

Considerations for the Successful Submission of MRL and Import Tolerance Applications for Agrochemicals

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Maximum residue limits (MRLs) and import tolerances (ITs) are important trading standards that relate to pesticide residues in food. An MRL is the maximum concentration of a pesticide residue or contaminant recommended by national authorities and international organisations such as the Codex Alimentarius Commission (CAC) to be legally permitted or recognized as acceptable in or on a food, agricultural commodity, or animal feed. An IT is an MRL set for imported products to meet the needs of international trade. While MRLs and ITs are not safety standards, consumer safety is assessed as part of the process.

Successful application for MRLs and ITs requires both technical knowledge and an understanding of the specific regulatory needs of importing countries. Many countries have historically relied on international standards established by the CAC for their MRL and IT requirements. This included the submission of a single application into the Codex system. In recent years, many countries have removed reliance on harmonized international standards and adopted their own national systems for MRL and/or IT submissions and approvals. As a result, grower groups and agrochemical companies must now customize their applications to meet the requirements of specific governments around the world.

Importance of a High-Quality MRL Submission

It is important to understand why MRLs are required for inter-country trade. If a grower group produces a food treated with a pesticide product that leaves a detectable residue, the lack of an MRL can create a significant barrier to trade. Without an MRL in place, a government can refuse the treated food at its port of entry. This refusal can lead to a number of complications, including the misconception among consumers that there is a safety issue.

For a batch of fruits, vegetables, or other foods to be compliant, an MRL submission must be accurate, technically strong and fulfill the latest regulatory requirements. If residues exceed an MRL, some countries will monitor future consignments of the crop for residues before they are allowed entry. This can have serious implications particularly for farmers and growers.

Understanding Varying Regulatory Requirements across Countries

While regulatory guidelines have similar themes across countries, specific requirements for residue trials, crop groupings, and more can vary from country to country. For example, a citrus crop imported into the European Union (EU) requires a regulatory package that covers large citrus and small citrus. Submission to the United States requires coverage of three different citrus crops with a different number of trials required compared to the EU. It is important for grower groups and agrochemical companies to understand that a compliant data set in the exporting country does not necessarily ensure compliance for the importing country; one cannot assume that a data package suitable for one of the more developed regulatory systems in the world will be sufficient for every regulatory agency.

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Navigating an Evolving Regulatory Environment

The Australian government recently coordinated an initiative to harmonize the regulatory requirements for MRLs and ITs throughout the Asia-Pacific Economic Cooperation (APEC) countries. While the goal is mutual acceptance of evaluations among APEC countries, the process requires a level of trust between regulators that has yet to be realized. Until this mutual acceptance comes to fruition, applicants who seek to import products into APEC countries must submit applications to each of the importing countries.

As regulatory requirements continue to evolve, it is becoming increasingly important for individuals compiling MRL and IT submissions to stay up to date on the regulatory landscape around the world.

A Real-World Case Study

Our team at Exponent recently partnered with fruit producers in Latin America to submit multiple IT applications to Japan, South Korea, Taiwan, Hong Kong, Russia, Australia, Europe, the United States, and Canada. We provided the technical expertise and regulatory knowledge needed to ensure we had the right data package to address the wide range of data requirements

for each country. From this, we created a single submission that we used as the basis to submit to each country. Because the client had placed the full range of work with Exponent, we were able to schedule the applications to be made into the countries with more challenging regulatory regimes like Europe and the United States. We also maintained strong communications with the regulatory authorities, being responsive to questions that arose during the evaluation process. This reduced the amount of time the applications would be in the evaluation stage with the various regulatory agencies.

By avoiding duplication of efforts across country submissions, our team was able to quickly and cost-effectively secure ITs for the most important markets for our client.

Exponent's Expertise

Exponent's multi-disciplinary team includes former regulators, industry experts, and agronomists familiar with growing a multitude of crops. Our cutting-edge international regulatory expertise in residues, toxicology, and analytical chemistry and our large-scale capacity enable us to quickly and cost-effectively submit high-quality MRLs and ITs across the globe.



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