

RESIDUES IN FOOD, TRADE, MRL HARMONIZATION AND IMPORT TOLERANCES

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Use of Crop Protection Chemicals (CPCs) and Residues in Food

The use of CPCs (herbicides, fungicides and insecticides) is necessary today if we are to feed an ever-growing world population. The current world population is approximately 6.8 billion and is growing at the rate of about 150 births per minute [1]. With limited land mass suitable for growing crops and with relentless onslaught by agricultural pests and diseases, mankind faces constant challenge in increasing future food supplies. In efforts to meet this challenge, biotechnology is playing its part by increasing crop yields, improving nutritional qualities, and introducing crops that are herbicide-tolerant, or more drought-tolerant, to name just a few examples. Likewise, the CPC industry is playing its part by developing new products that are safer, more effective and more environmentally friendly. One drawback of employing CPCs is that they may leave trace residues in the consumable commodities of the human food chain. The ideal goal is to produce food without residues, but in practice, using chemicals to protect crops can lead to undesirable residues. Reassuring the consumer is the knowledge that these trace residues are strictly regulated by multiple governmental authorities around the world. As part of the registration process, the human and environmental safety aspects of CPCs are exhaustively studied and reported. Total residues intake is assessed from all potential sources and is evaluated carefully with reference to toxicological human endpoints, i.e. the Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD), which are used for conducting long-term and short-term dietary risk assessments, respectively. Large margins of safety are considered when establishing the permissible levels of residues that may remain in food [2].

MRLs, Trade and Import Tolerances

One of the regulatory values resulting from the registration process is the Maximum Residue Level (MRL), the level of residue legally permitted to remain in/on a food or animal feedstuff following the use of a CPC according to Good Agriculture Practice (GAP), i.e. according to the specific label instructions of the approved product. MRLs are specific to particular CPC-crop combinations and are the regulatory standards which facilitate trade in the international export-import markets. MRL monitoring and enforcement are important components of governmental food inspection programs and both domestically grown and imported commodities are subjected to monitoring and MRL compliance. Residues falling at or below the MRL indicate that a CPC was used according to its approved label in the country where the produce was grown.

Recognizing the importance of supporting international trade, a number of authorities have implemented regulatory processes for establishing import tolerances. An import tolerance is simply an MRL established on the basis of a foreign GAP, and once established it becomes included in a country's national monitoring program. The implementation of stricter food standards around the world – a welcome trend in light of recent food scandals – has made import tolerances ever more important. Where an import tolerance MRL has not been established, a default value of 0.01 mg/kg is typically applied in the monitoring programs. This

low value commonly reflects the practical limit of quantification (LOQ) of the analytical methods used in inspection labs today.

Global MRL Disharmony

MRL disharmony amongst the major commodity trading countries of the world is fairly widespread. When an MRL is lower, or non-existent, in a foreign market compared to the country in which a crop is grown, an exporter is faced with an MRL trade barrier. The disharmony is a result of many factors: some countries have import tolerance regulatory procedures while others do not; different MRL calculation methods are used by different regulatory authorities; different regulatory conclusions are made when establishing the ADI and ARfD values; different residue definitions are decided with respect to what analytes (e.g. parent compound with or without metabolites) to include in an authority's MRL enforcement analytical method; different regional diets exist and the quality and quantity of consumption data used for dietary exposure assessments are different for different countries/regions. Add to all of this the need for different use patterns (GAPs) to combat different pests and disease pressures in different countries and it is not surprising that there is MRL disharmony around the world.

A particularly challenging problem for MRL harmonization is the issue of registration and MRL setting for minor crops. International trade in minor crops is on the rise, which increases the need for more MRLs. However, from a CPC registrant's perspective there is little to no incentive to generate registration residue data for minor crops because the return on investment is too low. Consequently, minor crop registrations depend heavily upon organizations like Interregional Project 4 (IR-4), the federally-funded US minor crops program, which works closely with US growers to identify opportunities and obtain registrations of CPCs for minor crops [3]. IR-4 takes the pragmatic approach of utilizing the concept of crop group MRLs when pursuing registrations. Residue data are generated for one or two representative crops of a crop group (e.g. bulb onion and green onion of the US bulb vegetables group) and extrapolated to other commodities of the group for the purposes of establishing a crop group MRL. Not only does this concept work for minor crops, but crop group MRLs for major crops (e.g. cereals) are also established by the same principle. However, on a global basis this simple solution of using crop groupings to aid minor crop registrations faces many problems. Some countries have crop groups; others do not. Where they do exist, they are not identical because different crops grow in different countries (tropical versus temperate). Crop groups are specific to national/regional legislations and changing them is not easy. International agreement on what commodities to include in a particular crop group, or what representative crops to select from a group, or what rules to use for data extrapolation, are all major challenges related to establishing crop group MRLs, especially for minor crops.

MRLs and Human Safety

Misinformation abounds with respect to MRLs and human safety. It is crucial to emphasize that MRLs are trading standards and/or GAP-compliance indicators; they are not human safety limits. MRLs are set such that there is a wide margin of safety in consideration of the human toxicological endpoints. When evaluating the safety of MRLs, the regulatory authority of a particular country/region takes into account the composition of that country/region's diet and the consumption data of the most sensitive sub-population. The outcome of these conservative dietary exposure assessments is a high degree of consumer protection. It is essential to understand that, as a result of these conservative assessments, exceedance of an MRL is rarely a

health concern. Only in exceptional circumstances, e.g. a deliberate contamination of a food item by a CPC, is there real cause for concern regarding human health.

