

[Unofficial Translation]

**Notification of Department of Agriculture
Entitled: Determination of Details, Criteria and Procedure for
Registration, Issuance and Extension of Hazardous Substances
Registration Certificate under the Responsibility of Department of
Agriculture B.E. 2552 (2009)**

By virtue of items number 3, 5, 6, 9, 10, 14(1)(2), 15, 19 and 20 of 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 dated 1 December 2551 (2008) which has been promulgated by virtue of Section 5 paragraph three, Section 20(1) and (4), Section 36 paragraph three and Section 37 of the Hazardous Substances Act B.E. 2535(1992) and amended by the Hazardous Substances Act (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 Director-General of the Department of Agriculture made the notification on Details of Criteria and Procedure for Registration, issuance and Extension of Hazardous Substances Registration Certificate under the Responsibility of Department of Agriculture as followed.

No. 1 To repeal

(1) Notification of Department of Agriculture entitled Details of Criteria and Procedure for Registration of Hazardous Substances under the Responsibility of Department of Agriculture dated 1 October B.E. 2541 (1998).

(2) Notification of Department of Agriculture entitled Details of Criteria and Procedure for Registration of Hazardous Substances under the Responsibility of Department of Agriculture(No.2) B.E. 2548 dated 19 April B.E. 2548 (2005).

(3) Notification of Department of Agriculture entitled Details of Criteria and Procedure for Registration of Hazardous Substances under the Responsibility of Department of Agriculture (No.3) B.E. 2549 dated 24 July B.E. 2549 (2006).

(4) Notification of Department of Agriculture entitled Experimental Plan and Report of Efficacy Trial for Hazardous Substance dated 24 October B.E. 2539 (1996).

(5) Notification of Department of Agriculture entitled Experimental Plan and Report of Residue Trial for Hazardous Substance dated 6 December B.E. 2550(2007).

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 together with complete set of documents and testimony specified in the said form, even though it is the hazardous substance which has the same active ingredient and produced by the same factory as the hazardous substance already registered, to the

authority at Pesticide Regulatory Sub-division, Office of Agricultural Regulation, Department of Agriculture.

In case the submitted application referred to in paragraph one contains information which is 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 a secret.

No. 4 Registration of hazardous substance shall consists of 3 phases as follows.

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 relating 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 in order to know efficacy and safety to human and the environment sufficiently if it is for use, 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 as follows:

(1) Experimental plan for efficacy test for 6 copies according to Criteria, Procedure and Conditions for Efficacy Test of Agricultural Hazardous Substance annexed to this Notification except submission the result of efficacy test conducted due to Criteria, Procedure and Conditions for Efficacy Test of Agricultural Hazardous Substance no longer than 5 years.

(2) Experimental plan for residue test for 6 copies according to Criteria, Procedure and Conditions for Residue Test of Agricultural Hazardous Substance annexed to this Notification unless there is the result of residue test conducted due to Criteria, Procedure and Conditions for Residue Test of Agricultural Hazardous Substance or result of residue test that followed the recognized scientific method in other country or being published in the referable and recognized journal in plant or plant group with the same or similar application method.

(3) Report on product analysis.

(4) Data requirement for hazardous substance registration annexed to this Notification.

In case of synthetic chemical, the applicant shall submit data in item number 1, 2, 3 and 4 of data requirement for hazardous substance registration annexed to this Notification. The information relating to toxicity of technical grade material and finished product must be generated by the GLP Certified Laboratory and followed OECD Standard. All the document relating to registration certificate for production of the hazardous substance applying for registration and the license certificate for production of the factory in the manufacturing country must be certified by the authority, represent the producing country and shall be international document.

In case of microbial pesticide, the applicant shall submit data in item number 5 of data requirement for hazardous substance registration annexed to this Notification.

In case of plant extract or plant parts, the applicant shall submit data in item number 6 of data requirement for hazardous substance registration annexed to this Notification.

In case of pheromone, the applicant shall submit data in item number 7 of data requirement for hazardous substance registration annexed to this Notification

No. 6 Having considered completeness of documents referred to in No. 3 and 5, the authority shall inform the result to the applicant with in 10 days commencing from the date of receiving the document, and proceed as follows;

(1) In case of not complete or incorrect document and testimony, the authority shall cancel the application and inform the applicant with reason(s).

(2) In case of complete and correct document and testimony, the officer 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. The sample of product shall be divided in to 3 parts.

Part 1 will be used for analysis, according to product specification, at laboratory of the Department of Agriculture or other government agency.

Part 2 will be used for efficacy trial.

Part 3 will be used for residue trial.

Sample must be kept at laboratory of the Department of Agriculture.

(3) Analysis of sample (part 1) shall be finished with in 45 days. When the analysis result complies with the specification, part 2 or part 3 of the sample shall be used for conducting the efficacy or residue trial.

(4) In perusal of experimental plan for efficacy or residue trial, the responsible or assigned agency shall finish and get the result with in 90 days commencing from the date receiving document from Office of Agricultural Regulation.

If the experimental plan for efficacy or residue trial is not approved, the authority shall inform the applicant to amend and finished with in 30 working days.

In amending experimental plan for efficacy or residue trial of agricultural hazardous substance, it is required to submit written document to the authority together with the original and the amended version. The responsible or assigned agency shall follow the same steps as for perusal of experimental plan.

(5) In perusal of data requirement for hazardous substance registration referred to in item No. 5, the responsible or assigned agency shall finish and get the result with in 90 days commencing from the date receiving document from Office of Agricultural Regulation.

If the data requirement for hazardous substance registration is not approved or additional information is required, the authority shall inform the applicant to amend or submit with in 180 days commencing from the date informed.

