

## **Data Requirements for Registration of Agricultural Chemicals** **(Limited to main text and Appendix Tables)**

The notification No.30-Shouan-6278, issued on March 29, 2019 by Director-General, Food Safety and Consumer Affairs Bureau,  
Ministry of Agriculture, Forestry and Fisheries

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# Data Requirements for Registration of Agricultural Chemicals

## Section 1 Specific details of test results to be submitted

The specific details of test results that an applicant (hereinafter referred to as “the applicant”) shall submit for registration of an agricultural chemical (excluding those having microorganisms as active ingredients; the same shall apply hereinafter) pursuant to Article 3, paragraph (2) of the Agricultural Chemicals Regulation Act (Act No. 82, 1948; hereinafter referred to as “the Act”) (including cases where applied mutatis mutandis pursuant to Article 34, paragraph (6) of the Act) and Article 2 of the Implementation Ordinance of the Act (Ordinance of Ministry of Agriculture and Forestry No. 21, 1951; hereinafter referred to as “Ordinance”) shall be as follows.

### 1 Test results regarding composition of an agricultural chemical and the technical grade active ingredient (TGAI) (Article 2, paragraph (1), item (i) of the Ordinance)

1. Test results, etc. used for evaluating the Agricultural chemical TGAI
  - [1] Types and contents of ingredients contained in an agricultural chemical TGAI and their concentrations
  - [2] Manufacturing methods of an agricultural chemical TGAI
  - [3] Impurities that are possible to be contained in an agricultural chemical TGAI and its origins
  - [4] Analysis of composition of an agricultural chemical TGAI
  - [5] Upper and lower limits on concentrations for ingredients in an agricultural chemical TGAI
  - [6] Equivalences of an agricultural chemical TGAI
2. Test results, etc. used for evaluating the agricultural chemical (formulation product)

Composition and manufacturing methods of an agricultural chemical

### 2 Test results regarding stability, degradability and other physical and chemical properties (Article 2, paragraph (1), item (ii) and item (xi) of the Ordinance)

1. Test results used for evaluation of an active ingredient
  - [1] Melting point
  - [2] Boiling point
  - [3] Density
  - [4] Vapor pressure
  - [5] Appearance (color/physical state)
  - [6] Odor
  - [7] Spectrum
    - (a) Ultraviolet visible absorption
    - (b) Infrared radiation absorption
    - (c) Nuclear magnetic resonance
    - (d) Mass spectrometry
  - [8] Solubility in water
  - [9] Solubility in organic solvents
  - [10] n-Octanol/water partition coefficient
  - [11] Hydrolysis
  - [12] Photolysis in water
  - [13] Dissociation constant

- [14] Thermal stability
- 2. Test results used for evaluation of formulation products
  - [1] Appearance (color/physical state)
  - [2] Fineness
  - [3] Particle size
  - [4] Stability of stock solution
  - [5] Stability of diluted solution or Wettability
  - [6] Water solubility or Solubility in water
  - [7] Suspension rate
  - [8] Density
  - [9] Inflammability
  - [10] Storage stabilityOther studies required for the formulation products
  
- 3 Test results regarding efficacy against applicable pests/diseases/weeds and crops, etc. (Article 2, paragraph (1), item (iii) of the Ordinance)**
  - 1. Efficacy against applicable diseases or pests/diseases/weeds and crops, etc.
  - 2. Biological Action of an agricultural chemical
  
- 4 Test results regarding phyto-toxicity to crops, etc. (Article 2, paragraph (1), item (iv) of the Ordinance)**
  - 1. Phyto-toxicity to applicable crops
  - 2. Residual odor of tea
  - 3. Smoking taste of tobacco
  
- 5 Test results regarding adverse effects on humans (Article 2, paragraph (1), item (v) of the Ordinance)**
  - 1. Test results regarding metabolism in animals (Article 2, paragraph (1), item (v) (a) of the Ordinance)
  - 2. Test results regarding acute toxicity, short-term toxicity, long-term toxicity, genetic toxicity, carcinogenicity, reproductive toxicity, neurotoxicity and other toxicities (Article 2, paragraph (1), (v) (b) of the Ordinance)
    - [1] Test results used for evaluating the active ingredient
      - (a) Acute oral toxicity
      - (b) Acute dermal toxicity
      - (c) Acute inhalation toxicity
      - (d) Skin sensitization
      - (e) 90-day repeated dose oral toxicity
      - (f) 90-day repeated inhalation toxicity
      - (g) 21-day repeated dose dermal toxicity
      - (h) Genetic toxicity
        - A) Reverse mutation (*in vitro*)

- B) Chromosomal aberration (*in vitro*)
  - C) Micronucleus (*in vivo*)
  - D) Gene mutation or DNA damage (*in vivo*)
  - (i) Chronic toxicity
  - (j) Carcinogenicity
  - (k) Reproductive toxicity
  - (l) Developmental toxicity
  - (m) Developmental neurotoxicity
  - (n) Acute neurotoxicity
  - (o) Acute delayed neurotoxicity
  - (p) 28-day repeated dose delayed neurotoxicity
  - (q) Repeated dose oral neurotoxicity
  - (r) Toxicity of additives and impurities
  - (s) Detoxification methods or emergency medical treatment
- [2] Test results used for evaluating an agricultural chemical (formulation products)
- (a) Acute oral toxicity
  - (b) Acute dermal toxicity
  - (c) Acute inhalation toxicity
  - (d) Skin irritation
  - (e) Eye irritation
  - (f) Skin sensitization
  - (g) Dermal absorption
  - (h) Exposure of operator to agricultural chemicals applying them in the field
  - (i) Estimation of exposure level of operator to agricultural chemicals

**6 Test results regarding metabolism in plants and residues in crops, etc. (Article 2, paragraph (1), item (vi) of the Ordinance)**

1. Metabolism in plants
2. Residues in crops
3. Residues in processed commodities
4. Residues in succeeding crops
5. Stability in stored commodities

**7 Test results regarding metabolism in livestock producing meat, chicken eggs and other livestock products and residues in livestock products (Article 2, paragraph (1), item (vii) of the Ordinance)**

1. Metabolism in livestock
2. Residues in livestock
3. Bioconcentration

**8 Test results regarding environmental behavior and residues in soil (Article 2, paragraph (1), item (viii) of the Ordinance)**

1. Behavior in Soil
  - [1] Aerobic flooding soil
  - [2] Aerobic soil
  - [3] Anaerobic soil
2. Residues in soil
3. Soil adsorption
4. Behavior in water
  - [1] Hydrolysis
  - [2] Photolysis in water
5. Derivation of predicted environmental concentration
  - [1] Water pollution
  - [2] Measurements of concentration in paddy water from a paddy lysimeter
  - [3] Runoff from simulated field surfaces
  - [4] Drift
  - [5] Monitoring of concentrations of the agricultural chemical in rivers
  - [6] Derivation of predicted water pollution concentration

**9 Test results regarding adverse effects on aquatic and terrestrial organisms in the environment (Article 2, paragraph (1), item (ix) of the Ordinance)**

1. Aquatic and terrestrial organisms in the environment
  - [1] Adverse effects on aquatic and terrestrial living environment organisms in waters
    - (a) Test results used for evaluation of an active ingredient
      - A) Fish acute toxicity
      - B) Acute immobilization on daphnids
      - C) Acute immobilization on daphnids (adults)
      - D) Adverse effects of coexistent organic substances on fish acute toxicity and daphnids acute immobilization
      - E) Acute immobilization on chironomid larvae
      - F) Acute toxicity on freshwater shrimps (*Paratya compressa compressa* and *Paratya compressa improvisa*) and amphipoda
      - G) Reproduction on daphnids
      - H) Growth inhibition on algae and cyanobacteria
      - I) Growth inhibition on *Lemna* sp.
      - J) Derivation of predicted environmental concentration in water
    - (b) Test results used for evaluation of an agricultural chemical (formulation products)
      - A) Acute toxicity on fishes
      - B) Acute immobilization on daphnids
      - C) Growth inhibition on algae and cyanobacteria

[2] Adverse effects on terrestrial organisms in the environment

(a) Adverse effects on avian

- A) Acute oral toxicity on avian
- B) Predicted exposure dose on avian
- C) Residues in seeds (excluding paddy rice)
- D) Residues in seeds (paddy rice)

(b) Adverse effects on wild bumblebees

- A) Acute dermal toxicity on adults
- B) Acute oral toxicity on adults
- C) Chronic oral toxicity on adults
- D) Oral toxicity on larvae
- E) Adverse effects on colonies
- F) Residues in pollen and nectar
- G) Estimated exposure level

2. Livestock

[1] Adverse effects on honeybees

- (a) Acute dermal toxicity on adults
- (b) Acute oral toxicity on adults
- (c) Chronic oral toxicity on adults
- (d) Oral toxicity on larvae
- (e) Adverse effects on colonies
- (f) Residues in pollen and nectar
- (g) Estimated exposure level

[2] Adverse effects on silkworms

**10 Test results regarding analysis methods on samples used in tests (Article 2, paragraph (1), item (x) of the Ordinance)**

1. Test results used for evaluation of an active ingredient

[1] Agricultural chemical TGAI

[2] Residues in crops

[3] Residues in livestock

[4] Residues in soil

[5] Residues in water

[6] Stability in stored commodities

2. Test results used for evaluation of formulation products

Active ingredients in an agricultural chemical

**11 Documents regarding sample tests of an agricultural chemical (Article 2, paragraph (2) of the Ordinance)**

## Section 2 Conditions regarding submission of test results

The documents listed in Section 1 shall be submitted in accordance with the conditions shown in Tables 1 to 11 below.

Notwithstanding the conditions listed in the tables, the Minister of Agriculture, Forestry and Fisheries shall request the submission of documents deemed necessary for review of an agricultural chemical for registration (Article 2, paragraph (1), item (xi) of the Ordinance).

(Definition of terms)

“Requirement of data submission” column: “○” indicates that submission of documents is required, “△” indicates that submission of some parts of documents is conditionally required, and “X” or blank indicates that submission of documents is not required.

“Paddy field”: Includes all the flooded fields intended to cultivate crops.

“Only use in paddy fields”: Indicate use the agricultural chemicals only in paddy fields between 14 days before flooding and harvest.

“Water-based crops”: The following crops that are cultivated in paddy fields:

Paddy Rice, Barnyard millet, Mizukakena, Water dropwort, Watercress, Kuwai /Arrowhead, Water shield, Makomotake, Mizuimo, Lotus tuber, Wasabi, Water chest nuts, Color, Indian lotus, Juncus effusus and Cyperus malaccensis

(Categories of crops)

Test results regarding efficacy against applicable diseases or pests, phyto-toxicity to applicable crops and residues in/on crops shall be conducted in accordance with the following crop categories

- High major crops (it means crops with particularly high production volume)

Crops used for food consumption (including industrial crops and crops used for livestock feed)

Rice (paddy rice and upland rice), Wheat, Satsuma mandarin, Persimmon, Pear (Japanese pear and European pear), Apple, Cabbage, Cucumber, Watermelon, Radish/Japanese radish (Daikon), Onion, Tomato, Eggplant, Carrot, Welsh onion/Leek, Chinese cabbage, Spinach, Head Lettuce, Sweet potato, Potato, Soya bean (dry), Tea, Pasture grass of the grass family, Pasture grass of the legume family, Corn for animal feed, Sorghum (stems and leaves for feed)

- Major crops (it means crops with high production volume)

Crops used for food consumption (including industrial crops and crops used for livestock feed)

Barley, Sweet corn, Iyo (Mandarins), Mandarins Shiranuhi, Natsudaidai (Pummelo), Hassaku (Pummelo), Japanese apricot, Kiwi fruit, Grapes, Peach, Komatsuna, Celerly mustard Chinese cabbage (type Pak-choi), Nozawana, Soya bean (succulent seeds in pods), Common bean (poroto) (pods and succulent seeds), Celery, Strawberry, Turnip/Swede, Pumpkins/Winter squash, Burdock (greater or edible), Chrysanthemum, Ginger (rhizome), Chinese chives, Peppers Sweet/Paprika/Peppers bell, Broccoli, Broccoli, Cherry tomato, Melons (except Watermelon), lotus tuber, Konjac, Taro/Dasheen, Chinese yam /Chamma, Adzuki bean (dry), Sugar cane, Sugar beet, Oats for animal feed

Crops excluding crops used for food consumption

Chrysanthemum and Lawn grass

- Minor Crops (it means crops with low production volume)

Crops excluding high major crops and major crops

### Section 3 Test methods

#### 1 Principles

1. The tests results listed in Section 1 shall be performed based on the test methods specified in the attachments. The test methods are currently standard test methods recommended for preparing test results to be submitted, and shall be improved in accordance with state-of-the art science.
2. In order to meet the objectives of tests more effectively, the modification of test methods shall not be precluded in accordance with the characteristics of test substances. However, if any test methods are modified, applicants shall clarify modifications and the reasons of the modifications in the reports, etc.

