



knoell

worldwide
registration

THINK GLOBALLY – ACT LOCALLY

CASE STUDY IMPORT TOLERANCE STRATEGY

Customer request

Business area: crop protection, **Regulation location:** global

A company with a US registration for a row-crop herbicide came to knoell for an import tolerance strategy that would deliver the best return on investment for obtaining maximum residue limits (MRLs) in international countries. This would allow US growers to export to those countries, increasing the herbicide's appeal. As the import tolerance/MRL landscape is shifting, with more importing countries doing enforcement testing, the company wanted to better understand the costs to obtain import MRLs in comparison to the risks without them.

Project advancement

Evaluated the studies used to support the product's US registration to verify key factors for global decision-making

- ▶ Study GAP (good agricultural practice) matched or was more critical than the label GAP
- ▶ Available residue data supported an import MRL based on the enforcement limit of quantitation for the crop of interest, as well as an additional related crop
- ▶ Submission to JMPR to request a Codex MRL would not be advantageous due to low residues

Determined the MRL status and tolerance process in key export markets

- ▶ Analyzed the global import/export market for the crop to determine current and future potential for the herbicide to be on traded goods
- ▶ Identified a major importing country with a zero-tolerance policy for residues when an MRL has not been established
- ▶ Precluded costly toxicology, animal metabolism, and processing studies by determining that the herbicide is already registered in the target import countries and that import MRLs are not typically set for processed commodities in those countries

Developed MRL strategies based on cost-benefit analysis and industry expertise

- ▶ Evaluated the risks of not establishing MRLs, taking into account the residue data, MRL and monitoring policies of the importing countries, expected product application acreage at market maturity, and potential punitive and consumer confidence consequences of a violation

- ▶ Proposed multiple MRL strategies that allowed the client to select the best option for their business—in this case a balanced approach to mitigate risk by applying to establish MRLs in a country with a zero-tolerance policy and one other major export market, while reducing costs by not applying for MRLs in lower-risk markets

Translated global strategy into local action

- ▶ Assembled country-specific dossiers to support the establishment of import MRLs for the target crops
- ▶ Submitted the MRL applications to the relevant regulatory authorities on behalf of the client
- ▶ Leveraged local knoell employees to ask questions directly of authorities, particularly in the ASEAN region, both prior to submission and for subsequent follow-up

End results for the client

Experts at knoell helped the client implement an import tolerance strategy that supports good return on investment while providing protection in the riskiest markets. Based on analysis of the residue data and global import/export markets, knoell also identified opportunities for profitable market expansion, including the inclusion of a second, related crop.

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Think globally, act locally. Our strength is to be where it matters.

Contact us at info@knoellusa.com



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