

Syngenta Commitment

Maximum Residue Limits



What are MRLs or tolerances?

A Maximum Residue Limit (MRL) restricts the amount of pesticide residues allowed on agricultural commodities at the farm gate.

MRLs, or tolerances, are a legally enforceable definition of the maximum concentration of pesticide residues that are allowed on an agricultural commodity at the point of market. MRLs are typically measured in parts per million (ppm). In other words, an MRL is measured by how many parts of pesticide are present per million parts of commodity.

In Canada, the Pest Management Regulatory Agency establishes MRLs on food only after the dietary exposure risk assessment confirms that there are no human health concerns to any segment of the population including children, pregnant women, seniors, etc. These risk assessments are based on modeling and a thorough scientific review of residue, use or value data, and toxicology data. The Canadian Food Inspection Agency and Agriculture and Agri-Food Canada conduct MRL enforcement.

MRLs ensure that growers apply pesticides according to government regulations.

Among the public, MRLs are frequently misunderstood to be a safety standard. It is important to note that MRLs are not a measure of toxicity; that is, the MRL is not a measure of the point at which residues will sicken a person. The toxicologically significant level is usually at least 100 times higher than the actual established MRL. Instead, MRLs are set and monitored for the purpose of ensuring that growers are applying the pesticide according to government regulations. MRLs also allow crops to be traded internationally and are established for each pesticide/ commodity combination.

Canada is not alone in establishing MRLs. A growing number of countries are establishing their own MRLs lists. Countries without established MRLs may rely on regional or Codex MRLs (see information on Codex on the following page).



What is the global challenge with MRLs?

Products meeting Canadian MRLs may not align with foreign market MRLs.

There is a growing global challenge with MRLs. As countries modernize their food safety systems, they frequently establish their own national MRL lists. Several countries have undertaken such changes in the past decade. For example, Japan established a comprehensive list in 2006 with tens of thousands of MRLs, while the European Union coordinated all member state MRLs at the community-wide level on September 1st, 2008. Other markets, including the US, along with Taiwan, Hong Kong and Indonesia, are in the process of establishing, revising and expanding existing MRL lists. In addition, the Canadian Regulatory Agency is also in the process of revising its Canadian MRL list.

Challenges for growers emerge when these foreign MRLs differ from the MRLs in Canada, or when a foreign market does not have an MRL established for a crop protection product approved in Canada. In such cases, growers can apply a crop protection product according to the label and be within the Canadian MRL, but have their product rejected in a foreign country because of a residue violation. Unfortunately, this trend has increased in the last few years with several Canadian commodity groups having their products rejected abroad.

Governments around the world are cooperating in an effort to establish synchronized MRLs and to minimize differing tolerances. This effort occurs on a bilateral basis as well as through multilateral international organizations such as the UN Codex Alimentarius Commission. Each year at Codex, numerous countries meet to establish tolerances that can be used as an international MRL standard. Codex MRLs are especially helpful for countries that do not otherwise establish pesticide MRLs or who have a limited list and then defer to Codex MRLs for additional MRLs. Some countries do not recognize Codex tolerances; however, much of Latin America, as well as countries in Southeast Asia, the Middle East and Africa, defer entirely to Codex MRLs. Other markets, such as South Korea, Singapore, New Zealand, South Africa and Israel, have limited National MRLs lists and use Codex MRLs to supplement those lists.

Growers and registrants also put forth efforts to create harmonized MRLs.

In addition to government efforts to harmonize MRLs, private sector entities such as registrants and grower groups are also seeking coordinated MRLs around the world. Pesticide registrants ensure that accurate and similar supporting data is submitted for review in countries around the world when new MRLs are being proposed. Grower groups are able to offer comments to Canadian and foreign governments when pesticide regulatory changes are announced. Often when comments are submitted early enough, MRLs can be adjusted so that they correspond with other global MRL standards.

All of these efforts are ongoing and have the same goal: to ensure that MRLs are harmonized around the world to the greatest extent possible to avoid unnecessary trade disruptions while ensuring the quality of food consumed by domestic populations.

How are MRLs determined?

Registration packages include data on acute reference doses and average daily intake values.