#### 2 Test substance

1. If an agricultural chemical TGAI is used as a test substance, it shall be equivalent to TGAI in the sample formulation product.  
If an agricultural chemical TGAI used as a test substance is not equivalent to an agricultural chemical TGAI in the sample formulation product, it shall be shown in each test that the differences between an agricultural chemical TGAI used as a test substance and an agricultural chemical TGAI in the sample formulation product do not complicate the test results, and that the agricultural chemical TGAI used for the test is valid as a test substance.
2. If a formulation product is used for tests, it shall be equivalent to a formulation product for which registration is applied.  
If a formulation product used as a test substance is not equivalent to a formulation product for which registration is applied, it shall be shown in each test that the differences between a formulation product used as a test substance and the formulation product for which registration is applied do not complicate test results, and that the formulation product used for tests is valid as a test substance.
3. Active ingredients, etc. labeled with radioisotopes or non-labeled active ingredients, etc.
  - [1] In principle, a test substance shall be the same as an active ingredient in a formulation product, including the case of such as salts, etc. However, even if a substance different from the active ingredient is used as a test substance, a test involving the substance shall be possible to be replaced the test involving the active ingredient as long as it is scientifically justifiable that test results using the substance do not differ from test results using the active ingredient itself as the test substance and if the description of the justification is attached.
  - [2] If major metabolic products, etc. of active ingredients fall under one of the following substance categories and shall be individually tested, the metabolic products, etc. also shall be used as test substances.
    - (a) If a test substance is a metabolic product produced by dissociation, degradation or metabolism, etc. of the active ingredients in organisms or in environments, and if the metabolic product is expected to give an adverse effect to humans, livestock or environments (they are metabolic products, etc. to be included in the tests on water pollution and soil residues, as well as compounds that are likely to exceed active ingredients in residual amount in the process of degrading and eliminating the active ingredient), the following test results shall be submitted in order to calculate the residual concentration in fish and shellfish and predicted environmental concentration.
      - A) Test results regarding n-Octanol/water partition coefficient, among test results regarding stability, degradability and other physical and chemical properties.
      - B) Test results regarding bioconcentration, among the test results regarding metabolism in livestock producing meat, eggs and other livestock products and the test results regarding the residues. (If n-Octanol/water partition coefficient is less than 3.5, it shall be possible not to submit test results regarding bioconcentration)
      - C) Soil adsorption, among the test results regarding fates in environments and residues in soils
    - (b) If a substance is expected to be subject to exposure assessment in a food health effect assessment of an agricultural chemical, it is desirable to submit the following test results.
      - A) Test results regarding acute oral toxicity among test results regarding effects on humans and reverse mutation (*in vitro*) among genetic toxicity test results.  
If a test result regarding reverse mutation (*in vitro*) is positive, or is suspected to be positive, test results regarding chromosomal aberration (*in vitro*), micronucleus (*in vivo*) and gene mutations or DNA damage (*in vivo*) shall be submitted.



In addition, other test results shall be submitted as necessary, taking into account chemical structures, etc. of metabolic products, etc.

- [3] If a labeled compound is used as a test substance, the labeling nuclide shall be  $^{14}\text{C}$  in principle, and the labeling position shall be a stable site against metabolism. If cleavage of a molecule is expected, it is desirable to use multiple compounds labeled in different positions in the molecule so that the fate of the cleavage substance is possible to be made clear.
4. One lot of the test substance shall be used during the test period. If another lot is also used for compelling reasons, the lot shall be similar enough in composition (type and concentration of ingredients) to the original lot.
5. Test results shall contain the lot number used and the following contents shall be clarified as much as possible
  - [1] For an agricultural chemical TGAI, the common name, chemical name, structural formula, purity, physicochemical properties and composition of impurities
  - [2] For a formulation product, the type, concentrations of active ingredients, and types of other ingredients, etc. shall be identified as much as possible.
6. If a test substance mixed with feed is administered in a toxicity test, etc., close attention shall be paid to its uniformity and stability, etc. If a test substance is administered with a solvent, etc., it is desirable that toxicity of the solvent is known and it does not significantly affect the test results.
7. For the health management of the operators, the waste disposal shall be operated with care to the hazard of the test substances. Particularly, sufficient care shall be taken to handle positive control substances used in the genetic toxicity test, etc.

### 3 Test organisms

In order to evaluate the safety of the agricultural chemicals effectively, it is desirable to use test organisms of the same species and the same strain across the tests. See the applicable items for each tests, to know the required conditions of the test organisms, etc. in each tests.

### 4 Handling of test animals

In terms of animal welfare, careful attention shall be paid to laboratory animal breeding and management, experimental operations and disposal methods, etc. in animal experiments, based on the Act on Welfare and Management of Animals (Act No. 105 of 1973), Standards Relating to the Care and Keeping and Reducing Pain of Laboratory Animals (Notice of the Ministry of Environment (hereinafter referred to as the “MOE”) No.88, 2006) and international regulations and trends, etc. concerning animal welfare.

Prior to the test, it is desirable to collect sufficient data to decide the necessity of the test. If the decision is made to conduct the test, it is desirable to develop the careful and adequate experiment plan based on the data collected beforehand and to subject the minimum number of animals to the experiments.

### 5 Test facility

The following test results 1.to 4. except for that are specified in Article 2 of the Ministerial Ordinance on Good Laboratory Practice for Agricultural Chemicals ((Ministry of Agriculture, Forestry and Fisheries (hereinafter referred to as the “MAFF”) Ordinance No. 76, 2018, hereinafter referred to as “Ministerial Ordinance on GLP for Agricultural chemicals”) shall be conducted at the test facilities specified in 1. to 4..

1. Analysis of dioxins in test results regarding components of agricultural chemical TGAI
  - [1] Test facilities certified to conform to the requirements stipulated in Articles 5 to 19 of the Ministerial Ordinance on Good Laboratory Practice for Agricultural Chemicals
  - [2] Organizations recognized as eligible for contract surveys involving the environmental measurements of dioxins by the MOE
  - [3] Operators registered for measurement certification business related to concentrations based on Article 107 of the Measurement Act (Act No. 51 of 1992) and certified for specific measurement certification business related to dioxins by the Minister of Economy, Trade and Industry, or a person designated by the Minister of Economy, Trade and Industry under Article 121 (2) of the said Act.
2. Test results regarding efficacy against applicable diseases or pests and crops, and phyto-toxicity to crops.

- [1] Official test/research facilities including independent administrative corporations, prefectural agricultural experimental stations and national university corporations, etc.
- [2] Plant protection stations of the MAFF, prefectural pest control stations, public interest corporations with specialized expertise, private universities and facilities exclusively for the cultivation and management, etc. of industrial crops almost equivalent to official test/research facilities
- [3] Private test facilities that meet the following requirements
  - (a) Standard Operating Procedures (SOPs) for conducting tests on efficacy and phyto-toxicity are in place.
  - (b) In principle, study plans, test field notes and final reports are maintained until the agricultural chemicals are registered.
  - (c) Apparatus and equipment necessary for conducting tests on efficacy and phyto-toxicity are available.
  - (d) The organizational capacity is in place to effectively implement cultivation management of crops and tests regarding efficacy and phyto-toxicity.

Note that the study personnel with the above-mentioned facilities is possible to rent farm fields, etc. temporarily from farmers during the required period and conduct a field study.

In addition, the following items shall be implemented in order to ensure the reliability of test results regarding efficacy.

- [4] The applicant shall ask experts to review whether the study has been carried out properly in accordance with the relevant guidelines, etc. before application. However, test results regarding to minor crops conducted by prefectural agricultural experimental stations or pest control stations are possible to be exempted from this review.
- [5] As a general rule, if any questions arise in relation to the study reports, the following documents shall be retained until the agricultural chemical is registered to ensure that the questions are solved.
  - (a) Study procedures
  - (b) Test plans, test field notes and final reports
  - (c) Summary of study review by experts
    - A) Organizer and expert participants of the review meeting
    - B) Date and place of the meeting
    - C) Review results regarding the appropriateness of the test

### 3. Test results regarding residues in applicable minor crops.

- [1] Official test/research facilities including independent administrative corporations, prefectural agricultural experimental stations and national university corporations, etc.
- [2] Plant protection stations of the MAFF, prefectural pest control stations, public interest corporations with specialized expertise, private universities and facilities exclusively for the cultivation and management, etc. of industrial crops almost equivalent to official test/research facilities.

Note that the study personnel with the above-mentioned facilities, etc. is possible to rent farm fields, etc. temporarily from farmers during the required period and conduct a field study.

Test results regarding analytical tests conducted by those who are not the applicant and who have been registered as a Registered Conformity Assessment Body under Article 33 of the Food Sanitation Act (Act No. 233 of 1947), an operator registered for measurement certification business related to concentrations under Article 107 of the Measurement Act or an operator certified as conforming to international laboratory accreditation standards, shall be treated as test results obtained from facilities almost equivalent to official test/research facilities stated in [2].

### 4. Test results regarding effects on residues in succeeding crops and soils, predicted environmental concentration, residual concentrations in seeds and silkworms

- [1] Public test/research facilities including independent administrative agencies, prefectural agricultural experimental stations and national university corporations, etc.
- [2] Public interest corporations with specialized expertise, private universities and facilities exclusively researching for cultivation and management of industrial crops almost equivalent to public test/research facilities
- [3] Test facilities that meet the following requirements
  - (a) SOPs are in place

- (b) In principle, study plans, test field notes and final reports are retained until the agricultural chemical is registered.
- (c) Necessary equipment for conducting the study is available.

Note that the study personnel with the above-mentioned facilities, etc. is possible to rent farm fields, etc. temporarily from farmers during the required period and conduct a field study.

Any test results regarding analytical study conducted by the applicant, etc. shall be treated as test results obtained from tests conducted by a public test/research facility, if the above-mentioned study personnel designs, instructs or evaluates the study.

## 6 Others

See the following documents to conduct studies and to submit test results.

