108.000	23.200	13.000	46.100	11.700			
<p>Product authorisation (new or renewal) Produktansøgninger (nye eller fornyelser)</p> <p>9210. Mutual recognition (Dir. 91/414) <i>The authorisation has been granted in accordance with directive 91/414/EEC. The reference member state belongs to the northern zone or have evaluated for all zones (i.e. use in greenhouses, post harvest treatment, treatment of empty rooms or containers used for storing plants or plant products, and for seed treatment)</i> Gensidig anerkendelse (Dir. 91/414) <i>Ansøgning på baggrund af en godkendelse givet i et andet land i samme zone eller for EU-lande til produkter til væksthuse, behandling af afgrøder efter høst, til tomme lagerrum eller bejdsning</i></p>	108.000	23.200	13.000	46.100	11.700			
<p>9241. Mutual recognition for which national addenda are submitted. Gensidig anerkendelse hvor der skal udarbejdes national addenda.</p>	177.000	36.600	29.700	46.100	11.700	16.200	7.500	5.360

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II. Godkendelse af kemiske plantebeskyttelsesmidler Authorisation of Chemical Plant Protection Products Godkendelsestype Type of application	Basic fee Grundgebyr	Tillægsgebyrer Additional fees						
		A Se note 1	B	C Se note 2	F Se note 3	Amendment I	Amendment II	Amendment III
		Assessment of residues and MRL (per AS) Vurdering pr. aktiv stof (FVST/DTU)	Assessment of Efficacy (Agro)	Assessment pr. active substance Vurdering af aktiv stof pr. AS (MST)	Assessment of co-formulants Vurdering af hjælpestoffer	of on-going application (MST)	of on-going application (FVST/DTU)	of on-going application (Agro)
9211. Mutual recognition for a product containing a <u>low risk AS</u> . The reference member state belongs to the northern zone or the evaluation covers all zones. <i>Gensidig anerkendelse for et produkt med et lavrisikoaktivstof og på baggrund af en godkendelse givet i et andet land i samme zone eller for EU-lande til produkter til væksthuse, behandling af afgrøder efter høst, til tomme lagerrum eller bejdsning</i>	64.400	17.200	13.000	38.600	11.700			
9212. Amendment of use or conditions for a use that is not covered by the previous evaluation (a <u>new</u> assessment for health and environment according to the Uniform Principles needs to be performed) <i>DK is the examining member state (ZRMS or national - new use)</i> <i>Ændret anvendelse eller udvidet anvendelse, som kræver ny sundheds- og miljøvurdering</i> <i>Danmark foretager vurderingen (ZRMS eller nationalt - ny anvendelse)</i>	139.000	24.200	34.400	83.500				
9213. Amendment of use or conditions for a use that is not covered by the previous evaluation (a <u>new</u> assessment for health and environment according to the Uniform Principles needs to be performed) <i>Other examining member state (CMS - new use)</i> <i>Ændret anvendelse eller udvidet anvendelse som kræver ny sundheds- og miljøvurdering</i> <i>DK foretager vurdering på baggrund af andet lands RR (CMS - ny anvendelse)</i>	84.100	17.700	17.200	46.100				
9214. Amendment of use or conditions for use that is covered by the previous evaluation (a new evaluation on health and environment according to the uniform principles does <u>not</u> need to be performed) <i>DK is the examining member state (ZRMS, national)</i> <i>Ændret anvendelse eller udvidet anvendelse. Danmark foretager vurdering for ændret anvendelse, der ligger inden for tidligere vurdering for miljø og sundhed (ZRMS eller national - ændret anvendelse)</i>	26.900	24.200	17.000	83.500				
9215. Amendment of use or conditions for use that is covered by the previous evaluation (a new evaluation on health and environment according to the uniform principles does <u>not</u> need to be performed). <i>DK is concerned member state (CMS)</i> <i>Ændret anvendelse eller udvidet anvendelse. DK foretager vurdering ud fra andet lands RR for ændret anvendelse, der ligger indenfor tidligere vurdering for miljø og sundhed (CMS)</i>	23.100	17.700	17.200	46.100				
9242. Assessment of Substitution Assessment per active substance <i>Substitution</i> <i>Vurdering pr. aktivstof</i>	36.600	11.200	19.000					
9216. Amendment of use or conditions for use that is not covered by the previous evaluation (a new evaluation according to the uniform principles needs to be performed) <i>Low risk plant protection product, DK performs the assessment (ZRMS, national - low risk)</i> <i>Ændret anvendelse - alternativer / low risk</i> <i>DK foretager en ny vurdering (ZRMS, national - lav risiko - ny anvendelse)</i>	97.300	20.400	34.400	37.600				

