

Global Harmonization

Background

The pressure to reduce or eliminate trade barriers is increasing as national economies become more dependent on international trade. The barriers to pesticide trade are particularly daunting, because pesticides are among the most intensely studied substances on earth, and many national governments have their own unique registration and data requirements. It is often difficult for U.S. companies to unravel the intricacies of foreign regulations and obtain the registrations necessary to export their products.

The lack of foreign registrations for many pesticide products, especially newer active ingredients, can dramatically affect food exports from the U.S., as well. U.S. growers, who rely heavily on export business, have a variety of newly developed chemistries available for their crop protection needs. However, importing nations turn away food shipments with residues of products that do not have international Maximum Residue Limits (MRLs) established – even though the residues have passed through the stringent safety reviews administered by the U.S. Environmental Protection Agency (EPA).

There are numerous efforts to harmonize pesticide registration procedures both globally and regionally. Under the North American Free Trade Agreement (NAFTA), for example, EPA and Canada's Pest Management Regulatory Agency (PMRA) have developed a "calculator" to jointly set MRLs. MRLs, which are known as tolerances in EPA parlance, establish safe levels of pesticide residues allowed in food. EPA has presented the spreadsheet procedures for this calculator at international conferences, as well.

The goal is that, one day in the not too distant future, MRLs will be globally harmonized. Codex Alimentarius, a standard setting body of the UN Food and Agriculture Organization (FAO) and World Health Organization (WHO), based in Rome, addresses a wide range of food safety issues on an international basis. Its Codex Committee on Pesticide Residues (CCPR) establishes

MRLs for pesticide residues in food, which are recognized as regulatory standards by many nations around the world, although there is no obligation for any nation to use the MRLs set by the Codex.

Recently, the CCPR and USDA's Interregional Project Number 4 (IR-4) announced a five-year plan to harmonize crop groupings for MRLs. This particular effort marks an important step towards regulatory harmonization because, among other reasons, nations differ in their nomenclature for food crops. Under the crop grouping approach (which is already used by EPA), Codex would set MRLs for a crop group, such as "leafy vegetables," based on residue data for selected representative crops from that group. This would spare individual nations the task of establishing MRLs separately for each leafy vegetable food crop. The use of Codex MRLs for crop groupings could thus eliminate many regulatory barriers to food crop imports in countries lacking MRLs for specific crops.

Meanwhile, harmonization of registration procedures is also making progress on a global scale. The Organization for Economic Cooperation and Development (OECD), whose membership numbers some 30 industrialized nations, is developing a global, pesticide registration review system which is expected to be fully operational by 2014.

To that end, the OECD is encouraging and facilitating international multilateral reviews of applications for new pesticide registrations. These exercises will ultimately reduce the regulatory workload for national and regional authorities, who can accept the results of review by fellow governments, rather than conduct separate scientific reviews of all studies supporting such applications. Under the OECD-sponsored joint review system, monographs (which are compilations of data reviews) would serve as the basis for risk assessments and regulatory decisions in OECD nations individually or regionally (such as those performed and issued by the

European Union). EPA and the PMRA are collaborating in a number of such joint reviews and have announced their intention to use regulatory tools developed through OECD efforts, such as study templates for electronic submission and review of data.

Position

- CropLife America supports the OECD initiative on international multilateral review of applications for pesticide registration to harmonize pesticide registration on a global basis.
- CropLife America supports the NAFTA initiative to harmonize and share the work required for joint pesticide registrations among the U.S., Canada, and Mexico.
- CropLife America supports projects seeking trilateral registrations for pesticide products, such as a current effort to simultaneously register a pesticide in the United States, Australia and the European Union.
- CropLife America supports Codex efforts to establish crop groupings on a global basis, and supports global recognition of Codex MRLs.