1. Literatures referenced in the OECD Guidelines for Testing of Chemicals or OECD Guidance Documents with which the test methods comply.
2. World Health Organization (WHO) International Program on Chemical Safety, Environmental Health Criteria (IPCS EHC Criteria)
3. Food Safety Risk Assessment Guidelines for Residual Agricultural Chemicals by Food Safety Commission of Japan and Decisions by Agricultural Chemical Task Force

## Section 4 Substitution of documentation to be submitted

- 1 If some test results that are supposed to be submitted as a part of registration application have already been submitted by other applicants, and if those test results are acceptable as test results for the agricultural chemicals covered by the application, the applicant can submit those test results in attachment form as a substitute for test results that shall be otherwise submitted to support the application. In this case, if a person who previously submitted the test results that are being submitted as substitutes is different from the applicant, the applicant shall submit a written consent to submission of the same test results granted by the person who previously submitted them.
- 2 If an agricultural chemical TGAI covered by the application is deemed to be equivalent to the TGAI of an agricultural chemical that is already registered under Article 3, paragraph (1) or Article 34, paragraph (1) of the Act (only agricultural chemicals registered 15 or more years ago are acceptable, “previously registered agricultural chemical”) in terms of ingredients and toxicity, the test results listed below are possible to be omitted from submission. However, the omission is acceptable only at least 15 years after the test results of the previously registered agricultural chemical were submitted, and if the test results of the previously registered agricultural chemical are adequate for the review specified in Article 3, Paragraph (4) of the Act (and Article 34, paragraph (6) of the Act applied mutatis mutandis). Applicants who wish to have the documentation omitted from the review shall submit an omission application in Form 3 attached to the Ordinance.
  1. Test results regarding stability, degradability and other physical and chemical properties (limited to test results regarding Hydrolysis and Photolysis in water)
  2. Test results regarding metabolism in animals
  3. Test results regarding metabolism in plants and residues in crops, etc.
  4. Test results regarding metabolism in livestock producing meat, chicken eggs and other livestock products and residues in livestock products
  5. Test results regarding environmental behavior and residues in soil
  6. Test results regarding acute toxicity, short-term toxicity, long-term toxicity, genetic toxicity, carcinogenicity, reproductive toxicity, neurotoxicity and other toxicities (limited to test results used for evaluating the active ingredient)
  7. Test results regarding adverse effects on aquatic and terrestrial organisms in the environment (limited to test results used for evaluating the active ingredient)

## Section 5 Archive

The person who is granted registration of the agricultural chemicals shall retain the following contents for the respective period listed below. However, this shall not be applicable if it is extremely difficult to preserve the contents due to their nature.

Contents	Retention period
Contents supporting the documents submitted for the application for new or revised registration of agricultural chemicals	The period from the date when the agricultural chemicals is newly registered or the registration is revised, to the date when the first re-evaluation is completed.
Contents supporting the documents submitted for re-evaluation	The period from the date when the re-evaluation is completed to the date when the next re-evaluation is completed.

## Supplementary provisions (April 1, 2019)

1. This notification shall be applied to test results submitted for agricultural chemical registration applications that are started on and after April 1, 2019.
2. Notwithstanding the provisions of the preceding paragraph, test methods regarding physical and chemical properties that are started on and before March 31, 2020 which are submitted for applications of agricultural chemicals registrations shall be possible to apply the previous provision of other data and information to be attached to the application for Registration of an Agricultural Chemical (The Notification, Ref.No.13-Seisan-3987, issued on 10 January 2002 by the Director General, Agricultural Production Bureau, MAFF of Japan) Appendix 1 I-III.
3. Notwithstanding the provisions of Paragraph 1, test methods regarding efficacy and phyto-toxicity that are started on and before March 31, 2020 shall be possible to apply the previous provision which are Data Requirements for Supporting Registration of Agricultural Chemicals (The Notification, Ref. No. 12-Nousan-8147, issued on November 24, 2000 by the Director-General, Agricultural Production Bureau, MAFF of Japan, hereinafter referred to as “old Notification of the Director General”) Annex 1 <Efficacy Test> and <Phytotoxicity Test>, and Implementing rules of “Data Requirement for Supporting Registration of Agricultural Chemicals” (The Notification, Ref. No. 13-Seisan-3986, issued on 10 October, 2001 by the Director, Agricultural Production Materials Division, Agricultural Production Bureau, MAFF of Japan, hereinafter referred to as “old Notification of the Director”) Appendix 3 <Efficacy and Phytotoxicity Test>.
4. Notwithstanding the provisions of Paragraph 1, numbers of trials regarding efficacy, phyto-toxicity, residues in crops and metabolism in plants submitted for agricultural chemical registration applications that are started on and before March 31, 2020 shall be possible to apply the previous provision which are old Notification of the Director General Annex 1 Appendix Table 1 and 2, and, old Notification of the Director 1 3.to 6.
5. Notwithstanding the provisions of Paragraph 1, the provision of test results regarding metabolism and residues in livestock that are related to agricultural chemicals specified in Appendix 5 of the old Notification of the Director General (May 15, 2014) shall be still valid.
6. Notwithstanding the provisions of Paragraph 1, when this notification shall be implemented, registration applications of agricultural chemicals that contain the same active ingredients as the agricultural chemicals that are currently registered (except those that have been re-evaluation under Article 8 (1) of the Act) shall apply the provision of Appendix 5 (2) of the old Notification of the Director General for the time being.

## Supplementary provisions (June 28, 2019)

1. The provisions revised by this notification shall be applied to test results submitted for agricultural chemical registration applications that are started on and after April 1, 2020. However, Appendix Form, the provision of “Component Analysis on Agricultural chemical TGAI” 3 (4) ① related to the Japanese Industrial Standards in Appendix <Components on Agricultural chemicals and TGAI> and the provision of “Genetic toxicity” 2 (2) of “(b) acute toxicity, short-term toxicity, long-term toxicity, genetic toxicity, carcinogenicity, reproductive toxicity, neurotoxicity and other toxicities” in Appendix <Adverse effects on human>, all of which are revised by this notification, shall be implemented on July 1, 2019.
2. Notwithstanding the provisions of the preceding paragraph, test results regarding physicochemical properties of agricultural chemicals that are started on and before March

31, 2020 shall be possible to apply in accordance with the previous examples regardless of Table 2 (2) [10] and [11] A) besides regardless of physicochemical properties of agricultural chemicals 2 (9) and (10) [1] listed in the Appendix <Stability, degradability and other physical and chemical properties>.

3. Notwithstanding the provisions of Paragraph 1, the number of trials, etc. regarding residues in crops submitted as a part of the agricultural chemical registration application that are started on and before July 1, 2020 shall be possible to apply to the Table 6 attachments 2 and 4 in the section 2 of the previous provision.
4. Notwithstanding the provisions of paragraph (1), the provisions of 5 (2) [2] (g) to (i) in Section 1, Table 5 (b) (2) [7] to [9] (including other provisions related to the test results specified in [7] to [9] in the same table) and, the provisions of “dermal absorption”, “exposure in a field of an agricultural chemical user” and “estimation of exposure in a field of an agricultural chemical user” in “(b) Acute toxicity, short-term toxicity, long-term toxicity, genetic toxicity, carcinogenicity, reproductive toxicity, neurotoxicity and other toxicities” in Appendix <Adverse effects on human>, all of which are revised by this notification, shall not be possible to be applied until the criteria stipulated by the Minister of Agriculture, Forestry and Fisheries, as provided in Item 1 of the notification of the MAFF No. 480 of 2019 (Notification establishing criteria for whether or not Article 4, Paragraph (1), Item 5 of the Agricultural Chemicals Control Act is applicable), are set out.
5. Notwithstanding the provisions of Paragraph 1, the test results regarding toxicity on aquatic or terrestrial living environment organisms for agricultural chemicals containing the same active ingredients as the agricultural chemicals applied for registrations on and before March 31, 2020 (except the agricultural chemicals subjected to re-evaluation under Paragraph (1) of Article 8 of the Act) shall apply the provisions of 9 (1) [1] or [2] in Section 1, Table 9 (1) [1] or [2] in Section 2, or, “Toxicity on Aquatic organisms” or “Toxicity on avian” in Appendix <Toxicity on aquatic organisms and livestock>, all of which are the provisions preceding the revision by the notification.
6. Notwithstanding the provisions of Paragraph 1, the provisions relating to agricultural chemicals on which the Minister of Agriculture, Forestry and Fisheries determines that it is difficult to conduct some of the studies covered by the test results on the effects on honeybees (test results listed by the provisions in 9 (2) [1] in Section (1), Table 9 (1) [3] in Section (2) (including other provisions related to the test results regarding effects on honey bees in the same table) and “a) Toxicity on honey bees” of “Toxicity on Livestock” in Appendix <Toxicity on living Environment organisms and Livestock>) shall be applied in accordance with the previous examples.

#### Supplementary provisions (August 21, 2020)

1. The provisions revised by this notification shall be applied to test results submitted for agricultural chemical registration applications that are started on and after October 1, 2020.
2. Notwithstanding the provisions of previous Paragraph, registration applications of agricultural chemicals that contain the same active ingredients as the agricultural chemicals applied for registrations on and before September 30, 2020 (except those that have been re-evaluation under Article 8 (1) of the Act) shall not apply the provision of 9 (1) [2] a) in Section (1), Table 9 (1) [3] in Section (2) (including other provisions related to the test results regarding adverse effects on wild bumble bees in the same table) and “b) Toxicity on wild bumble bees” of “Toxicity on terrestrial living environment organisms” in Appendix <Toxicity on living Environment organisms and Livestock>.

Table 1 Test results regarding composition of an agricultural chemical and the TGAI

1. Test results used for evaluating an agricultural chemical TGAI      Test substance: Agricultural chemical TGAI		
Test results	Requirement of data submission	Contents (Δ) of conditional requests, etc.
[1] Types and contents of ingredients contained in an agricultural chemical TGAI and their concentrations	○	
[2] Manufacturing methods of an agricultural chemical TGAI	○	
[3] Impurities that are possible to be contained in an agricultural chemical TGAI and its origins	○	
[4] Analysis of composition of an agricultural chemical TGAI		
Analysis of composition of an agricultural chemical TGAI	○	
Analysis of dioxins in an agricultural chemical TGAI	○	
Analysis of composition of an agricultural chemical TGAI used for toxicity studies	○	
[5] Setting upper and lower limits on concentrations for ingredients in an agricultural chemical TGAI	○	
[6] Equivalence of an agricultural chemical TGAI	○	
2. Test results used for evaluation of formulation products      Test substance: formulation product		
Test results	Requirement of data submission	Contents (Δ) of conditional requests, etc.
Composition and manufacturing methods of an agricultural chemical	○	

Table 2 Test results regarding stability, degradability and other physical and chemical properties

1. Test results used for evaluation of an active ingredient		
Test substance: Pure substance of active ingredients, etc. (in principle, purity of 98% or higher. If it is difficult to conduct a study by use of a pure substance, it is possible to use technical substance. If the active ingredient consists of multiple chemical substances and it is possible to be separated the substance, the study shall be conduct by use of the separated substances.)		
Test results	Requirement of data submission	Contents ( $\Delta$ ) of conditional requests
[1] Melting point	○	
[2] Boiling point	○	
[3] Density	○	
[4] Vapor pressure	○	
[5] Appearance (color / physical state)	○	
[6] Odor	○	
[7] Spectrum		
(a) Ultraviolet visible absorption	○	
(b) Infrared radiation absorption	○	
(c) Nuclear magnetic resonance	○	
(d) Mass spectrometry	○	
[8] Solubility in water	○	
[9] Solubility in organic solvents	○	
[10] n-Octanol /water partition coefficient	○	
[11] Hydrolysis	$\Delta$	If scientific knowledge on hydrolysis, such as half-life, etc., is obtained from the results of studies on fate in water, submission of test results is not required.
[12] Photolysis in water	$\Delta$	If scientific knowledge on photolysis in water, such as half-life, etc., is obtained from the results of studies on fate in water, submission of test results is not required.
[13] Dissociation constant	○	
[14] Thermal stability	○	
<p>If active ingredients are widely used in foods, etc. and clearly safe for humans, livestock and aquatic and terrestrial organisms, it is possible to submit papers or articles instead of test results.</p> <p>If active ingredients, which are expected not to flow into rivers and other water systems, are applicable to the following one of (1) to (5), it is not required to submit test results regarding hydrolysis and photolysis in water.</p> <p>(1) An agricultural chemical is used with the components enclosed, such as attractants, etc.</p> <p>(2) An agricultural chemical is used by placing it in certain locations, such as in the case of repellents, rodenticides and slug killing agents, etc.</p> <p>(3) An agricultural chemical is applied to applicable crops or injected into the trunk of applicable crops</p> <p>(4) An agricultural chemical is used only in facilities such as warehouses and greenhouses, etc.</p> <p>(5) An agricultural chemical is not used extensively and in large quantities at once, such as aerosols, etc.</p>		



Table 2 (continued)