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II. Godkendelse af kemiske plantebeskyttelsesmidler Authorisation of Chemical Plant Protection Products Godkendelsestype Type of application	Basic fee Grundgebyr	Tillægsgebyrer Additional fees						
		A Se note 1	B	C Se note 2	F Se note 3	Amendment I	Amendment II	Amendment III
		Assessment of residues and MRL (per AS) Vurdering pr. aktiv stof (FVST/DTU)	Assessment of Efficacy (Agro)	Assessment pr. active substance Vurdering af aktiv stof pr. AS (MST)	Assessment of co-formulants Vurdering af hjælpestoffer	of on-going application (MST)	of on-going application (FVST/DTU)	of on-going application (Agro)
Amendment of product authorisation Ændringer i produktgodkendelser	<p>9217. Amendment of use or conditions for use that is not covered by the previous evaluation (a new evaluation according to the uniform principles needs to be performed) <i>Low-risk plant protection product. DK is concerned member state (CMS - low risk - new use)</i> Ændret anvendelse - alternativer - low risk DK foretager en ny vurdering (CMS - lavrisiko - ny anvendelse)</p>	57.700	17.700	17.200	31.100			
	<p>9218. Amendment of use or conditions for use that is covered by the previous evaluation (a new evaluation according to the uniform principles does <u>not</u> need to be performed) <i>Low risk plant protection product (ZRMS, national - low risk - new use)</i> Ændret anvendelse. Danmark foretager vurdering lavrisikoprodukter for ændret anvendelse der ligger inden for tidligere vurdering for miljø og sundhedalternativer (ZRMS, national - lav risiko - ny anvendelse)</p>	26.900	20.400	34.400	37.600			
	<p>9219. Amendment of use or conditions for a use that is covered by the previous evaluation (a new evaluation according to the uniform principles does <u>not</u> need to be performed) <i>Low risk plant protection product (CMS)</i> Ændret anvendelse. Danmark foretager vurdering lavrisikoprodukter ud fra andet lands RR for ændret anvendelse der ligger inden for tidligere vurdering for miljø og sundhed (CMS)</p>	23.100	17.700	17.200	31.100			
	<p>9221. Change of product composition. DK performs assessment (ZRMS or national) Formuleringsændring DK foretager vurdering (ZRMS eller national)</p>	60.500		8.560		11.700		
	<p>9222. Change of product composition (CMS - composition change) Formuleringsændring DK foretager vurdering på baggrund af andet lands vurdering (CMS)</p>	40.600		4.280		11.700		

