Time and Fees of Hazardous Substance Consideration Processes Division of Cosmetics and Hazardous Substances Control, Food and Drug Administration

Last update: 29 Sep 2022

		Application Examination	Document Examination or Assessment/Facility Inspection		(Thai Baht)			
No.	Names of Public Manuals	Examination Time (*)	Execution Time as Specified in the New Public Manuals	Fees under the Order of the NCPO No. 77/2559			Administrative Fees under	
			the New Fublic Manuals	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act	
Proc	edures which incur no fee under th	ne Order of the National Council for Pe	eace and Order No. 77/2559	9				
1	Application for an operation	Immediately	2 Business days	None	None	None	None	
	notification for type 2 hazardous	(Submission through the						
	substances manufacturing, import,	e-submission system)						
	export, or possession for							
	professional use							
2	Application for variation of	Immediately	2 Business days	None	None	None	None	
	particular on an operation	(Submission through the e-						
	notification for type 2 hazardous	submission system)						
	substances manufacturing, import,							
	export, or possession for							
	professional use							
3	Renewal of a hazardous	This is carried out automatically by	Immediately	None	None	None	2,000	
	substance registration certificate	the e-submission system. If a mistake	(Once the system receives the					
		is found e.g. renewal fee has not	evidence of renewal fee					
		been paid, the system will notify the	payment under the HS Act)					

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			the New Public Manuals	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act
		applicant immediately, and the					
		system will not proceed further until					
		all mistakes have been corrected.					
4	Renewal of an operation	This is carried out automatically by	Immediately	None	None	None	None
	notification for type 2 hazardous	the e-submission system. If a mistake					
	substances manufacturing, import,	is found, the system will notify the					
	export, or possession for	applicant immediately.					
	professional use						
5	Renewal of a license to	This is carried out automatically by	Immediately	None	None	None	Between 500
	manufacture, import, export, or	the e-submission system. If a mistake	(Once the system receives the				and 3,000
	possess for professional use type	is found e.g. renewal fee has not	evidence of renewal fee				depending on
	3 hazardous substances	been paid, the system will notify the	payment under the HS Act)				the quantity
		applicant immediately, and the					manufactured/
		system will not proceed further until					imported/
		all mistakes have been corrected.					exported; or
							the quantity
							and size of
							storage space

		Application Examination	Document Examination or Assessment/Facility Inspection	Fees (Thai Baht)				
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			the New Public Manuals	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act	
							in the case of	
							possession	
6	Application for a substitute of the	Immediately	3 Hours	None	None	None	None	
	product notification for type 1	(Submission through the						
	hazardous substances	e-submission system) ****						
7	Application for a substitute of the	Immediately	2 Business days	None	None	None	None	
	operation notification for type 2	(Submission through the						
	hazardous substances	e-submission system) ****						
	manufacturing, import, export, or							
	possession for professional use							
8	Application for a substitute of							
	hazardous substance registration							
	certificate and application for a							
	substitute of license to							
	manufacture, import, export, or							
	possess for professional use type							
	3 hazardous substances							

		Application Examination	Document Examination or Assessment/Facility Inspection		Fees	(Thai Baht)	
No.	Names of Public Manuals	Examination Time (*)	Execution Time as Specified in the New Public Manuals	Fees under the Order of the NCPO No. 77/2559			Administrative Fees under
			the New Public Manuals	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act
	(8.1) Application for a substitute	Immediately	3 Business days	None	None	None	1,000
	of hazardous substance	(Submission through the					
	registration certificate	e-submission system) ****					
	(8.2) Application for a substitute	Immediately	3 Business days	None	None	None	500
	of license to manufacture, import,	(Submission through the					
	export, or possess for professional	e-submission system)					
	use type 3 hazardous substances						
Proc	edures which incur fees under the	Order of the National Council for Pea	ce and Order No. 77/2559				
9	Registration of hazardous	20 Business days	100 Business days	200	3,000	None	2,000
	substance within the category of	(Submission through the					
	pesticides or rodenticides, where	e-submission system)					
	the active ingredient has never						
	been registered (new substance)						
10	Registration of hazardous	20 Business days	100 Business days	200	3,000	None	2,000
	substance within the category of	(Submission through the					
	disinfectant products and laundry	e-submission system)					
	bleach products, where the active						
	ingredient has never been						
	registered (new substance)						