2. Test results used for evaluation of formulation products																															
Test substance: formulation product																															
Test results	Necessity to submit the test results																														
	Dustable powder		Granule				Dust-granule mixture, fine granule F, microgranule F	Powder	Wettable powder				water soluble powder			Emulsifiable concentrate	Soluble concentrate	Oil or oil miscible liquid	Aerosol	Microcapsules			Liniment			Smoke agent		Fumigant	Spreader		
			Ordinary	DL	Without water-soluble bag				In water-soluble bag		Ordinary	Granule, dry flowable	In water-soluble film	Suspension concentrate, sol	Dust					Granule	Tablet	Liquid	Solid	Paste	Dust	Liquid	Paste			Tablet	Dust
	Fine granule	Larger than fine granule			Fine granule	Larger than fine granule																									
[1] Appearance (color / physical state)	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○		
[2] Fineness	○	○					○	○																							
[3] Particle size			○		○					○	○																				
[4] Stability of stock solution														○	○	○													○		
[5] Stability of diluted solution or Wettability								○	○	○	○				○	○															
[6] Water solubility or solubility in water																															
[7] Suspension rate								○	○	○	○																				
[8] Density															○	○	○												○	○	
[9] Inflammability																														○	○
[10] Storage stability	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	
[11] Other studies required for the formulation products																															
A) Studies on DL dustable powder Mean particle size Particles with a diameter of 10 μm or less		○																													
B) Studies on formulation products in tablet form, etc. Size and weight				○		○																							○		
C) Studies on formulation products wrapped by water-soluble films Water-solubility of water-soluble bag						○	○																								
D) Studies on suspended concentrate and sol Viscosity																															
E) Studies on oil or oil miscible liquid Miscibility with hydrocarbons																															
F) Studies on aerosol Flame extension, internal pressure, Absence/presence of leakage of injected gas, injection status																															
G) Studies on microcapsules Physical state, film thickness, mean particle size, concentrations of non-microencapsulated active ingredients																															
H) Studies on paste Consistency																															
I) Studies on smoke Smoke emittance and smoke emitting period																															
J) Studies on fumigation Unevaporated residue																															
K) Studies on spreader, sticker Surface tension																															
L) Explosibility	If agricultural chemicals contain any explosive ingredients (active ingredients and other ingredients), on which it is necessary to submit test results.																														
<p>If the formulation products are not possible to be classified into any category in the table, it is necessary to submit documents on appearance (color tone / physical state), size, and weight. Documents on the water solubility of the water-soluble bag are required for the formulation product in water-soluble bag</p> <p>If an agricultural chemical falls under [9], [11] F) or [11] L), Article 2, Paragraph 1, Item 11 of the Regulations it is necessary to submit documents on the following studies.</p> <p>[9]: Study specified in Article 1-6 of the Cabinet Order Concerning the Control of Hazardous Materials (Cabinet Order No. 306, Dec. 1959) under the Fire Service Act (Act No. 186 of 1948)</p> <p>[11] F): Test methods described in the remarks column within the table in Ri, Item 3, Article 4, of the Notification Related to the Enforcement Order of High-Pressure Gas Safety Act (Notification of Ministry of International Trade and Industry No. 139, 1997) is applied to the flame length. Test guidelines specified in JIS S 3301 (Test methods for aerosols and other products) are applied to other test parameters.</p> <p>[11] L): Study specified in Article 1-7 of the Cabinet Order Concerning the Control of Hazardous Materials under the Fire Service Act</p>																															

Table 3 Test results regarding efficacy on applicable pests/diseases/weeds and crops, etc.

Test results	Requirement of data submission	Contents (Δ) of conditional requests, etc.
1. Efficacy against applicable diseases or pests/diseases/weeds and crops, etc.	○	In principle, it shall be performed at the same time as the phyto-toxicity test The necessary numbers of efficacy trials for combinations of applicable crops or crop groups, pests, weeds or other purposes of use and application methods shall be provided in the attachment Note that if a study is conducted in multiple test fields at the same time, test fields that are under different weather conditions shall be selected. If multiple tests are conducted on the same test field, different periods of time and seasons shall be assigned.
2. Biological Action of an agricultural chemical	Δ	The study report shall be submitted to apply for a formulation product containing a new active ingredient. Any additional information is submitted whenever it is obtained. If an application for a formulation product containing registered active ingredients is filed, it is not necessary to submit the study reports.
Test substance: formulation product If it is clear from the registered use whether or not it has effectiveness, it is not necessary to submit study reports on efficacy.		

Table 4 Test results regarding phyto-toxicity to crops, etc.

Test results	Requirement of data submission	Contents (Δ) of conditional requests, etc.
1. Phyto-toxicity to applicable crops	○	The necessary numbers of phyto-toxicity trials for combinations of applicable crops or crop groups and application methods shall be provided in the attachment
2. Residual odor of tea	Δ	If it is not used for tea, it is not necessary to submit test results. The necessary numbers of trials are provided in the attachment.
3. Smoking taste of tobacco	Δ	If it is not used for tobacco, it is not necessary to submit test results. The necessary numbers of trials are provided in the attachment
<p>Test substance: formulation</p> <p>If it is clear from the registered use whether or not it has phyto-toxic effects, it is not necessary to submit study reports on phyto-toxicity. If a test substance falls under (1) or (2), it is not necessary to submit test results on phyto-toxicity on applicable crops.</p> <p>(1) An agricultural chemical is used with the active ingredients enclosed, such as attractants, etc. (2) An agricultural chemical is used by placing it in certain locations, such as in the case of repellents, rodenticides and slug killing agents, etc.</p> <p>If A test substance falls under one of (1) to (3), it is not necessary to submit test results on the residual odor in tea.</p> <p>(1) An agricultural chemical is used with the active ingredients enclosed, such as attractants, etc. (2) An agricultural chemical is used by placing it in certain locations, such as in the case of repellents, rodenticides and slug killing agents, etc. (3) An agricultural chemical is used for treatment of soil (Excluding agricultural chemical with systemic action)</p> <p>If A test substance falls under one of (1) to (5), it is not necessary to submit test results on the taste of tobacco.</p> <p>(1) An agricultural chemical is used with the active ingredients enclosed, such as attractants, etc. (2) An agricultural chemical is used by placing it in certain locations, such as in the case of repellents, rodenticides and slug killing agents, etc. (3) An agricultural chemical is used for treatment of soil (Excluding agricultural chemical with systemic action) (4) An agricultural chemical is used in nursery bed. (5) An agricultural chemical is used directly attached to seeds, etc. like seed dressing.</p>		

## Attachment Required numbers of efficacy trials in applicable pests and crops, etc., and phyto-toxicity trials in applied crops

## 1. Principles

Efficacy and phyto-toxicity trials should be conducted at 6 or more test sites with different climate and cultivation conditions for all the combination of crops (if registration is sought for crop groups, representative crops of the groups), pests/diseases/weeds, and application methods, etc. However, in following cases, it is possible to reduce the numbers of trials as follows.

- (1) If a combination of a crop and a pest/disease/weed is the same as the combination covered by the registered agricultural chemical and one of the following conditions is satisfied, the trials could be conducted at 3 or more test sites that differ in climate and cultivation conditions for the combination. And, it is not necessary to conduct phyto-toxicity trials for case 4 and efficacy trials for case 5.
  1. An agricultural chemical contains the same active ingredients as the registered one, although its formulation type is different.
  2. An agricultural chemical contains the same active ingredients as the registered one and their formulation type is the same, although the agricultural chemical has a lower application concentration or amount of the active ingredients.
  3. An agricultural chemical contains more than one different active ingredient, which are also active ingredients of other registered agricultural chemicals, although the concentrations of those ingredients in the agricultural chemical individually differ each other from those in the registered agricultural chemicals.
  4. An agricultural chemical is a registered agricultural chemical, although the application concentration or amount of the active ingredients is decreased.
  5. An agricultural chemical is a registered agricultural chemical, although the application concentration or amount of the active ingredients is increased.
  6. An agricultural chemical is a registered agricultural chemical, although the application method is changed.
- (2) If a combinations of a crop and a pest/disease/weed is the same as the combination covered by the registered agricultural chemical and one of the following conditions is satisfied, the trials could be conducted at 2 or more test sites that differ in climate and cultivation conditions for the combination.
  1. An agricultural chemical is the same as a registered one in terms of active ingredients and the formulation type and the application concentration or amount of the active ingredients is equal to or greater than that of the registered one.
  2. An agricultural chemical contains more than one different active ingredient, which are also active ingredients of other registered agricultural chemicals, and the concentrations of those ingredients in the agricultural chemical are identical with the concentrations in the registered agricultural chemicals.

When one of the following conditions is met, the trials could be conducted at two or more test sites, which differ from each other in terms of climate and cultivation conditions for the combination of a crop and a pest/disease/ weed.

1. An agricultural chemical is a registered agricultural chemical, and registration is sought for a new minor pest/disease of a registered crop.
  2. An agricultural chemical is a registered agricultural chemical, and registration is sought for a new crop that has biological similarity to a registered crop regarding to the same pest/disease.
  3. Registration is sought for a crop that is produced only in limited areas or a minor crop
  4. Registration is sought for a pest/disease/weed which inhabit a limited area.
  5. An agricultural chemical is a registered agricultural chemical, and a pest/disease/weed needs to be urgently registered for plant protection purpose.
- (4) When one of the following conditions is satisfied, the trials could be conducted at 3 or more test sites which differ from each other in terms of climate and cultivation conditions for the combination of a crop and pest/ disease/weed.
1. An agricultural chemical is a mixture of a new active ingredient and active ingredients contained in other registered agricultural chemicals, and the combinations of crops and pests/diseases/weeds covered by the agricultural chemical include the same combinations of crops and pests/ diseases/weeds covered by the registered agricultural chemicals. The trials are conducted exclusively on the combinations covered by the registered agricultural chemicals.
  2. An agricultural chemical is a registered one and covers addition of a new crop regarding to a pest/disease that is not easily controlled and has wide host range.
  3. An agricultural chemical is a registered one and it is used in crop-free fields or under conditions that keeps it away from crops. It covers addition of a new crop regarding to a pest/disease that occurs on these situation.
- (5) Trials on an agricultural chemicals used in warehouses and silos, etc. could be conducted in 3 or more test sites for all the combinations of crops and pests.

(Note) Registered agricultural chemical mentioned in this provision refers to an agricultural chemical for which the applicant has obtained the registration and on which the applicant owns the right to use the associated test results.

## 2. Application for crop groups

Crop groups	Required numbers of CTES	
	Efficacy study	Phyto-toxicity study
Cereal grains	<ul style="list-style-type: none"> <li>• 6 or more trials in rice</li> <li>• 8 or more trials in total in wheat and barley ( 6 or more trials in at least one crop)</li> <li>• 2 or more trials in each of two or more crops that are classified into solghum gain and millet</li> <li>• 2 or more trials in one or more crops that are classified into amaranthace pseudocereal</li> <li>• 2 or more trials in buckwheat</li> </ul>	<ul style="list-style-type: none"> <li>• 6 or more trials in rice</li> <li>• 8 or more trials in total in wheat and barley ( 6 or more trials in at least one crop)</li> <li>• 2 or more trials in each of two or more crops that are classified into solghum gain and millet</li> <li>• 2 or more trials in one or more crops that are classified into amaranthace pseudocereal</li> <li>• 6 or more trials in sweet corn</li> <li>• 2 or more trials in buckwheat</li> </ul>
Barley, similar gains an Wheat, similar grains	8 or more trials in wheat and barley ( 6 or more trials in at least one crop)	8 or more trials in wheat and barley ( 6 or more trials in at least one crop)
Sorghum gain and Millet	2 or more trials in each of two or more crops that are classified into the crop group	2 or more trials in each of two or more crops that are classified into the crop group
Amaranthaceae pseudocereal	2 or more trials in one or more crops that are classified into the crop group	2 or more trials in one or more crops that are classified into the crop group
Corns	6 or more trials in sweet corn	6 or more trials in sweet corn
Citrus fruits	6 or more trials in total in crops that are classified into the crop group	6 or more trials in total in crops that are classified into the crop group
Pome fruits	<ul style="list-style-type: none"> <li>• 8 or more trials in total in apples and pears ( 6 or more trials in at least one crop)</li> <li>• 2 or more trials in loquat</li> </ul> <p>However, if loquat is not included in the applicable crops, totally 8 or more trials in apples and pears ( 6 or more trials in at least one crop)</p>	<ul style="list-style-type: none"> <li>• 8 or more trials in total in apples and pears ( 6 or more trials in at least one crop)</li> <li>• 2 or more trials in loquat</li> </ul> <p>However, if loquat is not included in the applicable crops, totally 8 or more trials in apples and pears ( 6 or more trials in at least one crop)</p>
* If loquat is not included in applicable crop, test results on apples and pears have to be submitted.		

