Advancement of Harmonized Approaches for Crop Protection Chemistry in Latin America

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As a leading agricultural producer and exporter, Latin America constitutes one of the four largest global crop protection chemistry markets. In 2004, sales of agricultural chemicals in Latin America amounted to USD 5.6 billion, which is 20% of the global total in sales of agricultural chemicals—an increase of 25%–35% from sales experienced during the late 1990s. As the use of crop protection chemicals has increased, so have environmental, food safety, and regulatory concerns. Against this backdrop, the International Workshop on Crop Protection Chemistry in Latin America was held 14–17 February 2005 in San Jose, Costa Rica. It was organized around three priority topics related to crop protection chemistry: regulatory harmonization, environmental assessment, and residues and human exposure. Key observations from each of the three major workshop topics are summarized below, and future action items for IUPAC are also outlined.

Regulatory Harmonization

A fundamental assumption for the regulatory process is that chemical pesticides play an important role in sustainable agriculture, provision of the world's food supply, and protection of public health. Their use has contributed to efficient use of existing agricultural lands, thus minimizing further encroachment into natural areas. Pesticide use has had a major role in the tripling of world food production experienced during the past 50 years. For example, the use of pesticides in Costa Rica has resulted in a three-fold increase in production value during the past 5–10 years, while actually reducing the area of land under cultivation. Meanwhile, Costa Rica has been able to protect nearly one-quarter of its territory as national parks or private reserves.

Over the past decade, sales of crop protection chemicals in Latin America have grown significantly; the region is now one of the four largest global markets for such chemicals. Analysis of market trends indicates the potential for increased use of some categories of products, particularly those targeted for public health protection. Compared to other regions, Latin America has been faster to adopt products with new active ingredients. However, the cost of developing each new active ingredient has soared, and current estimates place the associated R&D expenses at between USD 180 and 200 million. For industry, this cost escalation has increased concerns about regulatory data and patent protection.

One major market trend is an overall increase in reliance upon generically produced, off-patent products. In light of this trend, lecturers from both industry and nongovernmental organizations emphasized the critical importance of quality control of approved sources of pesticide active ingredients and formulations. This is important for ensuring efficacy while supporting human and environmental safety, particularly with respect to the correct assay of active ingredients and the minimization of relevant impurities.

There are a number of international approaches available to support local regulatory evaluation and management of crop protection chemistry. These include the FAO Code of Conduct, the FAO/WHO product quality specification process, OECD test guidelines, and Codex maximum residue limits. In addition, crop protection chemistry will be affected by implementation of international treaties and conventions that have recently entered into force, including those related to persistent organic pollutants (Stockholm Convention, May 2004) and prior-informed consent (Rotterdam Convention, February 2004). It was suggested that most evaluation systems be redesigned to assess the *benefits* of pesticides as well as the risks. Currently, no internationally harmonized guidelines are in place to do this.

Some interesting regional approaches to harmonization have been initiated recently in Latin America. During the late 1990s, the five Andean countries agreed to adopt a common norm for evaluation and regulation of pesticides, and a technical manual of evaluation criteria and procedures was developed. Implementation is still at an early stage, but many valuable lessons have already been learned. One remaining gap concerns evaluation criteria and an agreed-upon procedure for establishing generic versions of existing active ingredients. Similarly, the CATIE/GTZ-NOQ project, in cooperation with the

Agricultural Regional Organization of Central America, has drafted a common set of regulatory evaluation guidelines specifically for microbial and botanical pesticides, which are currently not well covered by guidelines for traditional, synthetic pesticides. The proposals arose following evaluation of guidelines available from OECD and several major OECD countries. It is hoped that in the future the seven Central American countries plus the Dominican Republic will adopt this harmonized approach.