In amending or submitting additional information for the second time, the responsible or assigned agency shall peruse the amended or additional information and get the result with in 90 days and inform the applicant to amend or submit with in 180 days commencing from the date informed.

Amending or submitting of additional information can be made not more that 2 times.

(6) After approval of items No. (3), (4) and (5), the agency assigned by the Department of Agriculture shall conduct the experiment.

(7) When the experiment is finished, the assigned agency shall submit report on result of efficacy or residue trial together with the approved statement to be put on the label in compliance with the Criteria, Procedure and Conditions for Efficacy

Test of Agricultural Hazardous Substance and the Criteria, Procedure and Conditions for Residue Test of Agricultural Hazardous Substance within 180 days commencing from the due date in the experimental plan for efficacy or residue trial at Pesticide Regulatory Sub-division, Office of Agricultural Regulation, Department of Agriculture.

The result of efficacy trial shall be valid no longer than 5 years commencing from the date receiving it from the assigned agency.

The result of efficacy or residue trial shall belong to the applicant only and it is not allowed for other persons to use it.

No. 7 In case that the experiment in phase 1, Trials Clearance, needs to produce or import samples of hazardous substance which is applying for registration or needs to import other hazardous substances for producing the hazardous substance applying 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 together with a copy of experimental plan.

Upon considered by the authority and deemed it appropriate to give a license, the authority shall issue the license certificate for production of hazardous substance sample using form HS./AC./DOA 13 or the license certificate for import of hazardous substance sample using form HS./AC./DOA 14, as the case may be.

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) Formulation and appearance of the product.
- (5) Use category
- (6) Precaution statement
- (7) Producer and source of production.
- (8) The statement "Hazardous substance samples used specifically for particular experiment only".

No. 9 In case the applicant for registration wishes to process into phase 2 - Provisional Clearance, the applicant for registration should submit 6 copies of the technical document which contains information according to No. 2 of data requirement for registration of hazardous substance, identify the location at which provisional clearance will take place and experimental plan for Provisional Clearance to the authority at Pesticide Regulatory Sub-division, Office of Agricultural Regulation, Department of Agriculture.

No. 10 When the authority considered that technical document, location, and experimental plan for Provisional Clearance referred to in No. 9 meet the criteria set by the Department of Agriculture, the authority should determine the quantity of hazardous substance to be produced or imported into the Kingdom, method for control usage of hazardous substance for Provisional Clearance, create the list of hazardous substance to be produced or imported, quantity applied and left over, 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, determine 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 at the responsible agency or the agency assigned by the Department of Agriculture.

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 *mutatis mutandis*.

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 in 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 enterprise 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 precaution statement, 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 The person who his/her name is listed and reported to the authority as the experimenter in the Provisional Clearance is exempted from license for having 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/she should proceed as follows.

(1) Submit 6 copies the technical document with details in accordance with No. 3 of the data requirement for registration of hazardous substance. The responsible or assigned agency shall peruse and get the result with in 1 year commencing from the date receiving the document from Office of Agricultural Regulation.

If the data requirement for hazardous substance registration is not approved or additional information is required, the authority shall inform the applicant to amend or submit with in 180 days commencing from the date informed.

In amending or submitting additional information for the second time, the responsible or assigned agency shall peruse the amended or additional information and get the result with in 90 days and inform the applicant to amend or submit with in 180 days commencing from the date informed.

Amending or submitting of additional information can be made not more that 2 times.

(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.

(3) Submit the sample or document or photograph showing the container.

No. 15 In applying 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 6 copies of the technical document of each hazardous substance and the technical document of hazardous substance mixture which has details according to No. 4 of the data requirement for registration of hazardous substance annexed to this Notification.

No. 16 When authority considers and evaluates at the stage of Trials Clearance and result of Provisional Clearance, the technical document according to data requirement for registration of hazardous substance, result of analysis in accordance with specification of hazardous substance, appearance of container, if decided to give the permission for registration of hazardous substance, the authority shall propose to the Sub-committee for Pesticide Registration for final evaluation with in 60 days. If it is deemed appropriate for registration, the authority shall issue the registration certificate using Form HS./AG/DOA 2.

The registration certificate shall be valid in six years commencing from the date issued.

No. 17 If the holder of hazardous substance registration certificate wishes to amend any item, he/she shall submit the application for amendment of hazardous substance registration certificate using Form HS/AG/DOA 15 at Pesticide Regulatory Sub-division, Office of Agricultural Regulation in order to propose to the Sub-committee for Pesticide Registration for perusal. If allowed, the amendment shall be made and inform the applicant except in the item that the Sub-committee for Pesticide Registration decided to exempt.

No.18 The person who wishes to extend validity of the hazardous substance registration certificate shall submit the application using Form HS/AC/DOA 3 to the authority at Pesticide Regulatory Sub-division, Office of Agricultural Regulation, Department of Agriculture within one hundred and eighty days prior to the expiry date of the hazardous substance registration certificate.

In perusal of the application for extension of the hazardous substance registration certificate, the criteria and procedure for issuance of the hazardous substance registration certificate according to Notification of Ministry of Agriculture and Co-operatives entitled Registration, Issuance and Extension of Hazardous Substance Registration Certificate under Responsibility of Department of Agriculture B.E. 2551 dated 1 December 2551 shall apply *mutatis mutandis*.

No. 19 Permission for extension of the hazardous substance shall be done by illustration 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 14 October B. E. 2552 (2009)

..... (Signature)
 (Mr. Somchai Charnnarongkul)
 Director-General
 Department of Agriculture