Unofficial Translation
(Draft)

Guideline on Principle, Procedure and Conditions for Efficacy Trial of Agricultural Hazardous Substance Annexed to Notification of Department of Agriculture entitled Details of Criteria and Procedure for Registration, Issuance and Extension of Hazardous Substances Registration Certificate under the Responsibility of Department of Agriculture B.E. 2552 (2009)

In order to make experimental plan and report of efficacy trial of agricultural hazardous substance the same technical principle and standard, the following details are set up:

Chapter 1
Experimental Plan and Report of Efficacy Trial for Trials Clearance

No. 1 Whoever wishes to apply for hazardous substance registration in Phase 1, Trials Clearance, shall submit application for conducting efficacy trial using the form annexed to this Guideline together with 6 copies of experimental plan to the authority at Pesticide Regulatory Sub-division, Office of Agricultural Regulation before commencing the experiment at least 3 months.

No. 2 Experimental Plan for insecticide, fungicide, herbicide or plant growth regulator shall specify the following details according to use category and specie of crop to be experimented.

(1) Experimental condition. It is required to specify plant specie, pest, location, experimental plan, number of replication, plot size, spacing, fertilizer application, and other details as set out in “Guidance on Efficacy Test for Agricultural Hazardous Substance” (Thai language) prepared by Department of Agriculture.

(2) Application method. It is required to specify dose rate, type of reference substance, control plot, procedure of experiment and other details as set out in “Guidance on Efficacy Test for Agricultural Hazardous Substance” (Thai language) prepared by Department of Agriculture.

(3) Data collection. It is required to record precipitation, temperature, humidity, immediate climate change during experimentation, insect count, impact on crop, impact on the environment, method for disease evaluation, weed count and classification, dry weight of weed, response of crop to plant growth regulator and other details as set out in “Guidance on Efficacy Test for Agricultural Hazardous Substance” (Thai language) prepared by Department of Agriculture.

No. 3 When the efficacy trial is finished, the agency assigned by Department of Agriculture to conduct the experiment shall report the result of experiment using the form for reporting efficacy trial annexed to this Guidelines with in 6 months commencing from due date of the experimental plan and submit to the authority at the same place as mentioned in No.1.

Chapter 2
Experimental Plan and Report of Efficacy Trial for Provisional Clearance

No. 4 Whoever wishes to apply for hazardous substance registration in Phase 2, Provisional Clearance, shall notify in written document together with 6 copies of experimental plan to the authority at the place mentioned in No.1 before commencing the experiment at least 3 months.

No. 5 Experimental Plan of hazardous substance for all use category shall contain the following details.

(1) Planner. Specify name and office of person responsible for planning.
(2) Government agency of supervisor. Specify name of government agency of supervisor for the experiment.
(3) Objective. Specify objective of Provisional Clearance.
(4) Location and experimental area. Specify location and experimental area clearly. Attached with location map, name and address of farmers.
(5) Quantity of hazardous substance to be applied.
(6) Duration of experiment. Specify commencing and finishing dates which should not exceed 2 years or 2 growing seasons.
(7) Crop. Specify crop specie and variety for use in the experiment which has to be the same as used in the Trials Clearance.
(8) Name of pest or pathogen. In case of common pest, specify common name. In case of plant pathogen, specify scientific name.
(9) Procedure. Specify method of experiment. There should be farmer's plot used as reference plot.
(10) Planning. Specify number of replication, plot size or dimension.
(11) Experimental plan. Specify statistical experimental plan.
(12) Implementation. Specify land preparation, weeding, method of hazardous substance application, harvesting, etc.
(13) Method of data collection of experimental plot and reference plot. Specify quantity of pest, impact on main crop and neighboring crops, impact on living organism and yield per rai.
(14) Analysis of data

No. 6 Area confined for Provisional Clearance

(1) The experimental area shall be less than 3 provinces.
(2) The experimental area in each province shall not less than 1% and not more than 30% of the infested area.
(3) The experimental area in each province shall not be adjacent to each other more than 2 plots.

No. 7 When the experiment for Provision Clearance is finished, the applicant for conducting experiment shall report the result of experiment using form annexed to this Guideline with in 6 months commencing from the due date in the experimental plan and submit such the report to the authority at the place mentioned in No.1.

Chapter 3
Miscellaneous

No. 8 Technical grade material, which active ingredient is the same as in the product already registered in Thailand and produced by the same manufacturer, is allowed to use efficacy trial result of the product for registration.

No. 9 Hazardous substance produced or imported for export to the foreign country, which is the same as hazardous substance registered in Thailand but different formulation and concentration, is not required to conduct efficacy trial.

No. 10 the Department of Agriculture assigns only the following agencies to conduct efficacy trial.

(1) Entomology and Zoology Association of Thailand
(2) Plant Pathologist Association of Thailand
(3) Weed Science Association of Thailand
(4) Horticulture Association of Thailand

Application for agricultural hazardous substance trials in Phase I - Trials Clearance

1. Trade name and /or Code No.
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2. Test results to be kept confidential or for registration
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3. Name and address of applying company
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4. Name and address of manufacturer of active ingredient
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5. Common name, if any
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6. Chemical name by IUPAC or chemical group
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7. Use category, e.g. insecticide, herbicide, fungicide, etc.
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8. Type and concentration of formulation
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9. Physical and Chemical properties of the active ingredient
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10. Scope and Aim of experiments and locations
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11. Quantity of chemical requested for trials
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12. Toxicity to tested animals
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13 Precaution
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14. First aid treatment

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15. Method of analysis

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16. Countries where registration have been approved, if any. Please submit registration certificate of other documents.

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17. In case the product has been registered in other countries, submit summary of recommendation for use.

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18. In case the product has been registered in Thailand, submit 2 copies of product label.

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19. I hereby agree to destroy the yield obtained from these trials or to follow authority's recommendation.

Name of applicant ……

Name of experimenter ……..

Name of supervisor (Private) ……..

Opinions of supervisor (Officials)

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Signature……
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Position……

Opinions of Director of Responsible agency

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Signature……
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Position……