#### [Unofficial Translation]

# Notification of Ministry of Agriculture and Cooperatives Entitled Registration, Issuance and Extension of Hazardous Substance Registration Certificate Under Responsibility of Department of Agriculture B.E. 2551(2008)

By virtue of Section 5 Paragraph three, Section 20(1) and (4), Section 36 Paragraph three and Section 37 of the Hazardous Substance Act B.E. 2535 (1992) amended by the Hazardous Substance Act B.E. (No. 3) B.E. 2551 (2008) which is the law that has some provisions relating to limitation of rights and freedom of a person under Section 29 in complement with Section 32, Section 33, Section 41, Section 43 and Section 45 of the Constitution of the Kingdom of Thailand provided contents to be able to enact a notification by virtue of the provisions of the Law , the Minister of Agricultural and Cooperatives with the opinions of the Hazardous Substance Committee made the notification as followed.

- **No. 1** Repeal Notification of Ministry of Agriculture and Cooperatives on Registration of Hazardous Substance under Responsibility of Department of Agriculture B.E. 2538 dated 3 May B.E. 2538 (1995).
- **No. 2** Hazardous substance in this notification means type 2 or type 3 hazardous substance under responsible of the Department of Agriculture according to Notification of Ministry of Industry entitled List of Hazardous Substances issued under Section 18 paragraph two which is excluded from the list of hazardous substance issued under Section 36 paragraph one of the Hazardous Substance Act B.E. 2535 (1992).
- **No.3** Whoever wishes to produce or import type 2 or type 3 hazardous substances, shall submit the application for registration using form HS./AC/AG 1 annexed to this notification, together with documents and testimony specified in the said form to the Department of Agriculture or the agency determined by the Department of Agriculture.

In case the submitted application referred to in paragraph one has the trade secret according to the regulation of the Ministry of Agriculture and Cooperatives on the Overseeing Trade Secret of Agricultural Chemical B.E. 2547 (2004), the applicant shall inform the authority of such secret.

- **No. 4** Registration of hazardous substance shall consists of 3 phases as followed.
- Phase 1 Trials Clearance for knowing the efficacy and information on acute toxicity. In this respect, production or importation of hazardous substance sample in a limited quantity is allowed for the efficacy or residue test, as the case may be.
- Phase 2 Provisional Clearance for demonstrating the usage and knowing information on sub-acute toxicity, chronic toxicity related to teratogenicity, reproductive effect, mutagenicity, toxicity to nervous system, oncogenicity and carcinogenicity (if any) and toxic residues. In this respect, production or importation of

hazardous substance sample in limited quantity for demonstration of usage in the limited area is allowed.

Phase 3 - Final evaluation for full registration by evaluating the results of experiments and various information so that efficacy and safety to human and the environment would be sufficiently known if it is for usage, including long term chronic toxicity (2 years) to testing animal.

The applicant may not apply for phase 2 (Provisional Clearance) in the case that he/she has the complete information required for phase 3 (Full registration).

- **No. 5** In processing phase 1- Trials Clearance, the applicant for registration must submit the technical documents, data requirement for hazardous substance registration, information on acute toxicity, experimental plan for efficacy test and/or experimental plan residue test, as the case may be, which is stipulated by the Department of Agriculture and published in the Government Gazette according to the data requirement for hazardous substance registration which is stipulated that the information relating to toxicity of technical grade material and finished product must be generated by the GLP Certified Laboratory according to OECD Standard and the registration certificate in the manufacturing country. All the documents must be certified by the authority, representative the country and shall be recognized as an international document.
- **No. 6** Upon considered on No. 3 and 5 by the authority and deemed it appropriate to give a license, the authority shall determine the quantity of hazardous substance samples to be produced or imported into the Kingdom, method for controlling, usage of the hazardous substance in the experiment, specify the prohibition on using or consuming the product obtained from experiment, surrender or dispose hazardous substance left over from experiment, including the time period for submitting the report on the result of efficacy test, and inform the applicant for registration.