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III. Godkendelse af biologiske plantebeskyttelsesmidler (produkter, der indeholder mikroorganismer) Authorisation of biological Plant Protection Products (products containing micro-organisms) Godkendelsestype Type of application		Basic fee Grundgebyrer (DKK)	Tillægsgebyrer (DKK) Additional Fees (DKK)						
			A <i>Se note 1</i>	B	C <i>Se note 2</i>	F <i>Se note 3</i>	Amendment I	Amendment II	Amendment III
			Assessment of residues and MRL Vurdering pr. aktiv stof (FVST/DTU)	Assessment of efficacy (Agro)	Assessment pr. active substance Vurdering af aktiv stof, pr. AS (MST)	Assessment of co-formulants Vurdering af hjelpestoffer	of on-going application (MST)	of on-going application (FVST/DTU)	of on-going application (Agro)
Product authorisation (new or renewal) Produktansøgninger (nye eller fornyelser)	9223. DK assessment of Plant protection product containing microorganisms (Zonal RMS, new AS in DK, me too or renewal of authorisation) DK foretager zonevurdering for mikroorganismer (ZRMS, nyt AS i DK, me too, fornyelse af tidligere godkendelser)	50.400	28.400	50.300	56.700		5.360	5.900	10.300
	9224. DK CMS for plant protection product containing micro-organisms DK foretager vurdering på baggrund af andet lands RR for mikroorganismer (CMS)	36.000	21.400	25.900			5.360	4.280	5.360
	9225. Mutual recognition for a plant protection product containing micro-organisms Gensidig anerkendelse for et produkt med mikroorganismer Ansøgning på baggrund af en godkendelse givet i et andet land i samme zone eller for EU-lande til produkter til væksthuse, behandling af afgrøder efter høst, til tomme lagerrum eller bejdsning, samt iht. 91/414	42.100	18.400	13.000					
Amendment of product authorisation Ændringer i produktgodkendelser (se note 4)	9226. DK assessment of amendment of use or conditions for use and change of product composition that is not covered by the previous evaluation (a new evaluation according to the uniform principles needs to be performed) for a ppp with <u>micro-organisms</u> (ZRMS and others)) DK foretager vurdering af ændret anvendelse og formuleringsændringer for <u>mikroorganismer</u> (ZRMS mm)	35.200	20.400	34.400					
	9227. Other MS assessment of amendment of use or conditions for use and change of product composition that is not covered by the previous evaluation (a new evaluation according to the uniform principles needs to be performed) for <u>micro-organisms</u> (CMS) Ændret anvendelse og formuleringsændringer DK foretager vurdering på baggrund af andet lands RR for <u>mikroorganismer</u> (CMS)	22.300	17.700	17.200					
	9228. Dk assessment of amendment of use or conditions for use and change of product composition that is covered by the previous evaluation (a new evaluation according to the uniform principles does not need to be performed) <u>micro-organisms</u> (ZRMS ao.) Ændret anvendelse og formuleringsændringer DK vurderer i hht. tidligere godkendelse for <u>mikroorganismer</u> (ZRMS)	13.300	20.400	34.400					
	9229. Other MS assessment of amendment of use or conditions for use and change of product composition that is covered by the previous evaluation (a new evaluation according to the uniform principles does not need to be performed) <u>micro-organisms</u> (CMS) Ændret anvendelse og formuleringsændringer DK vurderer på baggrund af andet lands RR og i henhold til tidligere godkendelse for <u>mikroorganismer</u> (CMS)	12.600	17.700	17.200					

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IV. Andre gebyrer for plantebeskyttelsesmidler (kemiske og biologiske) Other types of fees for Plant Protection Products (chemical and biological) Godkendelsestype Type of application		Basic fee Grundgebyrer (DKK)	Tillægsgebyrer (DKK) Additional fees (DKK)						
			A Se note 1	B	C Se note 2	F Se note 3	Amendment I	Amendment II	Amendment III
			Assessment of residues and MRL Vurdering pr. aktiv stof (FVST/DTU)	Assessment of efficacy (Agro)	Assessment pr. active substance Vurdering af aktiv stof, pr. AS (MST)	Assessment of co-formulants Vurdering af hjelpestoffer	of on-going application (MST)	of on-going application (FVST/DTU)	of on-going application (Agro)
Amendment of product authorisation Ændringer i produktgodkendelser (se note 4)	9230. Minor change that requires technical assessment (fx minor composition change, reclassification or change of active substance supplier) Mindre ændring med faglig vurdering (fx. mindre formuleringsændringer og omklassificeringer eller ændret aktivstofleverandør).	10.700		2.600		11.700			
	9231. Administrative amendments (e.g. change of product name, approval holder or production site) Administrative ændringer (fx Produktnavneændring, ændring af godkendelsesindehaver eller produktionssted).	4.960							
	9232. Label approval Etiketbehandling Vurdering og godkendelse af etiketter, når det ikke er en del af en ansøgning om godkendelse.	6.120		3.710					
Derogation Dispensationer	9233. Emergency situation which cannot be contained by any other reasonable means Dispensation Vurdering af dispensationsansøgning	32.000	21.400	3.710					
	9234. Emergency situation which can not be contained by any other reasonable means based on previous assessments Dispensation Vurdering af dispensationsansøgning på baggrund af tidligere vurderinger	11.700	A1 Vurdering 21.400 A2 Ekstra- polering 12.600	4.220					
	9235. Research and development purposes, experiment or test program Forsøgsmæssig afprøvning National godkendelse af forsøgsmæssig afprøvning	5.380			10.800				
Parallel trade permit Parallel	9236. Parallel import The plant protection product is authorised in another member state and is identical in composition to a plant protection product already authorised in DK Parallel import Produktet er godkendt i et andet land og identisk til et produkt der er godkendt i Danmark	19.200		3.710					
	9237. Kopi Identical product authorised in Denmark for the same use Identiske produkter Identisk produkt er godkendt i Danmark til samme anvendelse	10.700		2.690					
Extension of authorisation for minor uses Mindre anvendelse	9238. Minor use Assessment of a minor use (crop group) for similar products (Label approval not included) Mindre anvendelse (MA) Vurdering af en anvendelse (afgrødegroupe) for sammenlignelige produkter (Etiketbehandling ikke inkluderet)	6.120	A1 Vurdering 10.800 A2 Ekstra- polering 6.230	2.110					
	9239. Simple administrative updates (handling of minor administrative changes eg. change of product name, authorisation holder, revocation of authorisation) Administrative simple opdateringer (f.eks. overførsel af mindre anvendelser ifm. navneændring, adresseændring, afmeldelse af produkt)	1.280							

