Time and Fees of Hazardous Substance Consideration Processes

Division of Cosmetics and Hazardous Substances Control, Food and Drug Administration

Last update: 29 Sep 2022

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

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

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							in the case of possession
6	Application for a substitute of the product notification for type 1 hazardous substances	Immediately (Submission through the e-submission system) ****	3 Hours	None	None	None	None
7	Application for a substitute of the operation notification for type 2 hazardous substances manufacturing, import, export, or possession for professional use	Immediately (Submission through the e-submission system) ****	2 Business days	None	None	None	None
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						

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	(8.1) Application for a substitute of hazardous substance registration certificate	Immediately (Submission through the e-submission system) ****	3 Business days	None	None	None	1,000
	(8.2) Application for a substitute of license to manufacture, import, export, or possess for professional use type 3 hazardous substances	Immediately (Submission through the e-submission system)	3 Business days	None	None	None	500
Procedures which incur fees under the Order of the National Council for Peace and Order No. 77/2559							
9	Registration of hazardous substance within the category of pesticides or rodenticides, where the active ingredient has never been registered (new substance)	20 Business days (Submission through the e-submission system)	100 Business days	200	3,000	None	2,000
10	Registration of hazardous substance within the category of disinfectant products and laundry bleach products, where the active ingredient has never been registered (new substance)	20 Business days (Submission through the e-submission system)	100 Business days	200	3,000	None	2,000

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11	Registration of hazardous substance within the category of cleaning products, where the active ingredient has never been registered (new substance)	20 Business days (Submission through the e-submission system)	100 Business days	200	3,000	None	2,000
12	Registration of hazardous substance within the category of pesticides or rodenticides, where the active ingredient has been registered	10 Business days (Submission through the e-submission system)	60 Business days	200	2,000	None	2,000
13	Registration of hazardous substance within the category of pesticides or rodenticides, being a technical grade raw material of which the active ingredient has been registered	10 Business days (Submission through the e-submission system)	35 Business days	200	2,000	None	2,000
14	Registration of hazardous substance within the category of disinfectant products and laundry	10 Business days (Submission through the e-submission system)	60 Business days	200	2,000	None	2,000

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

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18	Registration of hazardous substance for export only, within the category of cleaning products, where the active ingredient has been registered	10 Business days (Submission through the e-submission system)	20 Business days	200	1,000	None	2,000
19	Registration of hazardous substance that has already been registered but change has been made to its trade name	10 Business days (Submission through the e-submission system)	25 Business days	200	500	None	2,000
20	Application for variation of particular of hazardous substance registration in accordance with the conditions prescribed and announced by the Division of Cosmetics and Hazardous Substances Control	10 Business days (Submission through the e-submission system)	15 Business days	200	500	None	None
21	Application for variation of particular of hazardous substance registration not in accordance	10 Business days (Submission through the e-submission system)	45 Business days	200	1,000	None	None

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	with the conditions prescribed and announced by the Division of Cosmetics and Hazardous Substances Control						
22	Application for variation of particular on a hazardous substance registration certificate	Immediately (Submission through the e-submission system)	3 Business days	200	200	None	None
23	Product notification and notification of additional information for type 1 hazardous substances						
	(23.1) Product notification for type 1 hazardous substances	Immediately (Submission through the e-submission system)	3 Hours	None	400	None	None
	(23.2) Notification of additional information for the product notification for type 1 hazardous substance	Immediately (Submission through the e-submission system)	3 Hours	None	100	None	None

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24	Application for permission to import or manufacture sample of hazardous substance						
	(24.1) Application for permission to import or manufacture no more than 5 kilograms or 5 liters of hazardous substance sample which is not a technical grade raw material or semi-finished material for pesticides or rodenticides	Application is to be submitted through the e-submission system and primary examination will be conducted automatically by the system. If a mistake is found, the system will notify the applicant immediately.	Immediately (Self-certification letter)	None	None	None	None
	(24.2) Application for permission to import or manufacture more than 5 kilograms or 5 liters of hazardous substance sample or to import of manufacture sample which is a technical grade raw material or semi-finished material for pesticides or rodenticides	10 Business days (Submission through the e-submission system)	3 Business days	200	300	None	300

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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 possession
26	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

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27	Application for a license to manufacture type 3 hazardous substances, in the case of new place of manufacturing or new production line	7 Business days (Submission at the OSSC, FDA/PPHO)	19 Business days	200	2,000	None	Between 500 and 3,000 depending on the quantity manufactured
28	Application for a license to import type 3 hazardous substances, in the case of new place of storage	7 Business days (Submission at the OSSC, FDA/PPHO)	14 Business days	200	1,000	None	Between 500 and 3,000 depending on the quantity imported
29	Application for a license to export type 3 hazardous substances, in the case of new place of storage	7 Business days (Submission at the OSSC, FDA/PPHO)	14 Business days	200	1,000	None	Between 500 and 3,000 depending on the quantity exported
30	Application for a license to possess for professional use type 3 hazardous substances	7 Business days (Submission at the OSSC, FDA/PPHO)	15 Business days	200	1,000	None	Between 500 and 3,000 depending on the quantity