Crop groups	Required numbers of CTES	
	Efficacy study	Phyto-toxicity study
Stone fruits	<ul style="list-style-type: none"> <li>• 6 or more trials in peach</li> <li>• 2 or more trials in one or more crops other than peach that are classified into the small stone fruits</li> </ul>	<ul style="list-style-type: none"> <li>• 6 or more trials in peach</li> <li>• 2 or more trials in one or more crops other than peach that are classified into the small stone fruits</li> </ul>
Peaches	6 or more trials in peach	6 or more trials in peach
Small stone fruit group	6 or more trials in total in crops that are classified into the crop group	6 or more trials in total in crops that are classified into the crop group
berries and other small fruits	<ul style="list-style-type: none"> <li>• 6 or more trials in grapes</li> <li>• 2 or more trials in blueberries</li> <li>• 2 or more trials in one or more crops other than blueberries that are classified into the crop group</li> </ul>	<ul style="list-style-type: none"> <li>• 6 or more trials in grapes</li> <li>• 2 or more trials in blueberries</li> <li>• 2 or more trials in one or more crops other than blueberries that are classified into the crop group</li> </ul>
Berries	<ul style="list-style-type: none"> <li>• 2 or more trials in blueberries</li> <li>• 2 or more trials in one or more crops other than blueberries that are classified into the crop group</li> </ul>	<ul style="list-style-type: none"> <li>• 2 or more trials in blueberries</li> <li>• 2 or more trials in one or more crops other than blueberries that are classified into the crop group</li> </ul>
Brassica vegetables (flower head and stem brassicas)	<ul style="list-style-type: none"> <li>• 6 or more trials in broccoli</li> <li>• 2 or more trials in Sichuan vegetable or Kohlrabi</li> </ul>	<ul style="list-style-type: none"> <li>• 6 or more trials in broccoli</li> <li>• 2 or more trials in Sichuan vegetable or Kohlrabi</li> </ul>
Flower head brassicas crop group	6 or more trials in broccoli	6 or more trials in broccoli
Stem brassicas	2 or more trials in Sichuan vegetable or Kohlrabi	2 or more trials in Sichuan vegetable or Kohlrabi
Tuberous and corm vegetables	12 or more trials in total in potato, sweet potato, taro and yam (6 or more trials in at least one crop and 2 or more trials in each of the other crops)	<ul style="list-style-type: none"> <li>• 6 or more trials in potato</li> <li>• 6 or more trials in sweet potato</li> <li>• 6 or more trials in taro</li> <li>• 6 or more trials in yam</li> </ul>
Fruiting Vegetable, Cucurbits	10 or more trials in total in one crop selected from cucumbers, watermelons or melons and pumpkins (6 or more trials in at least one crop and 2 or more trials in each of the other crops)	10 or more trials in total in one crop selected from cucumbers, watermelons or melons and pumpkins (6 or more trials in at least one crop and 2 or more trials in each of the other crops)
Fruiting Vegetable, Cucurbits (immature)	6 or more trials in cucumber	6 or more trials in cucumber
Fruiting Vegetable, Cucurbits (mature)	<ul style="list-style-type: none"> <li>• 6 or more trials in one crop selected from watermelon or melon</li> <li>• 2 or more trials in pumpkin</li> </ul>	<ul style="list-style-type: none"> <li>• 6 or more trials in one crop selected from watermelon or melon</li> <li>• 2 or more trials in pumpkin</li> </ul>
Stalk and Stem vegetables	<ul style="list-style-type: none"> <li>• 2 or more trials in one or more crops that are classified into taro petioles</li> <li>• 2 or more trials in fuki</li> <li>• 2 or more trials in asparagus</li> <li>• 2 or more trials in one or more crops that are classified into stalk and stem vegetables other than crops classified in taro petioles, fuki and asparagus</li> </ul>	<ul style="list-style-type: none"> <li>• 2 or more trials in one or more crops that are classified into taro petioles</li> <li>• 2 or more trials in fuki</li> <li>• 2 or more trials in asparagus</li> <li>• 2 or more trials in one or more crops that are classified into stalk and stem vegetables other than crops classified in taro petioles, fuki and asparagus</li> </ul>
Taro petioles	2 or more trials in one or more crops that are classified into the crop group	2 or more trials in one or more crops that are classified into the crop group
Fuki (Giant butterbur) group	2 or more trials in fuki	2 or more trials in fuki
Root vegetables	14 or more trials in total in one crop selected from Japanese radish or turnip, carrots, burdock, ginger and sugar beet (6 or more trials in at least one crop and 2 or more trials in each of the other crops)	<ul style="list-style-type: none"> <li>• 8 or more trials in total in Japanese radish and turnip (6 or more trials at least in one crop)</li> <li>• 6 or more trials in carrot</li> <li>• 6 or more trials in burdock</li> <li>• 6 or more trials in ginger</li> <li>• 2 or more trials in sugar beet</li> </ul>
Fruiting vegetable, Solanaceae plants	10 or more trials in total in tomato, eggplant and bell pepper (6 or more trials in at least one crop and 2 or more trials in each of the other crops)	10 or more trials in total in tomato, eggplant and bell pepper (6 or more trials in at least one crop and 2 or more trials in each of the other crops)
Peppers	6 or more trials in bell peppers	6 or more trials in bell peppers
Pulses	10 or more trials in total in soybean or edamame, kidney or string bean, and green or snap pea (6 or more trials in at least one crop and 2 or more trials in each of the other crops)	10 or more trials in total in soybean or edamame, kidney or string bean, and green or snap pea (6 or more trials in at least one crop and 2 or more trials in each of the other crops)
Legume vegetables		

Crop groups	Required numbers of CTES	
	Efficacy study	Phyto-toxicity study
Leaf vegetables	<ul style="list-style-type: none"> <li>• 8 or more trials in total in cabbage and Chinese cabbage (6 or more trials in at least one crop)</li> <li>• 2 or more trials in perilla and 2 or more trials in each of two or more crops other than perilla classified into Lamiaceae leafy vegetables</li> <li>• 6 or more trials in celery</li> <li>• 2 or more trials in each of 2 or more crops other than celery classified into Apiaceae leafy vegetables</li> <li>• 6 or more trials in spinach</li> <li>• 6 or more trials in lettuce or leaf lettuce</li> <li>• 6 or more trials in garland chrysanthemum</li> </ul>	<ul style="list-style-type: none"> <li>• 10 or more trials in total in komatsuna, cabbage and Chinese cabbage (6 or more trials in at least one crop and 2 or more trials in the other crops)</li> <li>• 2 or more trials in each of 2 or more crops other than komatsuna classified into leafy brassica</li> <li>• 2 or more trials in perilla and 2 or more trials in each of two or more crops other than perilla classified into Lamiaceae leafy vegetables</li> <li>• 6 or more trials in celery</li> <li>• 2 or more trials in each of 2 or more crops other than celery classified into Apiaceae leafy vegetables</li> <li>• 6 or more trials in spinach</li> <li>• 6 or more trials in lettuce or leaf lettuce</li> <li>• 6 or more trials in garland chrysanthemum</li> </ul>
Brassica leafy vegetables	<ul style="list-style-type: none"> <li>• 6 or more trials in komatsuna</li> <li>• 2 or more trials in 2 or more crops other than komatsuna that are classified into the crop group</li> </ul>	<ul style="list-style-type: none"> <li>• 6 or more trials in komatsuna</li> <li>• 2 or more trials in 2 or more crops other than komatsuna that are classified into the crop group</li> </ul>
Head Brassicas	8 or more trials in cabbage and Chinese cabbage (6 or more trials in at least one crop)	8 or more trials in cabbage and Chinese cabbage (6 or more trials in at least one crop)
Lamiaceae Labiatae leafy vegetables	2 or more trials in perilla and 2 or more trials other than perilla that are classified into the crop group	2 or more trials in perilla and 2 or more trials other than perilla that are classified into the crop group
Apiaceae leafy vegetables	<ul style="list-style-type: none"> <li>• 6 or more trials in celery</li> <li>• 2 or more trials in each of 2 or more crops other than celery that are classified into the crop group</li> </ul>	<ul style="list-style-type: none"> <li>• 6 or more trials in celery</li> <li>• 2 or more trials in each of 2 or more crops other than celery that are classified into the crop group</li> </ul>
Amaranthaceae leafy vegetables	6 or more trials in spinach	6 or more trials in spinach
Lettuce, chichory and endive	6 or more trials in lettuce or leaf lettuce	6 or more trials in lettuce or leaf lettuce
Asteraceae leafy vegetables except other than lettuce, chicory, and endive	6 or more trials in garland chrysanthemum	6 or more trials in garland chrysanthemum
Bulb vegetables	8 or more trials in bulb onions and green onions (6 or more trials in at least one crop)	8 or more trials in bulb onions and green onions (6 or more trials in at least one crop)
Bulb onions	6 or more trials in bulb onions	6 or more trials in bulb onions
green onions	6 or more trials in green onions	6 or more trials in green onions
Edible flowers	2 or more trials in each of 3 or more crops that are classified into the crop group	2 or more trials in each of 3 or more crops that are classified into the crop group
Edible fungi	2 or more trials in each of 3 or more crops that are classified into the crop group	2 or more trials in each of 3 or more crops that are classified into the crop group
Flowers and ornamental foliage plants	<ul style="list-style-type: none"> <li>• 6 or more trials in chrysanthemum</li> <li>• 2 or more trials in each of 2 or more crops that are classified into the crop group</li> </ul>	<ul style="list-style-type: none"> <li>• 6 or more trials in chrysanthemum</li> <li>• 2 or more trials in each of 2 or more crops that are classified into the crop group</li> </ul>
Trees	2 or more trials in each of 3 or more crops that are classified into the crop group	2 or more trials in each of 3 or more crops that are classified into the crop group

## 3. Residual odor in tea and taste of tobacco

Crops	Necessary numbers of CTES
Residual odor of tea	2 or more trials
Smoking taste of tobacco	2 or more trials (however, 3 or more trials if stem and leaves are directly exposed to the agricultural chemical or if the active ingredient of the agricultural chemical is absorbed from the root)

Table 5 Test results regarding adverse effects on humans

1. Test results regarding metabolism in animals			
Test results	Requirement of data submission		Contents (Δ) of conditional requests
	Applied on crops, etc. that are used for food or feed	Applied on crops, etc. that are not used for food or feed	
Animal metabolism	○	○	
Test substance: Active ingredient, etc. labeled with a radioisotope or unlabeled active ingredient, etc. If an agricultural chemical falls under one of conditions (1) to (3), it is not necessary to submit test results. (1) Active ingredients are widely used in foods, etc. and clearly safe for humans (2) An agricultural chemical is used with the active ingredients enclosed, such as attractants, etc. (3) An agricultural chemical is used by placing it in certain locations, such as in the case of repellents, rodenticides and slug killing agents, etc.			