		Application Examination	Document Examination or Assessment/Facility Inspection		Fees	(Thai Baht)	
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			the New Public Manuals	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act
11	Registration of hazardous	20 Business days	100 Business days	200	3,000	None	2,000
	substance within the category of	(Submission through the					
	cleaning products, where the	e-submission system)					
	active ingredient has never been						
	registered (new substance)						
12	Registration of hazardous	10 Business days	60 Business days	200	2,000	None	2,000
	substance within the category of	(Submission through the					
	pesticides or rodenticides, where	e-submission system)					
	the active ingredient has been						
	registered						
13	Registration of hazardous	10 Business days	35 Business days	200	2,000	None	2,000
	substance within the category of	(Submission through the					
	pesticides or rodenticides, being a	e-submission system)					
	technical grade raw material of						
	which the active ingredient has						
	been registered						
14	Registration of hazardous	10 Business days	60 Business days	200	2,000	None	2,000
	substance within the category of	(Submission through the					
	disinfectant products and laundry	e-submission system)					

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			the New Public Manuals	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act
	bleach products, where the active						
	ingredient has been registered						
15	Registration of hazardous	10 Business days	35 Business days	200	2,000	None	2,000
	substance within the category of	(Submission through the					
	cleaning products, where the	e-submission system)					
	active ingredient has been						
	registered						
16	Registration of hazardous	10 Business days	30 Business days	200	1,000	None	2,000
	substance for export only, within	(Submission through the					
	the category of pesticides or	e-submission system)					
	rodenticides, where the active						
	ingredient has been registered						
17	Registration of hazardous	10 Business days	30 Business days	200	1,000	None	2,000
	substance for export only, within	(Submission through the					
	the category of disinfectant	e-submission system)					
	products and laundry bleach						
	products, where the active						
	ingredient has been registered						

		Application Examination	Document Examination or Assessment/Facility Inspection		Fees	(Thai Baht)	
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			the New Public Manuals	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act
18	Registration of hazardous	10 Business days	20 Business days	200	1,000	None	2,000
	substance for export only, within	(Submission through the					
	the category of cleaning products,	e-submission system)					
	where the active ingredient has						
	been registered						
19	Registration of hazardous	10 Business days	25 Business days	200	500	None	2,000
	substance that has already been	(Submission through the					
	registered but change has been	e-submission system)					
	made to its trade name						
20	Application for variation of	10 Business days	15 Business days	200	500	None	None
	particular of hazardous substance	(Submission through the					
	registration in accordance with	e-submission system)					
	the conditions prescribed and						
	announced by the Division of						
	Cosmetics and Hazardous						
	Substances Control						
21	Application for variation of	10 Business days	45 Business days	200	1,000	None	None
	particular of hazardous substance	(Submission through the					
	registration not in accordance	e-submission system)					

		Application Examination	Document Examination or Assessment/Facility Inspection		Fees	(Thai Baht)	
No.	Names of Public Manuals	Examination Time (*)	Execution Time as Specified in the New Public Manuals	Fees under the Order of the NCPO No. 77/2559			Administrative Fees under
			the New Public Manuals	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act
	with the conditions prescribed						
	and announced by the Division of						
	Cosmetics and Hazardous						
	Substances Control						
22	Application for variation of	Immediately	3 Business days	200	200	None	None
	particular on a hazardous	(Submission through the					
	substance registration certificate	e-submission system)					
23	Product notification and						
	notification of additional						
	information for type 1 hazardous						
	substances						
	(23.1) Product notification for	Immediately	3 Hours	None	400	None	None
	type 1 hazardous substances	(Submission through the					
		e-submission system)					
	(23.2) Notification of additional	Immediately	3 Hours	None	100	None	None
	information for the product	(Submission through the					
	notification for type 1 hazardous	e-submission system)					
	substance						

		Application Examination	Document Examination or Assessment/Facility Inspection	Fees (Thai Baht)			
No.	Names of Public Manuals	Examination Time (*)	Execution Time as Specified in the New Public Manuals	Fees under the Order of the NCPO No. 77/2559			Administrative Fees under
			the New Fublic Mandats	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act
24	Application for permission to						
	import or manufacture sample of						
	hazardous substance						
	(24.1) Application for permission	Application is to be submitted	Immediately	None	None	None	None
	to import or manufacture no	through the e-submission system and	(Self-certification letter)				
	more than 5 kilograms or 5 liters	primary examination will be					
	of hazardous substance sample	conducted automatically by the					
	which is not a technical grade raw	system. If a mistake is found, the					
	material or semi-finished material	system will notify the applicant					
	for pesticides or rodenticides	immediately.					
	(24.2) Application for permission	10 Business days	3 Business days	200	300	None	300
	to import or manufacture more	(Submission through the					
	than 5 kilograms or 5 liters of	e-submission system)					
	hazardous substance sample or						
	to import of manufacture sample						
	which is a technical grade raw						
	material or semi-finished material						
	for pesticides or rodenticides						