After the applicant has accomplished the efficacy trials result or due date for trial clearance as specified by the authority has been met, the applicant for registration should inform the authority as specified by the Department of Agriculture and published in the Government Gazette.

**No. 7** In case that the experiment in phase 1, trials clearance, needs to produce or import samples of hazardous substance which is applied for registration or needs to import other hazardous substances for producing the hazardous substance applied for registration, the applicant for registration should submit the application for production or import hazardous substance samples to the authority using the form HS./AC./DOA 12 annexed to this notification.

Upon considered by the authority and deemed it appropriate to give a license, the authority shall issue the license certificate for production of hazard substance sample using form HS./AC./DOA 13 or the license certificate for import of hazard substance sample using form HS./AC./DOA 14 annexed to this notification.

The license referred to in paragraph two shall be made upon each application.

The recipient of the license referred to in paragraph two would be exempted from having the license for have in possession of that hazardous substance.

- **No. 8** Hazardous substance samples permitted to produce or import for experiment must post the label on which at least shows the following information that can be obviously seen.
  - (1) Trade name or code of the product.
- (2) Common name according to ISO system (if any) or common name in other system.
- (3) Scientific name of active ingredient. In case of chemical, specify the chemical name according to IUPAC system.
  - (4) Proportion of the mixture and nature of product.
  - (5) Usage type and plant, animal, crop or animal pest.
  - (6) Caution or warning.
  - (7) Producer and source of production plant of the product.
- (8) Statement "hazardous substance samples used specifically for particular experiment only".
- **No. 9** In case that the applicant for registration wishes to process into phase 2 provisional clearance, the applicant for registration should submit the technical document required for registration of hazardous substance, identify the location at which provisional clearance will take place and experimental plan as specified by Department of Agriculture and published in the Government Gazette.
- **No. 10** When the authority considers technical document, location, and experimental plan for provisional clearance referred to in No. 9 and decides to give the permission, the authority should specify the quantity of hazardous substance which will be produced or imported into the kingdom, method in controlling usage of hazardous substance for provisional clearance, create the list of hazardous substance and its produced or imported quantity, applied and left over quantity, names of person conducting experiment, location for which hazardous substance will be used, schedule to use product obtained from the experiment, surrender or dispose the hazardous substance left over from experiment, time period to notify the result of provisional clearance, method of curing the plaintiffs affected by this experiment and inform the applicant for registration.

When the result of the provisional clearance comes out or when the time period for this experiment ends as specified by the authority, the applicant for registration should inform the authority as specified by the Department of Agriculture and published in the Government Gazette.

- **No. 11** In case that the provisional clearance according to phase 2 needs to produce or import hazardous substance sample for Provisional Clearance or it needs to import other hazardous substance for producing hazardous substance for Provisional Clearance, the provisions of No. 7 shall apply <u>mutatis mutandis.</u>
- **No. 12** Hazardous substance samples permitted to be produced or imported for the experiment should have the label posted which at least contain the following information that can be seen obviously.
  - (1) Trade name or code number of the product.
- (2) Common name according to ISO system (if any) or common name according to other system.
- (3) Scientific name of active ingredient. In case of chemical, it should be specified by chemical name according to IUPAC system.
  - (4) Formulation and appearance of the product.
  - (5) Name and address of the business of the applicant for registration.