When new crop protection materials are developed, registrants prepare data packages for review by the regulatory authorities. The data packages typically include a combination of toxicological data (such as acute reference doses and average daily intake values) and data on likely residues generated from field trials. The regulatory authority evaluates this material, conducts risk assessments and then recommends and establishes MRLs. An official government document announces the MRL and establishes it as an official MRL for the country or region. Prior to June 1st, 2008, established MRLs were published in Canada Gazette Part II under the Food and Drugs Regulations. Since then, the Pest Management Regulatory Agency (PMRA) has adopted a new system, where the official government documents announcing MRLs are Established MRLs (EMRL series) or Proposed MRLs (PMRL) documents, which are published under the Pest Control Products Act (PCPA). This new system in Canada allows for faster additions, changes and revocations of established MRLs and faster notifications of these changes to the public. MRLs listed as PMRL on the PMRA website are eligible, official and legally binding.

The process for establishing MRLs varies from market to market.

While the specific MRL setting process varies from market to market, the process described here is similar to that employed by most countries. It is important to point out that the length of time required to establish an MRL varies greatly and is dependent upon the Local Regulatory Agencies specific requirements, workload and management issues.

How are MRLs monitored and enforced?

Federal, provincial or local governments collect samples from domestic and imported products for testing and they apply sanctions, as necessary. The Canadian Food Inspection Agency (CFIA) and Agriculture and Agri-Food Canada (AAFC) conduct random sampling from grocery stores, ports of entry, processors, elevators and other areas in Canada.

MRL control and enforcement measures differ from country to country, but most systems involve the federal, provincial or local government collecting samples of a variety of food products, including both domestic and imported products, and sending them to scientific laboratories for residue analysis. When a residue is discovered that has exceeded an established MRL, the country may notify the retailer, producer, shipper or grower and seek an explanation of the violation. A record of violations is typically retained, and if a source is deemed to be a repeat violator, additional sanctions may be applied.

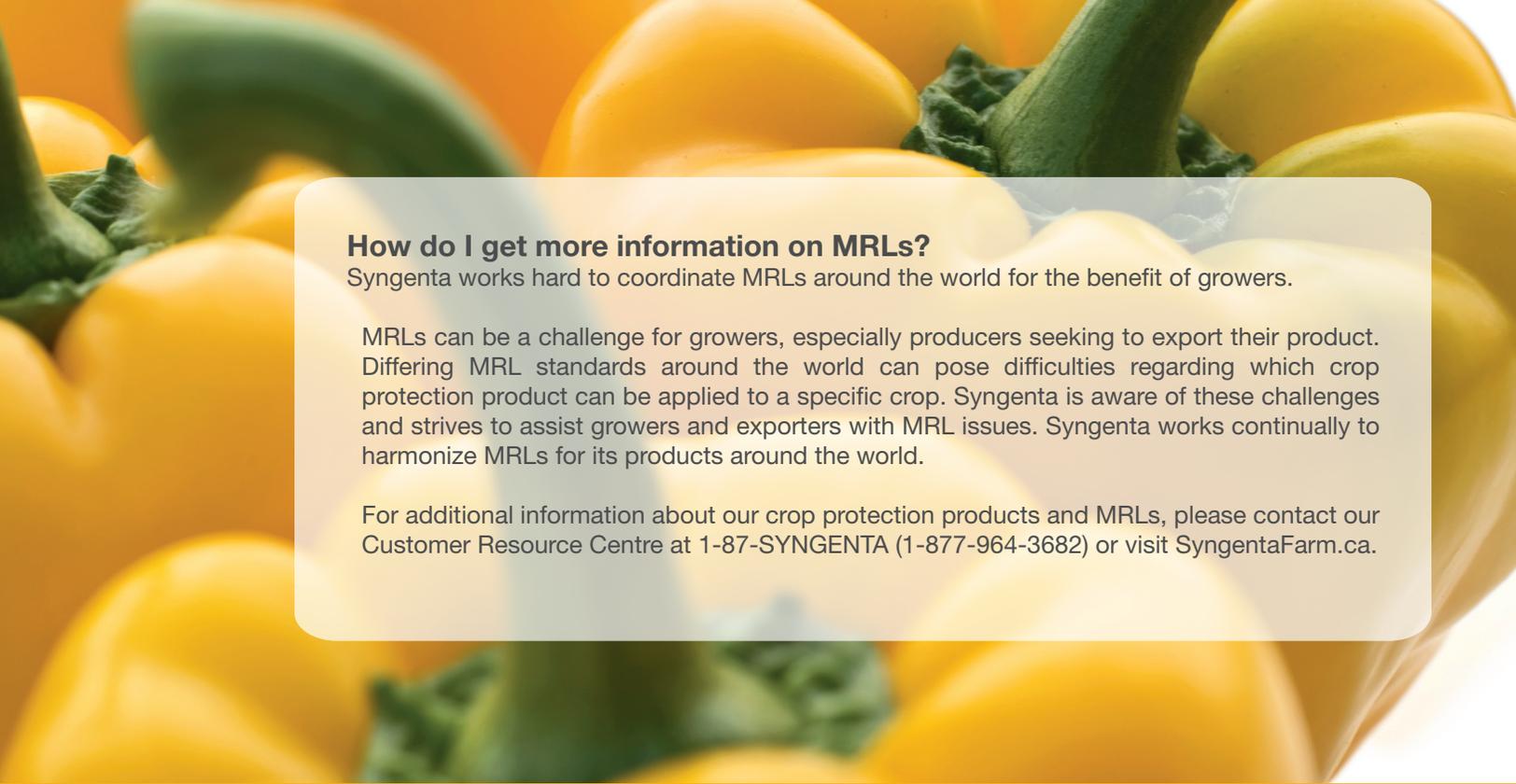
In Canada, the CFIA and AAFC conduct residue sampling in a variety of areas from grocery stores to ports of entry. Violations are noted and investigated. Increased sampling can be conducted on the source of the violation to ensure that there are no further problems. After a number of clean shipments, testing will return to normal levels. If residues are greater than the MRLs at the port of entry, commodities will not be able to enter the country or region. Such shipments may be returned or destroyed.

