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GAIN Report

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Pesticide Import Tolerance Application Process

Report Categories:

Sanitary/Phytosanitary/Food Safety

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Report Highlights:

This report provides a brief overview on how to apply for an import tolerance (IT) in Taiwan.

General Information:

The Ministry of Health and Welfare is responsible for establishing maximum residue limits (MRLs) in Taiwan. The Council of Agriculture (COA) is in charge of 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).

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 the 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

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 of impurity
9. Commercialized countries
10. Registered use (GAP) and the original efficacy documentation which supported the registration (submitted in accordance with the applied crops). Field trial numbers depend on applied crops. More than three trials data should be submitted for domestic major crops⁽¹⁾, other minor crops must submit at least one trial data.
11. Physical & chemical characteristics (GLP)⁽²⁾ (not required, only for domestic registrations)
 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 composition of end-product
12. Toxicology data (not required, only for domestic registrations)
 1. Acute oral toxicity
 2. Subchronic toxicity tests (at least 2 animals)
 3. Chronic feeding toxicity study and oncogenicity study (at least 2 animals)
 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
 6. Limitation of detection
16. Residue trial data (GLP)⁽²⁾
17. International banned and restricted data, MRLs and ADI of applied pesticide

Note:

1. Major crops in Taiwan include paddy rice, wheat, corn, small red bean, peanut, pak-choi, vegetable soybean, 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, prune, pear, jujube, guava, sweet sop, ponkan, coconut, grape, pineapple, wax apple, longan, pitaya, lemon, tea, sugarcane, lily, rose, chrysanthemum, and orchid etc.

1. The GLP test facilities shall be of the OECD members or the OEDC 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
 11. Target animal
 12. Route of drug delivery and dosage
 13. Purpose
 14. Withdrawal period
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1. Toxicology data (Not required, only for domestic registered veterinary drug)
 1. Acute oral toxicity
 2. Subchronic toxicity tests
 3. Chronic feeding toxicity study and oncogenicity study
 4. Reproductive study-2 generation
 5. Teratogenicity study
 6. Mutagenicity tests
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1. Metabolism in animal: absorption, distribution, metabolism, and excretion
 2. Analytical methods
 3. Residue trial data
 4. International banned and restricted data, MRLs and ADI of applied veterinary drug

Appendix C. Flow chart of MRL application process