Additional fees
Opkrævning af tillægsgebyrer

Fee A: Additional fee for assessment of residue levels/MRL of active substances in plant protection products. Applicable for plant protection products used on edible crops or fodder. Fee per active substance (FVST/DTU)

Gebyr A: Tillægsgebyr for vurdering af restkoncentrationer i fødevarer og foderudført af Fødevarestyrelsen/DTU. Gebyret opkræves for vurdering af restkoncentrationer (MRL) af aktivstoffet i plantebeskyttelsesmidler, der bruges på spiselige afgrøder og foder. Gebyr for hvert aktivstof

Note 1: If FVST finds no need to evaluate residues, or if the application is rejected during validation, a fee of only DKK 3.200 will be charged.

Note 1: Hvis FVST konstaterer, at der ikke skal vurderes restkoncentrationer, eller hvis ansøgningen afvises ved valideringen, nedsættes gebyret til 3.200 kr.

Fee B: Additional fee for assessment of efficacy, phytotoxicity and selectivity. Applicable for all applications for product authorisation (AGRO)

Gebyr B: Tillægsgebyr for vurdering af plantebeskyttelsesmidlets effektivitet, phytotoksicitet og selektivitet, udført af Aarhus Universitet, Institut for Agroøkologi (AGRO).

Fee C: Additional fee for assessment of a new active substance or microorganism in Denmark or renewal of an active substance or microorganism. Applicable for all plant protection products containing a new active substance or an active substance to be renewed. Fee per active substance in the product.

Gebyr C: Tillægsgebyr for første vurdering af nyt aktivstof (eller ny mikroorganisme) eller første fornyelse af et aktivstof i Danmark. Gebyr for hvert aktivstof.

Note 2: For application of the first plant protection product with the concerned active substance, if not previously approved in Denmark, or first application after re-evaluation of the active substance

Note 2: Ved ansøgning om det første plantebeskyttelsesmiddel med det pågældende aktivstof, hvis det ikke er godkendt i Danmark, eller ved første ansøgning efter at aktivstoffet er blevet revurderet i EU.

Fee F: Additional fee for assessment of co-formulants in plant protection products

Gebyr F: Tillægsgebyr for vurdering af hjælpestoffer i plantebeskyttelsesmidler

Note 3: For applications with alternative co-formulants the fee is *doubled*

Note 3: Ved ansøgninger om alternative hjælpestoffer *fordobles* gebyret

Note 4: New approved change entails the approval of a new label. A separate fee is charged for the approval of the new label (Fee No. 9232)

Note 4: Hvis godkendelsen af en ændring bevirker, at der skal godkendes en ny etiket, opkræves særskilt gebyr for etiketgodkendelsen (gebyr nr. 9232).

Additional fees for changes during assessment
Tillægsgebyrerne for ændringer under sagsbehandlingen opkræves således

Additional fee for EPA amendment of on-going application. Applicable when there is a need for a new assessment (e.g. addition of crop, change of dose or time for application)

Gebyret for Miljøstyrelsens vurdering omfatter nye vurderinger, for eksempel ved ændring af afgrøde, ændring af dosis eller ændring af tidspunkt for udbringning.

FVST/DTU: Additional fee for assessment of residue levels/MRL of plant protection products. Applicable for plant protection products used on edible crops or fodder.

Gebyret for Fødevarestyrelsens vurdering omfatter ændringer, der indebærer ny vurdering af restkoncentrationer i spiselige afgrøder og foder.

AGRO: Additional fee for assessment of efficacy, phytotoxicity and selectivity. Applicable for all applications

Gebyret til Aarhus Universitet, Institut for Agroøkologi omfatter ændringer, der kræver fornyet vurdering af effektivitet, phytotoksicitet og selektivitet.