2. Test results regarding acute toxicity, short-term toxicity, long-term toxicity, genetic toxicity, carcinogenicity, reproductive toxicity, neurotoxicity and other toxicities			
[1] Test results used for evaluating active ingredients		Test substance: Agricultural chemical TGAI	
Test results	Requirement of data submission		Contents (Δ) of conditional requests
	Applied on crops, etc. that are used for food or feed	Applied on crops, etc. that are not used for food or feed	
(a) Acute oral toxicity	○	○	
(b) Acute dermal toxicity	Δ	Δ	If an active ingredient falls under one of the characteristics mentioned below in (1) to (2), it is not necessary to submit test results. (1) TGAI has corrosive properties (strong acidity (roughly pH 2 or less) or strong alkalinity (roughly pH 11.5 or more), etc.). (2) TGAI has median lethal dose value exceeds 2,000 mg/kg body weight
(c) Acute inhalation toxicity	○	○	
(d) Skin sensitization	○	○	
(e) 90-day repeated dose oral toxicity	○1	○2	If TGAI falls under 1, test results involving 2 species of animals (usually rats and dogs) shall be submitted. If it falls under 2, test results involving 1 species (usually rats) shall be submitted. If an agricultural chemical contains volatile active ingredients including fumigation, etc., it is possible to submit 90-day repeated inhalation toxicity test instead of 90-day repeated dose oral toxicity.
(f) 90-day repeated inhalation toxicity	Δ	Δ	If an acute inhalation toxicity study shows that the inhalation toxicity is significantly stronger than other acute toxicity through other exposure routes, the test results shall be submitted.
(g) 21-day repeated dose dermal toxicity	Δ	Δ	If an acute dermal toxicity study shows that dermal toxicity is significantly stronger than acute toxicities through other exposure routes, the test results shall be submitted.
(h) Genetic toxicity			
A) Reverse mutation ( <i>in vitro</i> )	○	○	
B) Chromosomal aberration ( <i>in vitro</i> )	○	○	
C) Micronucleus ( <i>in vivo</i> )	○	○	
D) Gene mutation or DNA damage ( <i>in vivo</i> )	Δ	Δ	If test results on reverse mutation test ( <i>in vitro</i> ) shows positive or false positive, the test results shall be submitted.
(i) Chronic toxicity	○	X	It is possible to submit test results on a combined study with carcinogenicity study. If a combined study with carcinogenicity study shows carcinogenicity, etc. which is consider to be induce by non-genetic toxicity, the results considered on the mechanism suggested by additional studies, etc. shall be reported.
(j) Carcinogenicity	○	X	Test results involving 2 species of animals (usually rat and mouse) shall be submitted. It is possible to submit test results on a combined study with chronic toxicity study for the one species of the 2 species. If a combined study shows carcinogenicity, etc. which is consider to be induced by non-genetic toxicity, the results considered on the mechanism suggested by additional studies, etc. shall be reported.
(k) Reproductive toxicity	○	X	
(l) Developmental toxicity	○	○	Test results involving 2 species of animals (usually rat and rabbit) shall be submitted.
(m) Developmental neurotoxicity	Δ	Δ	If other studies on toxicity, such as neurotoxicity and reproductive toxicity, etc., show neurological effects (clinical neurotoxicity symptoms, functional/behavioral effects, brain weight changes, nervous system malformations, histopathological findings on nerve tissue, etc.) related to administration to animals at an adult or developmental stage and suggest the need to examine neurotoxicity in the developmental stage, the associated test results shall be submitted.

Test results	Requirement of data submission		Contents (Δ) of conditional requests
	Applied on crops, etc. that are used for food or feed	Applied on crops, etc. that are not used for food or feed	
(n) Acute neurotoxicity	Δ	Δ	If observations of general conditions in acute oral toxicity studies and observations of detailed conditions, functional study and histopathology, etc. in 90-day repeated dose oral toxicity studies using rat, showed no evidence suggesting specific neurotoxicity at doses less than the lethal dose, and if no similarity to any known neurotoxic substances is found in the chemical structure, or if repeated oral dose neurotoxicity or 28-day repeated dose oral neurotoxicity study (OECD Test No. 424) suggests no neurotoxicity, it is not necessary to submit the test results.
(o) Acute delayed neurotoxicity	Δ	Δ	If an active ingredient fall under one of the characteristics mentioned in (1) or (2) below, it is not necessary to submit the test results. (1) Other test results including acute toxicity study, etc. show that the active ingredient have no cholinesterase inhibition. (2) An active ingredient is phosphate ester compounds and is not cholinesterase inhibiting compounds.
(p) 28-day repeated dose delayed neurotoxicity	Δ	Δ	If an acute delayed neurotoxicity study is not required to be submitted, or if the acute delayed neurotoxicity study clearly shows no delayed neurotoxicity, it is not necessary to submit the test results.
(q) Repeated dose oral neurotoxicity	Δ	Δ	In order to assess neurotoxicity in association with general toxicity, combined study with repeated oral dose toxicity study is possible to be submitted. If detailed observations of conditions, function study and histopathology, etc. in 90 day repeated doses oral toxicity studies in rats, etc. show no evidence suggesting specific neurotoxicity at a dose less than the lethal dose, and if no similarity to any known neurotoxic substances is found in the chemical structure, or if a 28-day repeated dose oral neurotoxicity study (OECD Test No. 424) suggests no neurotoxicity, it is not necessary to be submitted the test results.
(r) Toxicity of additives and impurities	○	○	
(s) Detoxification methods or emergency medical treatment	Δ	Δ	If an active ingredient falls under one of the characteristics mentioned below in (1) to (3), it is not necessary to be submitted the test results. (1) an acute oral toxicity study shows that the median lethal dose value is 300 mg/kg or less (2) an acute dermal toxicity study shows that the median lethal dose is 1,000 mg/kg or less (3) an acute inhalation toxicity study shows that the median lethal concentration is 2,500 ppm or less for gas, 10 mg/L or less for steam, or 1 mg/L or less for dust or mist.
<p>If an active ingredient is widely used in foods, etc. and clearly safe for humans, it is not necessary to submit test results above mentioned. However, since reverse mutation (<i>in vitro</i>) is regarded as basic information on the toxicity of chemical substances, the test results shall be submitted, excluding substance widely used as foods such as nitrogen and starch, etc. that are recognized as safe.</p> <p>If an agricultural chemical is used with the active ingredients enclosed, such as attractants, etc., it is not necessary to submit all the test results mentioned above, excluding acute oral toxicity.</p> <p>If an agricultural chemical is used by placing it in certain locations, as in the case with repellents, rodenticides and killing slug agent, etc., and if agricultural chemical users clearly are not exposed to the agricultural chemical, it is not necessary to submit all the test results mentioned above, excluding an acute oral toxicity, acute dermal toxicity, skin sensitization, and reverse mutation (<i>in vitro</i>)</p> <p>If human consumption of the active ingredients, etc. through the crop is highly unlikely to occur because the agricultural chemical is used in the early stages of growth of applicable crops, etc., like agricultural chemicals, etc. used directly attached to seeds, etc. as seed dressing, it is not necessary to submit test results on chronic toxicity, carcinogenicity or reproductive toxicity.</p> <p>It is desirable to submit any test results necessary to help further examine the findings observed in the submitted toxicity studies (e.g., immunotoxicity and endocrine disruption studies, etc.).</p>			
[2] Test results used for evaluating an agricultural chemical (formulation products)		Test substance: formulation product	
Test results	Requirement of data submission		Contents (Δ) of conditional requests
(a) Acute oral toxicity	○		
(b) Acute dermal toxicity	Δ		If an active ingredient of an agricultural chemical fall under one of the characteristics mentioned below in (1) or (2), it is not necessary to submit the test results. (1) It is shown that it has corrosive properties (strong acidity (roughly pH 2 or less) or strong alkalinity (roughly pH 11.5 or more), etc.). (2) An acute oral toxicity study shows the median lethal dose value exceeds 2,000 mg/kg body weight
(c) Acute inhalation toxicity	Δ		If an active ingredient of an agricultural chemical are vaporized for use as is the case with fumigation and smoke, etc., it is necessary to submit the test results.
(d) Skin irritation	Δ		If it is shown that it has corrosive properties (strong acidity (roughly pH 2 or less) or strong alkalinity (roughly pH 11.5 or more) etc.), it is not necessary to submit the test results.
(e) Eye irritation	Δ		If an active ingredient of an agricultural chemical fall under one of the characteristics mentioned below in (1) or (2), it is not necessary to submit the test results. (1) It is shown that it has corrosive properties (strong acidity (roughly pH 2 or less) or strong alkalinity (roughly pH 11.5 or more), etc.). (2) It is suspected to be corrosive, etc. from the result of a skin irritation study.
(f) Skin sensitization	○		
(g) Dermal absorption	Δ		If an applicant wishes to take into account this test result for the evaluation, it is necessary to submit the test results.
(h) Exposure of operator to agricultural chemicals applying them in the field	Δ		If it is not possible to calculate a predicted exposure using the prediction formula, it is necessary to submit the test results. If an applicant wishes to use this test results to estimate the exposure of an agricultural chemical user, it is possible to be submitted the test results.

Test results	Requirement of data submission		Contents of conditional requests(Δ)
	Applied on crops, etc. that are used for food or feed	Applied on crops, etc. that are not used for food or feed	
(i) Estimation of exposure level of operator to agricultural chemicals	○		
<p>Notes on (a) to (f)</p> <p>If it is possible to be classify a formulation product into any mixture category defined by the Global Harmonized System for Classification and Labeling of Chemicals (GHS), according to the GHS mixture classification criteria (bridging principle, additivity formula, additivity method [cutoff value/concentration limit]), it is allowed to be replaced the above-mentioned test results with the classification results. If a classification results are submitted, the toxicity data on mixtures similar to the mixture to be used or on the components shall be submitted.</p> <p>If an active ingredients, etc. including attractants, etc. are encapsulated when the agricultural chemical is used, it is not necessary to submit the above-mentioned test results.</p> <p>Notices on (g) to (i)</p> <p>If an active ingredient is widely used in foods, etc. and clearly safe for humans, it is not necessary to submit the test results mentioned in (g) to (i).</p> <p>If an active ingredient is encapsulated when the agricultural chemical is used through preparation and spraying operations, as is the case with attractants and products packed by water-soluble film, etc., it is not necessary to submit the test results mentioned in (g) to (i).</p>			



Table 6 Test results regarding metabolism in plants and residues in crops, etc.

Test results	Requirement of data submission		Contents (△) of conditional requests, etc.
	Applied on crops, etc. that are used for food or feed	Applied on crops, etc. that are not used for food or feed	
1. Metabolism in plants	○	×	If an agricultural chemical is used for fumigation in warehouse and if it is possible to be easily inferred from the structures of the active ingredients that their metabolites are inorganic or volatile substances, it is not necessary to submit the test results. If an agricultural chemical is used for rice, paddy rice shall be included in the test crops.
2. Residues in crops	○	×	Necessary numbers of trials for each applicable crop and crop group shall be as shown in the attachment. Note that if a study is conducted in multiple test fields at the same time, test fields that are under different weather conditions shall be selected. If multiple studies are conducted on the same test field, they shall be conducted during different cultivation periods or seasons.
3. Residues in processed commodities	△	×	It is desirable to submit test results for the purpose of refining the estimated intake for dietary exposure assessments.
4. Residues in succeeding crops	△	△	In principle, if an estimated half-life of the active ingredients, etc. shown in the soil residue study does not exceed 100 days, it is not necessary to submit the test results.
<p>Test substance: [Metabolism in plants] Active ingredients, etc. labeled with radioisotope or non-labeled active ingredients, etc., [Residues in processed commodities] Active ingredients, etc. or formulation labeled with radioisotope, [Residues in crops, Residues in succeeding crops] formulation product</p> <p>If an agricultural chemical fall under at least one of the characteristics mentioned below in (1) to (4), it is not necessary to submit the above-mentioned test results.</p> <p>(1) Active ingredients are widely used in foods, etc. and clearly safe for humans</p> <p>(2) An agricultural chemical is used with its components enclosed, such as attractants, etc.</p> <p>(3) An agricultural chemical is used by placing it in certain locations, such as in the case of repellents, rodenticides and slug killing agents, etc.</p> <p>(4) Human intake of the components, etc. of the agricultural chemical through the crop is highly unlikely to occur because the agricultural chemical is used in the early growth stages of the applicable crops such as in the case of an agricultural chemical applied by directly attaching it to seeds, etc. like powder dressing, etc..</p>			

## Attachment: Required number of trials regarding residues in crops to be submitted

## 1. Principles

The applicable Crop and Conditions, etc.	Required numbers of trial CTES (per crop)
Crops with particular high production volume	6 or more trials
Crops with high production volume	3 or more trials
Crops with low production volume	2 or more trials
Crops to be fumigated in a warehouse after harvesting	2 or more trials
Crops which is clear that agricultural chemicals do not remain from application timings and methods	2 or more trials