- (6) Name of the product owner in case that the applicant for registration is not the product owner.
  - (7) Packing size
- (8) The statement concerning to the benefit, application method, storage method with warning, symptom of poisoning, first aid treatment, and the recommendation to take the patient to the physician immediately with the label or container.
  - (9) The statement "Not for Sale"
- (10) The statement "hazardous substance sample used specifically for provisional clearance in the specified area"
- **No. 13** Any person who is listed and reported to the authority as the experimenter in the provisional clearance is exempted from getting the permission to have in possession of that hazardous substance.
- **No. 14** In case that the applicant for registration already completed phase 1 trials clearance and phase 2- provisional clearance and wished to receive the registration certificate of hazardous substance, he should do the followings.
- (1) Submit the technical document according to the data required for registration of hazardous substance as specified by the Department of Agriculture and published in the Government Gazette.
- (2) Submit the analysis result of hazardous substance sample according to its specification issued by the laboratory of the Department of Agriculture or other government laboratories and private laboratories as specified by the Department of Agriculture and published in the Government Gazette.
- (3) Submit the sample or document or photograph showing the container.
- **No. 15** Application for registration of mixed hazardous substance, the applicant for registration should do the same as application for registration of hazardous substance which has only one hazardous substance. The applicant for registration must submit the technical document of each hazardous substance and the technical document of hazardous substance mixture according the data required for registration of hazardous substance as specified by the Department of Agriculture and published in the Government Gazette.
- **No. 16** When authority considers and evaluates at the stage of trial clearance and result of provisional clearance, the technical document according to data required for registration of hazardous substance, result of analysis in accordance with specification of hazardous substance, appearance of container, if decide to give the permission for registration of hazardous substance, the authority should issue the registration certificate using Form HS./AG/DOA 2 annexed to this announcement. The registration certificate shall be valid in six years commencing from the date issued.
- **No. 17** In considering the application for registration of hazardous substance, the authority may ask the applicant for registration to submit any information other than the data required for registration of hazardous substance or to submit any details of that hazardous substance or arrange for conducting further studies. This must be specified by the Department of Agriculture and published in the Government Gazette.

**No.18** In case of the application for registration of hazardous substance which is used to be registered or is licensed for production or import by any law, it is required to do the same process including not required to submit the complete set of dossiers according to the regulation and it is not allowed to use the letter of authorization as the substitution for submission of toxicological data.

Application for import registration is required to carry out the process following this new regulation. The existing registration which is registered under the Hazardous Substances Act B.E. 2535 shall be effective until the next 3 years commencing from the date the Hazardous Substances Act (No. 3) B.E. 2551 (2008) enters into force.

- **No. 19** If the recipient of the registration certificate of hazardous substance wishes to amend some items in the registration certificate, he or she should submit the application for amendment using the Form HS/AC/DOA 15 annexed to this notification to the Department of Agriculture or the agency specified by the Department of Agriculture. In this regard, the authority may notify the applicant to perform testing or something else as it deemed appropriate. And if the authority considered that the request for amendment is reasonable and suitable, the amendment of the items in the registration certificate will be done and notified to the applicant respectively.
- **No. 20** Any person wishes to extend validity of the hazardous substance certificate shall submit the application using Form HS/AC/DOA 3 annexed to this notification to the Department of Agriculture or the agency specified by the Department of Agriculture within one hundred and eighty days prior to the expiry date of the hazardous substance certificate.

In perusal of the application for extension of the hazardous substance certificate, the criteria and procedure for issuance of the hazardous substance certificate shall apply <u>mutatis mutandis</u>.

**No. 21** Permission for extension of the hazardous substance shall be done by indication at the back of the registration certificate or by issuance of the new registration certificate.

This Notification is effective one day after it is announced in the Government Gazette onward.

Announced on Date 1 December B.E. 2551	(2008)
(Signature)	
(Mr. Theerachai Saengkaew)	
Deputy Minister of Agriculture and Coopera	atives

# **Application for Hazardous Substance Registration**

	Date	Mor	nth		B.E	
I		_Age				
(Natural person/Jur		,				
Taxation Identification Number_						
Address of the applicant for regis	stration o	f hazardo	us sub	stance: N	0	_Moo
Trok/SoiStreet	Tambo	on/Kwaen	g	A	mphur/K	het
Trok/SoiStreetPostcode	Tel:	Fa	ax	E-	mail	
Apply for registration of hazardou	ıs substa	nce: 🗆	type 2	□ type	3: for	☐ import
oxdot production with the following						
<ol> <li>Name of hazardous sub</li> </ol>						
<ol><li>Formulation and</li></ol>			of	active	ingredi	ent and
appearance						
<ol><li>Trade name or code</li></ol>						
4. Producer and Source of	f origin					
5. Importer						
6. Dealer /Distributor		. , ,				
7. Type and appearance of	or contain			S		
8. Use category						
<ol><li>Document and sample</li></ol>	to be sub	mitted as	the sup	oplement	ary for re	gistration:
Copy of identificati				l		
Copy of the Juristic						
Letter of authoriza						
Technical Informati					of hazard	lous
substance set by D	•	_		•		
☐ Experimental plan	for effica	cy and res	sidue tr	ials 6 cop	ies	
☐ Sample or docume	ent or pho	tograph s	howing	g appeara	nce of co	ontainer
☐ Sample of label an						
☐ Report on analysis						
Others (specify)						
	(Signatu	ıre)			Apr	olicant
	,	,				

