USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Voluntary _ Public

Date: 12/30/2015
GAIN Report Number: CH12064

China - Peoples Republic of

Post: Beijing

China Releases Guide for the Establishment of Maximum Residue Level

Report Categories:
Policy and Program Announcements

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Report Highlights:
In October 2015, the Chinese Ministry of Agriculture (MOA) released the Guide for the Establishment of Maximum Pesticide Residue Limits (MRL) of Pesticides in Foods. The Guide outlines the general procedures for MRL setting, re-evaluation, periodic assessment, special circumstances for MRL setting, and terminologies.

This report provides an unofficial translation of the MOA Guide.

General Information:
BEGIN TRANSLATION

Guide for the Establishment of Maximum Pesticide Residue Limits of Pesticides in Food

This guide is formulated according to the "Food Safety Law of the People's Republic of China", the "Quality Safety Law of Agricultural Products of the People's Republic of China", the "Regulations on Agricultural Pesticide Management" and the "Regulations on Registration Information of Agricultural Pesticides" to ensure the scientific, standardized and reasonable formulation of maximum pesticide residue limit in food.
The formulation of maximum residue limit in food (including the edible agricultural products) is defined as the maximum level of pesticide residues recommended according to the good agricultural practice (GAP) for pesticides application and supervised field trails, and the maximum residue limit (MRL) recommended by reference to the results of risk assessment of pesticide residues.
This guide is used to guide the formulation and revision of the maximum pesticide residue limit in food.

I. General Procedures

1. Determination of Supervised Trails Median Residue (STMR) and Highest Residue (HR)

Carry out the supervised field trails under the conditions of good agricultural practice (GAP) for pesticide application in accordance with the requirements of the "Regulations on Registration Information of Agricultural Pesticides" and the "Criteria on Pesticide Residue Field Trails" (NY/T 788), and determine the supervised trails median residue (STMR) and highest residue (HR) based on the results of the field trails.

1. Determination of Acceptable Daily Intake (ADI) and / or Acute Reference Dose (ARfD)

Formulate the acceptable daily intake based on the results of metabolic kinetics and toxicological evaluations. And determine the acute reference dose for the pesticides with acute toxicity.
Determine the maximum residue level according to China's dietary consumption data, calculate the national estimated daily intake, or short-term dietary intake according to the supervised field trails data to conduct dietary intake risk assessment and propose the national standard of maximum residue limit (MRL) for food safety.
For the recommended maximum residue limits, if lower than 10mg/kg, it will be rounded off to one significant figure, if higher than 10mg/kg and lower than 99mg/kg, it will be rounded to two significant figures, and if higher than 100mg/kg, it will be expressed in a multiple of 10. The maximum residue limits are usually set to 0.01, 0.02, 0.03, 0.05, 0.07, 0.1, 0.2, 0.3, 0.5, 0.7, 1, 2, 3, 5, 7, 10, 15, 20, 25, 30, 40 and 50 mg/kg.
The maximum residue limit applicable to the crops of the same group can be formulated according to the "Classification of Crop for Formulation of Standards of Pesticide Residue Limit".

I. Re-evaluation

In the following circumstances, the maximum pesticide residue limit already formulated should be reevaluated:
(a) When the approved good agricultural practice (GAP) for pesticide application have relatively significant changes;
(b) When the toxicological study approved that there is new potential risk;
(c) The monitoring data of the field trails data show new intake risks.
(d) Other cases identified by the Committee for Review of Standards of Pesticide Residues.
The reevaluation should be made in compliance with the procedure for formulation of standards of maximum pesticide residue limit.

I. Periodic Assessment

In order to guarantee the timeliness and validity of maximum pesticide residue limit, implement the periodical assessment system for maximum pesticide residue limit with an evaluation period of 15 years, while the evaluation period duration for the temporary limit and the extraneous maximum residue limit (EMRL) is 5 years.

I. Exceptional Cases

1. Temporary Limit

In the following circumstances, the temporary limit standards may be formulated:

1. When the daily intake is temporary;
2. When there are no perfect or reliable dietary data;
3. When there is no required standard of field trail method;
4. When there is international trade and import inspection needs as the pesticides or pesticide/crop combinations are not registered in China;
5. In emergency cases, the pesticide has been approved for use on an unregistered crop, an emergency limit standard should be formulated and the scope and time of its application should be defined;
6. When other information doesn't fully meet the requirement of the assessment procedure.