## 2. Application for crop groups

Crop groups	Test crops used for the study	Required numbers of CTES
Cereal grains	Rice	6 or more trials
	Barley	3 or more trials
	Maize/Corn (harvested dried grains)	3 or more trials
	Sweet corn	3 or more trials
	Barley, similar grains and Wheat, similar grains	Wheat Barley
Sorghum grain and Millet	1 crop classified into Sorghum grain and Millet	3 or more trials
Amaranthaceae pseudocereals	1 crop classified into Amaranthaceae pseudocereals (If the application method is the same as that to wheat, it is possible to be submitted test results regarding wheat instead of Amaranthae pseudocereals)	3 or more trials
Maize cereals and Sweet corns	Maize/Corn (harvested dried grains)	3 or more trials
	Sweet corn	3 or more trials
Citrus fruits	Satsuma	6 or more trials
	A) Kabosu, Sudachi and Yuzu B) Lemon C) Kumquats	3 or more trials in A), B) or C)
	Apple and Pear	12 or more trials in total (4 or more trials in 1 crop)
Pome fruits * If loquat is not included in applicable crops, test results regarding apples and pears shall be submitted	Loquat	3 or more trials
Stone fruits	Peach or Japanese apricot	3 or more trials
	Plum	2 or more trials
	Sweet Cherry	3 or more trials
Peaches	Peach	3 or more trials
Small stone fruits	Japanese apricot Plum	3 or more trials 2 or more trials
Berries and other small fruits	Grapes	3 or more trials
	Blueberries or Gooseberries	3 or more trials
	Blueberries	3 or more trials
	Raspberries	3 or more trials
Berries group	Berries other than blueberries or raspberries (1 crop)	2 or more trials

Crop groups	Test crops	Required numbers of trials
Brassica vegetables (Flowerheads and Stem Brassicas)	Broccoli	3 or more trials
	Kohlrabi or Stem mustard	3 or more trials
	Flowerhead Brassicas	Broccoli
Stem Brassicas	Kohlrabi or Stem mustard	3 or more trials
Tuberous and corm vegetables	Potato or Sweet potato	6 or more trials
Fruiting vegetables, Cucurbits	Cucumber	6 or more trials
	Zucchini	3 or more trials
	Pumpkin /Winter squash or Melons, except Watermelon	3 or more trials
Fruiting vegetables, Cucurbits (immature)	Cucumber	6 or more trials
	Zucchini	3 or more trials
Fruiting vegetables, Cucurbits (mature)	Pumpkin /Winter squash or Melons, except Watermelon	3 or more trials
Stalk and Stem vegetables	Zuiki or Indian taro (petiole)	3 or more trials
	Asparagus	3 or more trials
	Taro petioles	Zuiki or Indian taro/Giant elephant ear (petiole)
Fuki (Giant butterbur) group	Fuki/Giant butterbur	3 or more trials
Root vegetables	Turnip/Swede	3 or more trials
	Japanese radish (Daikon)	6 or more trials
	Carrot	6 or more trials
Fruiting vegetables, Solanaceous plant	Tomato and Cherry tomato	6 or more trials (3 or more trials in Cherry tomato)
	Bell pepper	3 or more trials
	Peppers other than Bell pepper	3 or more trials
Peppers	Eggplant	6 or more trials
	Bell pepper	3 or more trials
	Peppers other than Bell pepper	3 or more trials
Pulses	Soya bean (dry)	6 or more trials
	Adzuki bean (dry) or Common bean/Kidney bean (dry)	3 or more trials
	Pea/Field pea (dry) or Broad bean (dry)	3 or more trials
Legume vegetables	Soya bean (succulent seeds in pods)	3 or more trials
	Common bean (poroto) (pods and succulent seeds)	3 or more trials
	Garden pea (succulent seeds) or Broad bean (immature pods and succulent seeds)	3 or more trials
Leaf vegetables	Komatsuna or Mizuna	3 or more trials
	Cabbage/Savoy or Chinese cabbage	6 or more trials
	Head lettuce or Leaf lettuce	6 or more trials (4 or more trials in Leaf lettuce)
	Spinach	6 or more trials
	Brassica leafy vegetables	Komatsuna or Mizuna
Head Brassicas	Cabbage or Chinese cabbage	6 or more trials
Lamiaceae leafy vegetables	Perilla leaves	3 or more trials

Crop groups		Test crops	Required numbers of trials	
Apiaceae leafy vegetables		Celery	3 or more trials	
		Coriander leaves, Parsley leaves or Japanese honewort	3 or more trials	
	Amaranthaceae leafy vegetables		Spinach	6 or more trials
	Lettuce, chicory and endive	Head lettuce	4 or more trials	
		Leaf lettuce	4 or more trials	
Asteraceae leafy vegetables, except lettuce, chicory and endive		Garland chrysanthemum	3 or more trials	
Bulb vegetables		Bulb Onion	6 or more trials	
		Welsh onion/Leek	6 or more trials	
	Bulb onions	Bulb Onion	6 or more trials	
	Green onions	Welsh onion/leek	6 or more trials	
Edible flowers		Edible Chrysanthemum or other edible flowers	3 or more trials	
Edible fungi		Shiitake mushroom	3 or more trials	
		Edible fungi other than Shiitake mushroom (1 crop)	3 or more trials	

## 3. Application method of the agricultural chemical on that the residues in crops is likely to below the limit of quantification

Crop groups	Test crops used for the study	Required number of trials
Cereal grains	Rice and grains other than Gramineae	4 or more trials
Fruits	3 or more families of fruits	6 or more trials
Vegetables	5 or more families of vegetables	10 or more trials

## 4. Special notes on test crops

Crops	Test crops	Required number of trials
Grapes	Small fruit type grapes and large fruit type grapes	3 or more trials
Pear	Japanese, Chinese or European pear	6 or more trials
Tomato	Tomato and Cherry tomato	6 or more trials (3 or more trials in Cherry tomato)
Eggplant	konasu and other eggplant	6 or more trials
Welsh onion/Leek	Hanegiand Nebukanegi (earthed up after planting)	3 or more trials

Table 7 Test results regarding metabolism in livestock producing meat, chicken eggs and other livestock products and residues in livestock products

Test results	Requirement of data submission		Contents (Δ) of conditional requests, etc.
	Applied on crops, etc. that are used for food or feed	Applied on crops, etc. that are not used for food or feed	
1. Metabolism in livestock	Δ	×	If a residue study on the crops or by-products (rice straw, etc.) used for livestock feed shows that the residues concentrations of the test substance and major metabolites are below the limit of quantification, it is not necessary to submit the test results. In principle the limit of quantification shall be set aiming at around 0.01 to 0.05 mg/kg (the limit of quantification for the feed crops, etc., to which the maximum residue limits for pasture grass is applied, shall be set aiming at the concentration which become equivalent to 0.01 to 0.05 mg/kg if the moisture content of crop is converted to 10%).
2. Residues in livestock	Δ	×	If a livestock metabolism study shows that the residual concentrations of the test substance and its major metabolite in the livestock product were both less than 0.01 mg/kg, or if the fact that the test substance or major metabolite remained in the livestock product, and all the following results (1) to (3) are found, it is not necessary to submit the test results. (1) Residue concentration of test substances and major metabolites measured in livestock products are very close to the limit of quantification. (2) The test substances dose to livestock in the livestock metabolism study is significantly higher than the estimated maximum dietary burden of livestock based on the residual concentration obtained by the test on residues in crops. (3) Residue concentration scientifically estimated from the ratio of the estimated maximum dietary burden of livestock to the dose administered to livestock in the livestock metabolism study is less than 0.01 mg/kg.
3. Bioconcentration	Δ	Δ	If a n-Octanol /water partition coefficient, indicative of the physical and chemical properties, is 3.5 or more, it is necessary to submit the test results.
<p>Test substance: [Metabolism in livestock, Bioconcentration] Active ingredient labeled with a radioisotope, etc. or unlabeled active ingredient etc. [Residue in livestock] Active ingredient, etc.            If the active ingredients, etc. are widely used in foods, etc. and clearly safe for humans, it is not necessary to submit the test results above mentioned.            If use of an agricultural chemical falls under at least one of the following descriptions (1) to (3), it is not necessary to submit the test results regarding metabolism in livestock and residue in livestock.</p> <p>(1) An agricultural chemical is used with its components encapsulated, such as attractants.            (2) An agricultural chemical is used by placing it in certain locations, such as in the case of repellents, rodenticides and slug killing agents, etc..            (3) Human intake of the components, etc. of the agricultural chemical through the crop is highly unlikely to occur because the agricultural chemical is used in the early growth stages of the applicable crops, such as in the case of agricultural chemical applied by directly attaching it to seeds, etc. like powder dressing</p> <p>If an agricultural chemical falls under at least one of the following usage descriptions (1) to (6), it is not necessary to submit the test results regarding bioconcentration.</p> <p>(1) An agricultural chemical is used with its components enclosed, such as attractants, etc.            (2) An agricultural chemical is used by placing it in certain locations, such as in the case of repellents, rodenticides and slug killing agents, etc.            (3) An agricultural chemical is applied to applicable crops or injected into the trunk of applicable crops            (4) An agricultural chemical is used only in warehouses or greenhouse, etc.            (5) An agricultural chemical is not used extensively or in large quantities at once, such as aerosols, etc.            (6) An agricultural chemical is used directly attached to seeds, etc. like seed dressing.</p>			