The European Union (EU) informs member states of desired testing requirements and then member states take the required samples and perform the laboratory analysis. EU member states are free to establish additional sampling requirements beyond the EU levels. Violations in Europe are typically reported through the European Food Safety Authority's Rapid Alert System.

Each March, in Japan, the government publishes a sampling plan with numbers of samples to be taken of certain products. Local authorities and ports conduct the sampling and send results to laboratories for analysis. When a violation occurs, sampling is increased to 30 percent of like shipments from an industry. A second violation for the same product can result in an entire industry being tested and products being held awaiting test results.

It should also be noted that the food chain (e.g. supermarkets) may have their own requirements for residue limits that are lower than the MRL.





How do I get more information on MRLs?

Syngenta works hard to coordinate MRLs around the world for the benefit of growers.

MRLs can be a challenge for growers, especially producers seeking to export their product. Differing MRL standards around the world can pose difficulties regarding which crop protection product can be applied to a specific crop. Syngenta is aware of these challenges and strives to assist growers and exporters with MRL issues. Syngenta works continually to harmonize MRLs for its products around the world.

For additional information about our crop protection products and MRLs, please contact our Customer Resource Centre at 1-87-SYNGENTA (1-877-964-3682) or visit SyngentaFarm.ca.

Crop protection products are an integral part of producing a supply of food that is safe, reliable and abundant.

As a leading producer of crop protection products, Syngenta is committed to product stewardship and works closely with its customers to ensure that Syngenta products are properly developed and used.

In recent years, many growers, especially growers whose products are exported, have learned of the term Maximum Residue Limit (MRL).

As part of its continuing commitment to the agricultural community, Syngenta provides the following primer on MRLs for its customers.

For further information, please contact our Customer Resource Centre at 1-87-SYNGENTA (1-877-964-3682) or visit SyngentaFarm.ca

Users of this brochure are advised that national, regional and international regulations affecting permissible Maximum Residue Limits frequently change. Although this brochure is updated periodically, the user accepts that the information on Maximum Residue Limits in it may not be completely up-to-date or error free. Additionally, commodity nomenclature and residue definitions vary between countries and country policies regarding deferral to national, regional and international standards are not always transparent. This brochure is intended to be an initial reference source only, and users must verify any information obtained from it with the relevant regulatory agencies in the market of interest prior to the sale or shipment of any products. Syngenta shall not be liable for any loss or damages, including, but not limited to, direct or consequential damages, loss of profit, loss of business, loss of revenue, demands, claims, actions, proceedings, damages, payments, expenses, or other liabilities occasioned to or suffered by any person acting or refraining to act as a result of the information relating to Maximum Residue Limits contained in this brochure, or otherwise caused by or arising, in whole or in part, in any way from user's use of this brochure.

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Syngenta Canada Inc.
140 Research Lane, Research Park
Guelph ON N1G 4Z3
Canada