# (Garuda Emblem)

#### HS./AC./DOA/2

# **Hazardous Substance Registration Certificate**

Department of Agriculture Ministry of Agriculture and Cooperatives

No Granted to		Date	_ Month		B.E
Taxation Identification I	Numhar	I valionant	у		
Address of the recipier					No Moc
Trok/Soi Province	Sileeii	ambon/Kwa	ieng	AIII	priui/District
to be the		ration of haz	zardous	substance	Type
for as follo	WS:				
1. Name of haza	ardous substance				
2. Formulation	and concentration of	of active ing	redient a	and appea	rance
3. Trade name _					
4. Producer and	Source of origin				
5. Importer					
6. Dealer /Distri	butor				
7. Use category					
8. Type and app	earance of containe	r sizes			
9. Others (specif	fy)				
This hazardous substa	_	ertificate is	valid un	til the Dat	e
Month	_D.E				
	(Signature)_			Auth	

List of extension of hazardous substance registration certificate No.\_\_\_\_\_

No. of application	Approval for exte substance registration	nsion of hazardous	Authority
''	Date received	Valid until	

List of amendment of hazardous substance registration certificate No.\_\_\_\_\_

No. of application	Date received	Amending Items	Authority

# **Application for Extension of Hazardous Substance Registration Certificate**

	Date	Month	1	B.E	
I		_Agey	ears. Nat	tionality	
(Natural perso	on/Juristic pers	on)		•	
Taxation Identification Num	ıber				
Address of the applicant fo	or extension of	hazardous s	substance	registration c	ertificate
No Moo Trok/					
Amphur/Khet Provi					
E-mail Desire	to apply for ex	tension of h	nazardous	substance re	gistration
certificate No I do					
as follows:	-		_		
☐ Hazardous Subs	tance Registrat	tion Certifica	ate		
Copy of identification					
□ Copy of the Juris	tic person regis	stration			
Letter of authoriz	ation (In case o	of authorizat	tion)		
Technical Inform	ation (Data req	uired) for re	gistration c	of hazardous	
substance set by		•	-		
Experimental plan	an for efficacy a	and residue	trials (if an	y)	
☐ Sample or docu	ment or photog	raph showir	ng appeara	nce of contai	ner
☐ Sample of label		•	0		
□ Report on analyst	sis of samples				
Others (specify)	•				
( )					
	(Signatu	ıre)		Appl	icant
	(				)

# **Application for Production or Import of Hazardous Substance Sample**

		Date	Month		B.E	
I _		A	.geyea	ars. N	lationality	
	(Natural person/Jul	ristic person	)			
Taxation	Identification Number_					
Address	Identification Number_ of the applicant:	No	Moo	Tro	ok/Soi	Stree
	Tambon/Kw	/aeng	·	_	Amphur/Khet_	
Province_	Tambon/Kw Postcode	Tel:_	Fa	ax		E-mai
	Desire to apply for	or approval	of 🗖 in	nport	production	sample
of hazard	lous substance for regis	stration				
Name ar	nd address of produc	tion/storage	place of	hazard	dous substance	: Name
	Located a	t No	Moo	Tro	ok/Soi	Stree
	Tambon/Kw Postcode_	/aeng		_	Amphur/Khet_	
Province_	Postcode	T	el:	_Fax_		E-mai
	with the following	g details:				
1.	Name of hazardous su	ıbstance				
2.	Name of hazardous su Formulation and cond	entration of	active ingr	edient	and appearance	e
3.	Trade name or Code _					
	Producer and Source					
5.	. Importer					
	. Quantity					
7.	. Document and sample	required to	support the	e applic	cation	
	Copy of identification					
	□ Copy of the Juris	tic person re	egistration			
	Letter of authoriz			ization	)	
	Experimental pla	n for efficac	y and residu	ue trials	s (if any)	
	☐ Material Safety D				. •,	
	☐ Others (specify)_					
		(Signature	)		Appli	cant
		1			,	