		Application Examination	Document Examination or Assessment/Facility Inspection		Fees	(Thai Baht)	
No.	Names of Public Manuals	Examination Time (*)	Execution Time as Specified in the New Public Manuals	Fees under the Order of the NCPO No. 77/2559			Administrative Fees under
			the New Public Manuals	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act
25	Application for a license to manufacture, import or export type 3 hazardous substances, where its original production line or place of storage was previously granted permission	Immediately (Submission through the e-submission system)	5 Business days	200	500	None	Between 500 and 3,000 depending on the quantity manufactured/ imported/ exported; or the quantity and size of storage space in the case of
26	Application for variation of	E Pusinoss days	2 Pusinoss davis	200	200	None	possession
20	Application for variation of particular on a license to manufacture, import, export, or possess for professional use type 3 hazardous substances, where facility inspection is not required	5 Business days (Submission through the e-submission system)	3 Business days	200	200	None	None

		Application Examination	Document Examination or Assessment/Facility Inspection		Fees	(Thai Baht)	
No.	Names of Public Manuals	Examination Time (*)	Execution Time as Specified in the New Public Manuals	Fees under the Order of the NCPO No. 77/2559			Administrative Fees under
			the New Public Manuats	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act
27	Application for a license to	7 Business days	19 Business days	200	2,000	None	Between 500
	manufacture type 3 hazardous	(Submission at the OSSC, FDA/PPHO)					and 3,000
	substances, in the case of new						depending on
	place of manufacturing or new						the quantity
	production line						manufactured
28	Application for a license to import	7 Business days	14 Business days	200	1,000	None	Between 500
	type 3 hazardous substances, in	(Submission at the OSSC, FDA/PPHO)					and 3,000
	the case of new place of storage						depending on
							the quantity
							imported
29	Application for a license to export	7 Business days	14 Business days	200	1,000	None	Between 500
	type 3 hazardous substances, in	(Submission at the OSSC, FDA/PPHO)					and 3,000
	the case of new place of storage						depending on
							the quantity
							exported
30	Application for a license to	7 Business days	15 Business days	200	1,000	None	Between 500
	possess for professional use type	(Submission at the OSSC, FDA/PPHO)					and 3,000
	3 hazardous substances						depending on
							the quantity

		Application Examination	Document Examination or Assessment/Facility Inspection		Fees	(Thai Baht)	
No.	Names of Public Manuals	Examination Time (*)	Execution Time as Specified in the New Public Manuals	Fees under the Order of the NCPO No. 77/2559			Administrative Fees under
			the New Public Manuals	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act
							and size of
							storage space
31	Application for variation of	7 Business days	19 Business days	200	1,000	None	None
	particular on a license to	(Submission at the OSSC, FDA/PPHO)					
	manufacture type 3 hazardous						
	substances, where facility						
	inspection is required						
32	Application for variation of	7 Business days	14 Business days	200	500	None	None
	particular on a license to import	(Submission at the OSSC, FDA/PPHO)					
	type 3 hazardous substances,						
	where facility inspection is						
	required						
33	Application for variation of	7 Business days	14 Business days	200	500	None	None
	particular on a license to export	(Submission at the OSSC, FDA/PPHO)					
	type 3 hazardous substances,						
	where facility inspection is						
	required						

		Application Examination	Document Examination or Assessment/Facility Inspection	Fees (Thai Baht)			
No.	Names of Public Manuals	Execution Examination Time (*)	Execution Time as Specified in the New Public Manuals	Fees under the Order of the NCPO No. 77/2559			Administrative Fees under
			the New Public Manuals	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act
34	Application for variation of	7 Business days	15 Business days	200	500	None	None
	particular on a license to possess	(Submission at the OSSC, FDA/PPHO)					
	for professional use type 3						
	hazardous substances, where						
	facility inspection is required						
35	Application for a Good						
	Manufacturing Practice (GMP)						
	certificate/certificate						
	renewal/addition of area to be GMP						
	certified for the manufacturing of						
	hazardous substances under the						
	responsibility of the Food and Drug						
	Administration, GMP-related						
	document assessment stage						
	(35.1) Application for a Good	7 Business days (Please call in advance	45 Business days for document	200	3,000	None	None
	Manufacturing Practice (GMP)	to make an appointment)	assessment				
	certificate	(Submission at the OSSC, FDA)					

