

**Voluntary Report** – Voluntary - Public Distribution

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**Report Name:** UPDATE - Pesticide Import Tolerance Application Process

**Country:** Taiwan

**Post:** Taipei

**Report Category:** Sanitary/Phytosanitary/Food Safety

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**Report Highlights:**

This report provides a brief overview on how to apply for a maximum residue limit (MRL) import tolerance (IT) in Taiwan. This report is a voluntary update to GAIN Report TW19013, published April 10, 2019; changes are highlighted in yellow. Taiwan has removed the data efficacy requirement on IT MRL applications.

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## General Information:

The Ministry of Health and Welfare is responsible for establishing MRLs in Taiwan. The Council of Agriculture (COA) oversees registering pesticides for domestic use. Any MRLs set as part of a domestic registration are automatically extended to imports. All food products, imported and domestic, must comply with Taiwan's "[Pesticide Residue Limits in Food](#)", which lists allowable residue tolerances.

Taiwan does not automatically adopt MRLs established by Codex as default standards. Many pesticides and animal drugs commonly used in the United States and internationally do not yet have established MRLs in Taiwan. The default tolerance in Taiwan for most pesticide residues is 0.01 parts per million (ppm).

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## Import Tolerance Application Process

Taiwan's Food and Drug Administration (TFDA) accepts MRL applications on imported products from interested parties, including registrants, chemical companies, grower groups, and the representative offices of exporting countries. Applicants are required to prepare the information listed in Appendix A and B. A flow chart of the application process is provided in Appendix C. TFDA will review the application to see if all required documents have been properly prepared. If not, applicants will need to provide any missing information.

The application will be further reviewed by the Food Sanitation safety and nutrition advisory committee. This committee is overseen by TFDA and includes experts and scholars specialized in food safety, toxicology, and risk assessment in accordance with Article 4 of the Act Governing Food Safety and Sanitation. If committee members raise concerns, the applicant may be required to provide additional information or clarifications.

If TFDA and the committee have no further questions and approve the application, TFDA will notify a draft standard domestically and to World Trade Organization (WTO) with a sixty-day comment period. The application process can take anywhere from six month to several years. TFDA will issue applicants an access code for its on-line status tracking system, which allows applicants to check the latest status of submission.

### Point of contact for MRL applications:

Taiwan Food and Administration, Food Safety Division: [sy77@fda.org.tw](mailto:sy77@fda.org.tw)

## Attachments:

No Attachments.

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**Update:** Effective February 5, 2020, the instructions have been revised and published by TFDA.

### Appendix A. [Requirements for establishing the tolerance of pesticide residue on crops](#)

1. Applicant
2. Common name
3. Commercial name or code
4. Chemical name (IUPAC)
5. Chemical Abstracts Service (CAS) Number
6. Chemical class
7. Functional class: Insecticide Fungicide Herbicide Others
8. End-product name, content (%), and any risk impurity
9. Commercialized countries
10. **Registered use (GAP)**
11. Physical & chemical characteristics (GLP) (2)( not required only for domestic registered pesticide)
  - (1). Active ingredient: common name, chemical name (IUPAC), Chemical Abstracts Service (CAS) Number, chemical formula, molecular weight.
  - (2). Technical grade: appearance, odor, melting point or boiling point, density or specific gravity, pH value, vapor pressure, octanol/water partition coefficient, dissociation constant, solubility in water, solubility in other solvents.
  - (3). Composition of technical-grade (5 batches report), Manufacturing process and discussion of impurities formation.
  - (4). Formulation and its composition of end-product
12. Toxicology data (Not required only for domestic registered pesticide)
  - (1). Acute oral toxicity
  - (2). Subchronic toxicity tests (at least 2 animals)
  - (3). Chronic feeding toxicity study and oncogenicity study (at least 2 animals for each study)
  - (4). Reproductive study-2 generation
  - (5). Teratogenicity study (at least 2 animals)
  - (6). Mutagenicity tests (Test items including bacteria, cell and in vivo tests)
13. Metabolism in animal
14. Metabolism in plant
15. Analytical methods
  - (1). Crop

- (2). Target
- (3). Abstract of analytical methods
- (4). Apparatus
- (5). Recovery
- 15. Analytical methods Cont'd.
  - (6). Limitation of detection
- 16. Residue trial data (GLP) 2 (submitted in accordance with the applied crops). Field trial numbers depend on applied crops. More than 3 trial data shall be submitted for domestic major crops 1; other minor crops at least submit 1 trial data.
- 17. International banned and restricted data, MRLs and ADI of applied pesticide

**Note:**

- 1. Major crops in Taiwan are including paddy rice, wheat, corn, small red bean (adzuki), peanut, pak-choi, vegetable soybean (edamame), cabbage, sweet potato (including leaf), bamboo shoot, watermelon, taro, celery, cauliflower, melon, onion, cucumber, carrot, bitter melon, eggplant, chinese chive, cantaloupe, mushroom, strawberry, potato, co-ba, tomato, chinese cabbage, lettuce, garlic, green onion, ginger, water spinach, radish, pumpkin, sesame, golden mushroom, pepper (including sweet pepper and hot pepper), pomelo, papaya, plum, mango, loquat, persimmon, orange, banana, peach, litchi, tankan mandarin, Chinese plum (Prunus mume), pear, Indian jujube, guava, sweet sop (including atemoya), ponkan mandarin, coconut, grape, pineapple, wax apple, longan, pitaya, lemon, tea, sugarcane, lily, rose, chrysanthemum, and orchid etc.
- 2. The GLP test facilities shall be of the OECD members or the OECD Mutual Acceptance of Data (MAD) system participants, the data can also be issued by the test facilities supervised by the countries with agreement on mutual acceptance of data with Taiwan.

**Appendix B. [Requirements for establishing the tolerance of veterinary drug residue in foods](#)**

- 1. Applicant
- 2. Common name
- 3. Commercial name or code
- 4. Chemical name (IUPAC)
- 5. Chemical Abstracts Service (CAS) Number
- 6. Chemical class
- 7. Functional class: Antibacterial agent Anti-parasitic agent Others
- 8. End-product name, content (%), and any risk impurity
- 9. Commercialized countries
- 10. Usage of veterinary drug
  - (1). Target animal
  - (2). Route of drug delivery and dosage
  - (3). Purpose

- (4). Withdrawal period
- 11. Toxicology data (Not required, only for domestic registered veterinary drug)
  - (1). Acute oral toxicity
- 11. Toxicology data (Not required, only for domestic registered veterinary drug) Cont'd.
  - (2). Subchronic toxicity tests
  - (3). Chronic feeding toxicity study and oncogenicity study
  - (4). Reproductive study-2 generation
  - (5). Teratogenicity study
  - (6). Mutagenicity tests
- 12. Metabolism in animal: absorption, distribution, metabolism, and excretion
- 13. Analytical methods
- 14. Residue trial data
- 15. International banned and restricted data, MRLs and ADI of applied veterinary drug

**Appendix C. Flow chart of MRL application process**