Table 8 Test results regarding environmental behavior and residues in the soil

Test results	Requirement of data submission		Contents of conditional request (Δ), etc.
	Used in paddy fields	Used in fields other than paddy fields	
1. Behavior in Soil			
[1] Aerobic flooded soil	○	×	
[2] Aerobic soil	Δ	○	If an agricultural chemical is used only in paddy fields, and if the half-life of active ingredients, etc. in aerobic flooded soil exceeds 100 days, it is not necessary to submit the test results.
[3] Anaerobic soil	Δ	Δ	If use of an agricultural chemical falls under one of the following descriptions (1) to (3), it is not necessary to submit the test results. (1) It is used only in paddy fields (2) Half-life of an active ingredients, etc. in aerobic soil is 100 days or less. (3) Water solubility is 10mg/L or lower or where the soil adsorption coefficient (K <sub>ads</sub> F <sub>oc</sub> ) is 500 or larger.
2. Residues in soil	Δ	Δ	If it is recognized that concentration in soil is very low (the concentration in soil calculated from the amount used is 0.01 or less mg/kg) because it is directly attached to such seeds, etc. as seed dressing, it is not necessary to submit the test results.
3. Soil adsorption	○	○	
4. Behavior in water			
[1] Hydrolysis	○	○	
[2] Photolysis in water	○	○	If it is used in paddy fields, it is necessary also to submit test results using natural water.
5. Derivation of predicted environmental concentration			
[1] Measurements of concentration in paddy water from a paddy lysimeter	Δ	×	If test results are not used to calculate the predicted environmental concentration (derivation of predicted environmental concentration for risk assessment on human health, and derivation of predicted environmental concentration for risk assessment on aquatic organisms and avian), it is not necessary to submit the test results.
[2] Measurements of concentration in paddy water from a paddy field	Δ	×	If test results are not used to calculate the predicted environmental concentration (derivation of predicted environmental concentration for risk assessment on human health, and derivation of predicted environmental concentration for risk assessment on aquatic organisms), it is not necessary to submit the test results.
[3] Runoff from simulated field surfaces	×	Δ	
[4] Drift	Δ	Δ	
[5] Monitoring in rivers	Δ	Δ	Monitoring only covers existing registered agricultural chemicals. If test results are not used as a substitute for predicted environmental concentrations (derivation of predicted environmental concentration for risk assessment on human health, and derivation of predicted environmental concentration for risk assessment on aquatic organisms), it is not necessary to submit the test results.
[6] Derivation of predicted water pollution concentration	○	○	
<p>Test substance: [Behavior in soil, soil adsorption, behavior in water] active ingredient, etc. labeled with a radioisotope or unlabeled active ingredient, etc. [Residues in soil, Derivation of predicted environmental concentration for risk assessment on human health] formulation products.</p> <p>If an active ingredient is widely used in foods, etc. and clearly safe for humans, livestock and animals and plants in human living environment, it is not necessary to submit the above test results.</p> <p>If an active ingredient falls under the following (1) to (5), where it is considered that there is no risk that active ingredients, etc. is mixed into soil, it is not necessary to submit test results regarding behavior in soil, residue in soil and soil absorption.</p> <p>(1) An agricultural chemical is used with its components enclosed, such as attractants, etc.  (2) An agricultural chemical is used by placing it in certain locations, such as in the case of repellents, rodenticides and slug killing agent, etc.  (3) An agricultural chemical is applied to applicable crops or injected into the trunk of applicable crops  (4) An agricultural chemical is used only in a warehouse, etc. or any facility where the soil is not exposed  (5) An agricultural chemical is not used extensively and in large quantities at once, such as aerosols, etc.</p> <p>If an active ingredient falls under the following (1) to (5), where it is considered that there is no risk that an active ingredient flow into water systems such as river, etc., it is not necessary to submit test results regarding behavior in water.</p> <p>(1) An agricultural chemical is used with its components enclosed, such as attractants, etc.  (2) An agricultural chemical is used by placing it in certain locations, such as in the case of repellents, rodenticides and killing slug agent.  (3) An agricultural chemical is applied to applicable crops or injected into the trunk of applicable crops  (4) An agricultural chemical is used only in warehouses or greenhouses, etc.  (5) An agricultural chemical is not used extensively and in large quantities at once, such as aerosols, etc.</p> <p>If an active ingredient falls under the following (1) to (6), where it is considered that active ingredients are not afraid to be mixed into farmlands and flow into water systems of rivers, etc., it is not necessary to submit the test results regarding derivation of predicted environmental concentration.</p> <p>(1) An agricultural chemical is used with its components enclosed, such as attractants, etc.  (2) An agricultural chemical is used by placing it in certain locations, such as in the case of repellents, rodenticides and slug killing agents, etc.  (3) An agricultural chemical is applied to applicable crops or injected into the trunk of applicable crops  (4) An agricultural chemical is used only in warehouses or greenhouses, etc.  (5) An agricultural chemical is not used extensively and in large quantities at once, such as aerosols, etc.  (6) An agricultural chemical is used directly attached to seeds, etc. like seed dressing.</p>			

Table 9 Test results regarding adverse effects on aquatic and terrestrial organisms in the environment

(1) Test results used for the evaluation of active ingredient		Test substance: Agricultural chemical TGAI (formation product is used for effects on honeybee colonies and residue in pollen/nectar)	
Test results	Requirement of data submission	Contents (Δ) of conditional requests, etc.	
[1] Adverse effects on aquatic and terrestrial environment organisms in waters			
A) Fish acute toxicity	○		
B) Acute immobilization on daphnids	○		
C) Acute immobilization on daphnids (adults)	△	If an age of crustaceans is taken into consideration to evaluate the agricultural chemical, it is possible to submit the test results.	
D) Adverse effects of coexistent organic substances on fish acute toxicity and daphnids acute immobilization	△	If a coexisting organic substance of the agricultural chemical (excluding agricultural chemical containing metal elements) is likely to have significant interactions with cationic chemical substances, and humic acids are evaluated for possible effects on fish and daphnia in their actual environment, it is possible to submit the test results.	
E) Acute immobilization on chironomid larvae	△	If an agricultural chemical has insecticidal activity derived from its mechanism of action, it is possible to submit the test results.	
F) Acute toxicity on freshwater shrimps ( <i>Paratya compressa compressa</i> and <i>Paratya compressa improvisa</i> )	△	If differences from other species in crustaceans, etc. are taken into consideration to evaluate the agricultural chemical, it is possible to submit the test results.	
G) Acute toxicity on amphipoda	△	If differences from other species in crustaceans, etc. are taken into consideration to evaluate the agricultural chemical, it is possible to submit the test results.	
H) Reproduction on daphnids	△	If an agricultural chemical has insect growth regulative activity, including chitin synthesis inhibition, etc., and if its estimated half-life in water is 4 or more days, it is required to submit the test results.	
I) Growth inhibition on algae and cyanobacteria	○	Test results on <i>Raphidocelis subcapitata</i> shall be submitted. If differences from other species in algae, etc., are taken into consideration to evaluate the agricultural chemical, it is possible to submit additional test results on species other than <i>R. subcapitata</i> .	
J) Growth inhibition on <i>Lemna</i> sp.	△	If an agricultural chemical is a herbicide or plant growth regulator, test results on growth inhibition shall be submitted. The study report has to be submitted. If the differences from other species in algae, etc. are taken into consideration to evaluate the agricultural chemical, it is possible to submit the additional test results.	
K) Derivation of predicted environmental concentration in water	○		
[2] Adverse effects on avian			
A) Acute oral toxicity on avian	○		
B) Predicted exposure dose on Avian	○		
C) Residues in seeds (excluding paddy rice)	△	If the test results are to be used in the calculation of the estimated exposure level, it is necessary to submit the test results.	
D) Residues in seeds (Paddy rice)	△	If the test results are to be used in the calculation of the estimated exposure level, it is necessary to submit the test results.	
[3] Adverse effects on honeybees and wild bumblebees			
A) Acute dermal toxicity on adults honeybees	○		
B) Acute oral toxicity on adults honeybees	△	If oral exposure to adult honeybees due to ingestion of pollen or nectar with agricultural chemical residues is expected, it is necessary to submit the test results.	
C) Chronic oral toxicity on adults honeybee	△	If honeybee acute oral exposure assessments show that the ratio of exposure dose to toxicity index exceeds a certain level (0.04), it is necessary to submit the test results, because it is predicted to have adverse effects on adult honeybees by the repeated oral dose of the excess.	
D) Oral toxicity on honeybee larvae	△	If oral exposure to honeybee larvae is expected due to ingestion of pollen or nectar with agricultural chemical residues, it is necessary to submit the test results.	
E) Adverse effects on colonies	△	If exposure assessments in individual honeybees show that the ratio of the exposure dose to toxicity index exceeds the level of concern (0.4), it can submit the test results.*	
F) Residues in pollen and nectar	△	If measured values exposure of pollen/nectar to the agricultural chemical is taken into account to evaluate the oral exposure, it is necessary to submit the test results.	
G) Estimated exposure level	○		

Article 4, paragraph 1, item 8 of the Act (including cases where it is applied mutatis mutandis in Article 34, Paragraph 6 of the Act) is not applicable, it is desirable to submit the test results using additional species.

If an active ingredients are widely used in except agricultural chemicals and clearly safe for the animals and plants involved in the above-mentioned studies, it is not necessary to submit the test results.

If the following (1) to (5) where it is considered that that active ingredients, etc. are not afraid to flow into the water system of rivers, etc. it is not necessary to submit the test results regarding adverse effects on aquatic organisms in the environment.

- (1) An agricultural chemical is used with its components enclosed, such as attractants, etc.
- (2) An agricultural chemical is applied to applicable crops or injected into the trunk of applicable crops
- (3) An agricultural chemical is used only in facilities such as warehouses and greenhouses, etc.
- (4) An agricultural chemical is not used extensively and in large quantities at once, such as aerosols, etc.
- (5) An agricultural chemical is used directly attached to seeds, etc. like seed dressing.

If the following (1) to (5) where it is considered that avian is not afraid to be exposed to active ingredients, etc. it is not necessary to submit the test results regarding avian acute oral toxicity

- (1) An agricultural chemical is used with its components enclosed, such as attractants, etc.
- (2) An agricultural chemical is applied to applicable crops excluding their edible portions or injected into the trunk of applicable crops
- (3) An agricultural chemical is used only in facilities such as warehouses and greenhouses, etc.
- (4) An agricultural chemical is soil fumigation used for field or nursery bed treatment, etc.
- (5) An agricultural chemical is used only to repel birds

If the following (1) to (5) where it is considered that avian is not afraid to be exposed to active ingredients, etc. it is not necessary to submit the test results regarding avian acute oral toxicity and avian predicted exposure dose.

- (1) An agricultural chemical is used with its components enclosed, such as attractants, etc.
- (2) An agricultural chemical is used by placing it in certain locations, such as in the case of repellents, rodenticides and slug killing agents, etc.
- (3) An agricultural chemical is used only in warehouses or other facilities where bees are not released
- (4) An agricultural chemical is not used extensively and in large quantities at once, such as aerosols, etc.
- (5) An agricultural chemical is applied on crops to be harvested before flowering or crops that do not flower (including crops that are controlled so as not to flower).
- (6) An agricultural chemical is applied on flowering crops whose flowers are found not be visited by honeybees

Crops mentioned in (5) and (6) are listed in the Attachment "Crops to which honeybees are unlikely to be exposed".

\* For details on evaluation and required Test results, refer to Attachment 2 "Guidelines for evaluating the effects of agricultural chemicals on honeybees.

Exposures related to the effects on honeybees should be estimated for every combination of formulation product, crops and uses.



(2) Test results used to evaluate the formulation product		Test substance: formulation product
Test results	Requirement of data submission	Contents (Δ)of conditional requests, etc.
[1] Adverse effects on aquatic organisms in the environment		
A) Acute toxicity on fish	Δ	If applicable crops include water-intensive crops, it is necessary to submit the test results.
B) Acute immobilization on daphnids	Δ	
C) Growth inhibition on algae and cyanobacteria	Δ	
[2] Adverse effects on silkworms	Δ	If mulberry is included in the applicable crops, it is necessary to submit the test results.
<p>If an active ingredient falls under the following (1) to (6), where it is considered that an agricultural chemical is not afraid to flow into the water system of rivers, etc. it is not necessary to submit the test results regarding adverse effects on aquatic organisms in the environment.</p> <p>(1) An agricultural chemical is used with its components enclosed, such as attractants, etc.  (2) An agricultural chemical is used by placing it in certain locations, such as in the case of repellents, rodenticides and slug killing agents, etc.  (3) An agricultural chemical is applied to applicable crops or injected into the trunk of applicable crops.  (4) An agricultural chemical is used only in a warehouses or greenhouse, etc.  (5) An agricultural chemical is not used extensively and in large quantities at once, such as aerosols, etc.  (6) An agricultural chemical is used directly attached to seeds, etc. like seed dressing.</p> <p>If an active ingredient falls under the following (1) and (2), where it is considered that active ingredients are not afraid to be exposed to silkworm, it is not necessary to submit the test results regarding adverse effects on silkworms.</p> <p>(1) An agricultural chemical is used with its components enclosed, such as attractants, etc.  (2) An agricultural chemical is used by placing it in certain locations, such as in the case of repellents, rodenticides and slug killing agents, etc.</p>		

Table 10 Test results regarding analysis methods on samples used in tests

1. Test results used for the evaluation of an active ingredient			
Test results	Requirement of data submission		Contents (Δ) of conditional requests
	Applied on crops, etc. that are used for food or feed	Applied on crops, etc. that are not used for food or feed	
[1] Agricultural chemical TGAI	○	○	
[2] Residues in crops	○	X	
[3] Residues in livestock	○	X	
[4] Residues in soil	○	○	
[5] Residues in water	○	○	
[6] Stability in stored commodities	Δ	Δ	If samples are analyzed after storage, it is necessary to submit the test results.
Other than [1], it is possible to include it in each residual test result and submit it.			
2. Test results used for evaluation of formulation products			
Test results	Requirement of data submission		Contents (Δ) of conditional requests, etc.
	Applied on crops, etc. that are used for food or feed	Applied on crops, etc. that are not used for food or feed	
Active ingredients in an agricultural chemical	○	○	

Table 11 Documents regarding sample tests of an agricultural chemical

Test results	Requirement of data submission	Remarks
Analysis results on agricultural chemical formulation sample	△	When samples of the agricultural chemical and the test results report of the samples are submitted, it is necessary to submit the test results.