		Application Examination	Document Examination or Assessment/Facility Inspection	Fees (Thai Ba		(Thai Baht)	nt)	
No.	Names of Public Manuals	Examination Time (*)	Execution Time as Specified in the New Public Manuals	Fees under the Order of the NCPO No. 77/2559			Administrative Fees under	
			the New Fublic Manuals	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act	
	(35.2) Application for a Good	7 Business days (Please call in advance	45 Business days for document	200	1,000	None	None	
	Manufacturing Practice (GMP)	to make an appointment)	assessment					
	certificate renewal	(Submission at the OSSC, FDA)						
	(35.3) Application for addition of	7 Business days (Please call in advance	45 Business days for document	200	1,500	None	None	
	area to be GMP certified	to make an appointment)	assessment					
		(Submission at the OSSC, FDA)						
36	Application for a Good							
	Manufacturing Practice (GMP)							
	certificate/certificate							
	renewal/addition of area to be GMP							
	certified for the manufacturing of							
	hazardous substances under the							
	responsibility of the Food and Drug							
	Administration, place of							
	manufacturing inspection stage							
	(36.1) Place of manufacturing with	7 Business days (Please call in advance	60 Business days for facility	None	30,000	3,000	None	
	not more than 20HP machines	to make an appointment)	inspection and certificate					
	and 1-50 workers	(Submission at the OSSC, FDA)	issuance only where no mistake					
			is found					

		Application Examination	Document Examination or Assessment/Facility Inspection		Fees (Thai Baht)				
No.	Names of Public Manuals		Execution Time as Specified in	Fees under the Order of the NCPO No. 77/2559			Administrative Fees under		
			the New Public Manuals	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act		
	(36.2) Place of manufacturing with	7 Business days (Please call in advance	60 Business days for facility	None	45,000	3,000	None		
	more than 20HP but not more	to make an appointment)	inspection and certificate						
	than 50HP machines or 51-200	(Submission at the OSSC, FDA)	issuance only where no mistake						
	workers		is found						
	(36.3) Place of manufacturing with	7 Business days (Please call in advance	60 Business days for facility	None	60,000	3,000	None		
	more than 50HP machines or	to make an appointment)	inspection and certificate						
	more than 200 workers	(Submission at the OSSC, FDA)	issuance only where no mistake						
			is found						
37	Assessment of technical								
	documents relating to hazardous								
	substance advertising								
	(37.1) Advertising of hazardous	7 Business days (Please call in advance	60 Days	None	6,000	None	None		
	substance through television,	to make an appointment)							
	movie and electronic media	(Submission at the OSSC, FDA)							
	(37.2) Advertising of hazardous	7 Business days (Please call in advance	60 Days	None	3,000	None	None		
	substance through print media,	to make an appointment)							
	radios and other media	(Submission at the OSSC, FDA)							
38	Application for a certificate of								
	product registration, certificate of								

		Application Examination	Document Examination or Assessment/Facility Inspection	Fees (Thai		(Thai Baht)	Baht)	
No.	Names of Public Manuals Examination Time (*)	Execution Time as Specified in the New Public Manuals	Fees under the Order of the NCPO No. 77/2559			Administrative Fees under		
			the New Fublic Manuats	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act	
	free sale, or certificate of							
	manufacturer for a hazardous							
	substance product							
	(38.1) Where its trade name	Immediately	1 Business days	None	None	200	None	
	corresponds to its registered	(Submission through the						
	name	e-submission system)						
	(38.2) Where its trade name	Immediately	5 Business days	None	None	200	None	
	differs from its registered name	(Submission through the						
		e-submission system)						
39	Application for certification of an	Immediately	2 Business days	None	None	500	None	
	English translation of document	(Submission through the						
	relating to hazardous substance	e-submission system)						
	permission							
40	Request for search, photocopying	Immediately	10 Business days					
	or certification of a copy of	(Submission through the						
	document relating to hazardous	e-submission system)						
	substance permission (***)							

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	(1) Search and examination of			None	None	100 per	None
	document relating to permission					Search	
	(***)						
	(2) Photocopying of document			None	None	5 per Page	None
	relating to permission (***)						
	(3) Certification of a copy of			None	None	5 per Page	None
	document relating to permission						
	(***)						
41	Consideration for certification of	Immediately	3 Business days	None	None	50 per	None
	document relating to hazardous	(Submission through the				Page	
	substance permission	e-submission system)					
42	Request for technical query or	Immediately	50 Business days	None	None	1,000	None
	consultation regarding hazardous	(Submission through the					
	substance, with a written reply as	e-submission system)					
	evidence						
43	Request for consideration as to	Immediately	30 Business days	None	None	1,000 per	None
	whether a substance is a	(Submission through the e-				Paper	
	hazardous substance under the	submission system/in person at the					