The development of temporary limit standard shall be carried out according to the procedures for formulation of the maximum pesticide residue limit. When new data are obtained, the amendment should be made in time.

1. Extraneous Maximum Residue Limit (EMRL)

For the pesticides that are forbidden to use and not easy to be degraded, the development of extraneous maximum residue limit is required because of the residue on the crop caused due to long-term and stable existence in the environment. The residue limit is formulated and revised based on the risk assessment obtained by the implementation of the national monitoring program.

1. **Exception of Residue Limit**

In the following circumstances, the formulation of residue limit is exceptional:

1. When the pesticide toxicity is very low and the pesticide is used in accordance with the provisions on the label, the pesticide residue in the food shall not cause unacceptable risk to the health;
2. When the use of pesticides only has a small dietary intake risk.

The pesticides exceptional for formulation of the residue limit should be determined by risk assessment one by one according to the toxicity and use methods of the specific pesticides.

1. **Maximum residue limit in spices and seasonings**

Under conditions of lack of the supervised field trail data, the monitoring data can be used, but providing detailed cultivation and production information as well as adequate monitoring data is required, the procedures shall be developed referring to the formulation of the maximum pesticide residue limit standard.

I. **Terminology**

1. **Good Agricultural Practice (GAP) for pesticide application:**

The good agricultural practice for pesticide application refers to the method, scope, dose, times and safety interval for the application of the pesticides.

1. **Supervised Field Trials:**

They refer to the tests carried out to obtain the highest residue of the recommended pesticides that may be used in the edible primary agricultural products (or as feed) and soil, as well as degradation dynamics of these pesticides in soil (or water) under conditions of good agricultural practice (GAP) and good laboratory practice (GLP) or similar conditions.

1. **Maximum Residue Limit (MRL):**

It is the maximum concentration of pesticide residues permitted by law in the food or agricultural products or on their surface, expressed in milligrams of pesticide residue per kilogram of food or agricultural product (mg/kg).

1. **Extraneous Maximum Residue Limit (EMRL):**

Although some persistent pesticides have been prohibited for use, but they also long-term remain in the environment, so that the residue is formed in the food, therefore their residue in food is formulated in order to control the pollution of this kind of pesticide residue to food, expressed in milligrams of pesticide residue per kilogram of food or agricultural product (mg/kg).

1. **Acceptable Daily Intake (ADI):**

The estimated dose of a certain substance that the people consume daily in all life without producing detectable danger to their health, expressed in acceptable intake per kilogram of the body weight (mg/kg).

1. **Acute Reference Dose (ARfD):**

The estimated dose of a certain substance that the people consume a substance over a period of 24 hours or less by eating or drinking without producing detectable danger to their health, expressed in acceptable intake per kilogram of the body weight (mg/kg).

1. **Risk Assessment:**

It refers to the scientific assessment of the known or possible serious adverse effects on health of human beings as a result of exposure to hazardous substances. Including the hazard identification, hazard characterization, exposure assessment and risk presentation.

1. **Supervised Trials Median Residue (STMR):**

Intermediate value of effective residue data.

1. **Highest Residue (HR):**

Maximum value of effective residue data.

1. **National Estimated Daily Intake (NEDI):**

Estimation on long-term pesticide residue. It is calculated based on the per-capita average daily food consumption and the supervised trails median residue, including the change in residue in the process of food processing, and other sources of dietary intake and the transformed products with toxicological significance. In the unit of mg.

1. **National Estimated Short Term Intake (NESTI):**

Estimation on short-term pesticide residue. It is calculated based on the per-capita daily (per meal) intake of a certain food and the maximum residue of supervised trails residue, considering mainly the residue of the edible portion of food, including other sources of dietary intake and the transformed products with toxicological significance. In the unit of milligrams per kilogram of body weight

1. **Good Laboratory Practice (GLP):**

It is a quality system for designing, implementing, inspecting, recording, filing, reporting and other processes of organization related to non-clinical human health and environmental safety tests

*Full text of the Guide in Chinese could be found at:
http://www.moa.gov.cn/zwllm/tzgg/gg/201510/t20151012_4860918.htm

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