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							and size of storage space
31	Application for variation of particular on a license to manufacture type 3 hazardous substances, where facility inspection is required	7 Business days (Submission at the OSSC, FDA/PPHO)	19 Business days	200	1,000	None	None
32	Application for variation of particular on a license to import type 3 hazardous substances, where facility inspection is required	7 Business days (Submission at the OSSC, FDA/PPHO)	14 Business days	200	500	None	None
33	Application for variation of particular on a license to export type 3 hazardous substances, where facility inspection is required	7 Business days (Submission at the OSSC, FDA/PPHO)	14 Business days	200	500	None	None

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34	Application for variation of particular on a license to possess for professional use type 3 hazardous substances, where facility inspection is required	7 Business days (Submission at the OSSC, FDA/PPHO)	15 Business days	200	500	None	None
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 Manufacturing Practice (GMP) certificate	7 Business days (Please call in advance to make an appointment) (Submission at the OSSC, FDA)	45 Business days for document assessment	200	3,000	None	None

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	(35.2) Application for a Good Manufacturing Practice (GMP) certificate renewal	7 Business days (Please call in advance to make an appointment) (Submission at the OSSC, FDA)	45 Business days for document assessment	200	1,000	None	None
	(35.3) Application for addition of area to be GMP certified	7 Business days (Please call in advance to make an appointment) (Submission at the OSSC, FDA)	45 Business days for document assessment	200	1,500	None	None
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 not more than 20HP machines and 1-50 workers	7 Business days (Please call in advance to make an appointment) (Submission at the OSSC, FDA)	60 Business days for facility inspection and certificate issuance only where no mistake is found	None	30,000	3,000	None

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	(36.2) Place of manufacturing with more than 20HP but not more than 50HP machines or 51-200 workers	7 Business days (Please call in advance to make an appointment) (Submission at the OSSC, FDA)	60 Business days for facility inspection and certificate issuance only where no mistake is found	None	45,000	3,000	None
	(36.3) Place of manufacturing with more than 50HP machines or more than 200 workers	7 Business days (Please call in advance to make an appointment) (Submission at the OSSC, FDA)	60 Business days for facility inspection and certificate issuance only where no mistake is found	None	60,000	3,000	None
37	Assessment of technical documents relating to hazardous substance advertising						
	(37.1) Advertising of hazardous substance through television, movie and electronic media	7 Business days (Please call in advance to make an appointment) (Submission at the OSSC, FDA)	60 Days	None	6,000	None	None
	(37.2) Advertising of hazardous substance through print media, radios and other media	7 Business days (Please call in advance to make an appointment) (Submission at the OSSC, FDA)	60 Days	None	3,000	None	None
38	Application for a certificate of product registration, certificate of						

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	free sale, or certificate of manufacturer for a hazardous substance product						
	(38.1) Where its trade name corresponds to its registered name	Immediately (Submission through the e-submission system)	1 Business days	None	None	200	None
	(38.2) Where its trade name differs from its registered name	Immediately (Submission through the e-submission system)	5 Business days	None	None	200	None
39	Application for certification of an English translation of document relating to hazardous substance permission	Immediately (Submission through the e-submission system)	2 Business days	None	None	500	None
40	Request for search, photocopying or certification of a copy of document relating to hazardous substance permission (***)	Immediately (Submission through the e-submission system)	10 Business days				

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

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	responsibility of the Food and Drug Administration	Health Products Consultation Center, Building 6, Floor 4)					
44	Application for a transit permit of type 1, type 2 and type 3 hazardous substances, and application for variation of particular on a transit permit of hazardous substances under the responsibility of the Food and Drug Administration	Immediately (Submission through the e-submission system)	10 – 20 Business days	200	None	None	(1) 500 – 3,000 depending on the quantity of type 1 or type 2 substances in each transit (2) 1,000 – 6,000 depending on the quantity of type 3 substances in each transit
Additional procedures from relevant public manuals, in the case where additional assessment/analysis by specific-field expert is necessary							
1.	Additional assessment of technical document for an application for hazardous substance registration or for variation of particular of						

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	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 of technical document	Assessment time spent by a specific-field expert will be included in the total completion time prescribed for each type of application.	None	12,000	None	None
	(2) Risk assessment (if any)			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)			None	12,000	None	None
	(4) Assessment of new product type or new technology used to manufacture product (if any)			None	12,000	None	None
	(5) Other assessments in addition to (1) - (4) (if any)			None	15,000	None	None

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

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

Persons exempted from all fees 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.