		Application Examination	Document Examination or Assessment/Facility Inspection Execution Time as Specified in	Fees (Thai Baht)			
No.	Names of Public Manuals	Examination Time (*)		Fees under the Order of the NCPO No. 77/2559			Administrative Fees under
			the New Public Manuals	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act
	responsibility of the Food and	Health Products Consultation Center,					
	Drug Administration	Building 6, Floor 4)					
44	Application for a transit permit of	Immediately	10 – 20 Business days	200	None	None	(1) 500 – 3,000
	type 1, type 2 and type 3	(Submission through the					depending on
	hazardous substances, and	e-submission system)					the quantity of
	application for variation of						type 1 or type
	particular on a transit permit of						2 substances
	hazardous substances under the						in each transit
	responsibility of the Food and						(2) 1,000 – 6,000
	Drug Administration						depending on
							the quantity of
							type 3
							substances in
							each transit
Addi	tional procedures from relevant pu	ublic manuals, in the case where addit	ional assessment/analysis by spec	ific-field ex	pert is neces	sary	
1.	Additional assessment of technical						
	document for an application for						
	hazardous substance registration or						
	for variation of particular of						

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			the New Public Manuals	List 1 (**)	List 2 (**)	List 3 (**)	the HS Act
	hazardous substance registration, or a request for technical consultation regarding hazardous substance which needs to be assessed by a						
	specific-field expert (1) Assessment of toxicological information (if any)	Already included in the stage of examination or assessment	Assessment time spent by a specific-field expert will be	None	12,000	None	None
	(2) Risk assessment (if any)	of technical document	included in the total completion	None	12,000	None	None
	(3) Assessment of criteria and methodology used in product efficacy test that deviate from the standard, benefit claim and label instruction (if any)		time prescribed for each type of application.	None	12,000	None	None
	(4) Assessment of new product type or new technology used to manufacture product (if any)(5) Other assessments in addition			None None	15,000	None None	None None
	to (1) - (4) (if any)						

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				List 1 (**)	List 2 (**)	List 3 (**)	the HS Act		
2	Additional inspection of place of	Already included in the stage of	Assessment/analysis time spent	None	12,000	None	None		
	manufacturing for an application	facility inspection	by specific-field expert will be						
	for permission or an application		included in the total completion						
	for variation of particular on a		time prescribed for each type of						
	license (where a specific-field		application.						
	expert is necessary for facility								
	inspection)								
3	GMP inspection where specific-	Already included in the stage of	Assessment/analysis time spent	None	12,000	None	None		
	field expert is necessary for place	facility inspection	by specific-field expert will be						
	of manufacturing's laboratory		included in the total completion						
	inspection		time prescribed for each type of						
			application.						

Notes:

(*) Where an application, document or evidence is incomplete and/or contains a mistake which makes it impossible to consider such application, document or evidence, the official will make a record of such mistake and additional document or evidence required, and the applicant must correct the mistake or submit additional document within 10 business days. Once the applicant corrects such mistake within the specified period, the official will check its correctness and completeness within the period prescribed for the consideration of each type of application. Where the mistake is not corrected within the specified period, or the correction is not

- complete, the application will be returned to the applicant. If the applicant wishes to proceed with the application, a new application must be submitted and a new fee will be charged.
- (**) Fees under the Notification of the Ministry of Public Health Re: Fees to Be Collected from Applicants in the Consideration Processes for Hazardous Substance Product Permission under the Responsibility of the Food and Drug Administration, B.E. 2560 (2017)
 - List 1 means consideration of application and examination of document correctness
 - List 2 means assessment/analysis of technical document and facility inspection
 - List 3 means other considerations or inspections in addition to List 1 and List 2 $\,$
 - <u>Persons exempted from all fees</u> in the Lists annexed to the Notification:
 - (1) Royal project or royal-initiated project
 - (2) Registered enterprise under the law on community enterprise promotion
- (***) No collection of fee for search and examination of document relating to permission and fees under (1), (2) and (3) in combination shall exceed 2,000 Thai Baht per application.
- (****) An application for a substitute may be necessary only in case of notifications, licenses or registration certificates issued before the launch of the e-Submission system.

 Where the documents are issued by the e-submission system, you may print them from the system at any time without having to apply for their substitute.