Secondary Standards versus MRLs

The misperception of the MRL as a safety standard has been cleverly exploited by Greenpeace and other non-governmental organizations (NGOs) that protest the use of CPCs. NGO activity has influenced consumers and consumer pressure has caused retailers and food processors alike to introduce more and more secondary, or private, standards. The safety of the MRL is ignored in favor of an arbitrary residue level, such as 50% or 33% of the regulatory MRL. Many of the major European supermarkets, in efforts to stand out and woo the consumer by adopting “greener” images, are including such standards on the check-lists of requirements that their suppliers must meet. As food companies become more globalized, secondary standards become ever more pervasive. The pressure on farmers, especially small farmers of developing countries, to meet these standards is considerable. Not only does the farmer of today have to contend with the difficulty of disharmonized MRLs when he considers his export markets, but he also has the added hurdle of complying with his customer’s secondary standards. Under these conditions, the GAP (i.e. application rate, number of applications, pre-harvest interval, etc.) specified on a particular product label, which underpinned the setting of the safe MRL, is irrelevant and the grower must devise his own GAP in order to meet the non-regulatory, stricter standard of his customer. Amidst the concern and confusion of secondary standards and retailers’ CPC blacklists, private sector organizations such as GLOBALGAP (formerly EUREPGAP) have emerged to provide grower certification/auditing services which enable growers to gain access to food chain markets [3]. Without certification, growers may face no business today.

International Efforts to Harmonize MRLs

Awareness is growing amongst authorities on the need to harmonize certain aspects of the CPC registration process. The North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides in its work on MRL harmonization has eliminated various trade barriers amongst NAFTA countries and the rest of the world. An international Residue Chemistry Expert Group (RCEG) working under the auspices of the Organization for Economic Cooperation and Development (OECD) has made tremendous progress in developing and advancing both guidelines and guidance documents for the harmonization of the core metabolism and residue studies that are required for worldwide registrations. A sub-group of the RCEG is currently working on modifying the NAFTA MRL Calculator – currently used by US and Canadian regulators to estimate MRLs – in an effort to create a statistical tool that might be accepted and used internationally to estimate MRLs.

Regulatory authorities and the CPC Industry are becoming more and more involved in OECD work-shares and joint reviews for the registration of new chemistries, which helps facilitate the global harmonization of MRLs. To support OECD work-shares, the CPC Industry is paying much more attention to identifying critical GAPs suitable for worldwide registration and against which global residue data packages can be generated.

The Codex Committee on Pesticide Residues (CCPR), the body that oversees the development of Codex international MRLs, recently streamlined its lengthy step-wise process to enable more efficient setting of Codex MRLs. CCPR is also involved in a multi-year project to revise the crop groups of the Codex Classification of Foods and Animal Feeds. Aiding this

effort is the work of the International Crop Grouping Consulting Committee to revise the US/Canadian crop groups.

In December, 2007, the Food and Agriculture Organization, US Dept. of Agriculture-Foreign Agricultural Service (USDA-FAS), IR-4 Project and the US Environmental Protection Agency hosted a global summit to review the issues associated with minor crop registrations and establishing MRLs for minor crops. Several recommendations emerged from the summit, perhaps the most exciting of which was the idea of conducting a CCPR pilot project whereby the Joint Meeting on Pesticide Residues would propose Codex MRLs during an OECD work-share prior to national governments setting their own MRLs. This would have facilitated harmonization of Codex MRLs with national MRLs. Unfortunately, at the end of a lively debate within the 2009 CCPR plenary session, the pilot project failed because of a lack of consensus. There, amongst political rhetoric and debate, an important opportunity to advance global MRL harmonization for new chemistries was lost. Another initiative spawned by the 2007 summit was an effort to raise awareness and action to support global MRL harmonization by African nations. This project did meet with some success. However, much more needs to be done, especially in light of the fact that the developing African countries have much to gain from internationally harmonized MRLs.

Other initiatives to improve minor crop registrations are in progress by the OECD Expert Group on Minor Uses, a sister group to the OECD RCEG, formed in 2007 with the mandate to find ways to obtain more registrations for minor crops and facilitate MRL setting/harmonization for minor crops.

Conclusions

Trace residues originating from CPCs are undesirable in the food chain, but strict regulatory oversight by registration authorities around the world show that such residues are safe for the consumer. The disharmony of MRLs, often the cause of trade barriers, is the result of many factors, none of which is easily controllable. An increase in food exports-imports around the globe during the past decade has prompted a great deal of activity to harmonize certain aspects of CPC registration, especially amongst OECD countries. Several encouraging initiatives are underway to improve the process for minor crop registrations as well as work toward the ideal goal of MRL harmonization. Continued progress depends on how well governmental authorities can work together to agree upon and implement change because so many of the factors contributing to global MRL disharmony are governed by existing national or regional (European Union) regulatory policies.

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