## **Hazardous Substance Sample Production License Certificate**

Department of Agriculture Ministry of Agriculture and Cooperatives

License N	Jo				1	)ate	Mont	h	B.E.	
Granted t	•0 ∩		_		Na	tionalit	_ 1V1O110	· •		
Taxation	Identifi	cation	Number_		1	illoriant <sub>.</sub>	у			
Address	of	he	recipient	of	license	certifi	cate:	No.	Moo	
r/District			Provir	nce	·	Post	code			pe.
Tel:	Fa	ax							_	
			ocated at I	No	Moo	Tr	rok/So		substance:	Street
		_	Tambon/k	(wae	ng			Amp	hur/Khet be the reci	
					ion license	certific	cate to	o be ι	used for haz	zardous
			as follows:							
2.	Formu	lation	and conce	entrat	tion of act	ve ingr	edient	and	appearance	·
3.	Trade n	ame	or Code							
4.	Produce	er and	d Source of	origi	n					
5.	Import	er								
6.	Quanti	tv								
7.	Others	(spe	cify)							
		` '	3,							
This licen	se certi	ficate	is valid un	til the	Date	Mon	th		B.E	
				(Si	gnature)				Auth	ority

## **Hazardous Substance Sample Import License Certificate**

				Departmer	nt of Agriculture
		N	linistry of Ag	riculture an	d Cooperatives
ense No			Date Mor	nth	B.E
Granted to		N	ationality		
Taxation Identification	Number				
Address of the	recipient o	f license	certificate:		
Trok/Soi	_				
Trok/Soi Street	Tambon/Kwa	eng	Amph	ur/District_	
Province	Postcod	e1	el:	Fax	
Name and address of	storage place	of hazardou	ıs substance	: Name	
Located at No		Trok/Soi		_Street	
Tambon/Kwaeng Postcode	Ar	nphur/Khet_		Provinc	e
Postcode	Tel:	Fax_			
to be the recipient of				t license c	ertificate to be
used for hazardous su					
<ol> <li>Name of haz</li> </ol>					
<ol><li>Formulation</li></ol>	and concent	ration of ac	tive ingredie	nt and app	earance
3. Trade name	or Code				
<ol><li>Producer and</li></ol>	d Source of or	igin			
5. Importer					
6. Quantity					
<ol><li>Others (spec</li></ol>	cify)				
This license certificate	is valid until t	he Date	Month		B.E
		(0)			A (1 - 2)
		· • · · · ·			Authority
					1

# **Application for Amendment of Hazardous Substance Registration Certificate**

		Date	Mc	onth	B.	E
I			_Age	years.	Nationality_	
	(Natural person/Ju	ristic perso	on)		-	
Taxation Ide	entification Number					
Address of	the applicant for regi	stration of	hazard	ous subst	ance: No	Moo
Trok/Soi	Street	Tambo	n/Kwae	ng	Amphu	ır/Khet
Province	Postcode	Tel:	F	-ax	E-mail	
Desire to ap No.	oply for amendment of	of hazardo	us subs	tance reg	istration certi	ficate
Item reques	sted for amendment					
•	attach the supporting Hazardous Substar	•			on as follows	:
	Copy of identification					
	Copy of the Juristic					
	Letter of authorizati				)	
	Relating evidences	`			,	t as follows:
	rtolating ortaonooc	to cappo		20101111		it do ronorror
	Others (specify)					
		(Signatu	re)			Applicant