Lecturers also emphasized the importance of education as a complement to regulation to support effective management of crop protection chemistry throughout the region. Health and environmental risks, especially those that may be associated with misuse, are largely a preventable problem. Safe pesticide use requires safe equipment and good systems for training and educating pesticide applicators and farm workers. In addition, good regulation and enforcement by a well-trained authority are essential. In Costa Rica, for example, the Ministry of Agriculture and Agricultural Pesticide Chamber trained nearly 130 000 people during the past 20 years in safe pesticide use practices. The appropriate management of an ever-expanding information base related to crop protection chemistry was also emphasized. The Internet in particular has become a vast resource for exchanging information on pesticide chemistry. Navigating this information, with respect to both availability and reliability, is an increasing challenge. Perhaps two quotes from classical scholars summarize well the present situation:

"The next best thing to knowing something is to know where to find it." — *Samuel Johnson, English author (1709–1764)*

"Man's most judicious trait is a good sense of what not to believe." — *Euripides, Greek philosopher (c. 480–406 BC)*

To this end, the recently initiated IUPAC project on global agrochemical information management was introduced as a means of improving the situation. In partnership with FAO and IAEA, this project aims to increase availability of reliable information on the most important pesticides and pesticide information sources.

Environmental Assessment

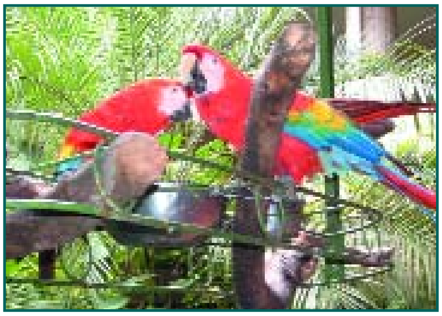
Environmental fate and ecological risk assessment were important areas of emphasis at the workshop, particularly in light of growing environmental awareness in the Latin America region. Although past IUPAC project (*PAC* **69**(6), 1349–1371 [1997]) conclusions highlighted the overall tendency for more rapid dissipation of pesticides under tropical or sub-tropical conditions, it was noted that much of the area in Latin America where pesticides are used heavily actually falls within the temperate climate zone (e.g., grain and soybean-growing regions of Southern Brazil and Argentina; fruit-growing regions of Argentina and Chile). The wide diversity of agricultural, soil, and climatic conditions present in both temperate and tropical areas of Latin America make it important to understand the processes governing fate and transport under these conditions. On the other hand, it was noted that testing has consistently revealed a similar level of sensitivity to pesticide exposure within major groups of non-target wildlife in temperate and tropical area species. Thus, it is possible to refer to standardized OECD test guidelines and organisms without having to implement specific tests on locally prominent species.

Attendees and speakers at the Workshop on Crop Protection Chemistry in Latin America.

The off-target movement of pesticide residues during and following application was emphasized as an important factor not to be neglected. Considerations of such movement include direct human exposure, deposition on sensitive non-target crops or plants, and contamination of surface water resources. Spray drift of fine particulates during application may be an inevitable process, but preliminary results of an ongoing IUPAC project (# 2001-023-1-600) indicate that a variety of drift mitigation practices are available.

Options for best management practices for drift mitigation include sprayer technology (e.g., drift-reducing nozzles, properly calibrated equipment), chemical technology (e.g., spray tank adjuvants), and operational practices (e.g., wind speed restrictions, no-spray zones). Pesticide labeling regulations and education are also important factors for ensuring that applicators understand their responsibilities and take appropriate precautions.

Although application spray drift and post-application surface water runoff/sediment erosion are perhaps the greatest contributors to offsite movement of pesticides from agricultural areas, volatilization was also noted as a potentially significant loss process for some chemicals in combination with favorable meteorological and soil conditions. Although research in Latin American countries is limited, work in other regions indicates that under some conditions, from 5% to 20% or more of applied residues for certain pesticides may volatilize from soil and foliar surfaces into the atmosphere, where they may constitute sources for exposure or redeposition into sensitive areas. Unique combinations of environmental conditions and agricultural practices may contribute in some regions to higher pesticide volatilization (e.g., frequent pesticide application, frequent precipitation/irrigation, high temperature, low organic carbon content soils). In some cases, minor use pesticides may also be major constituents of atmospherically derived residues depending on their particular solubility, sorption, persistence, and volatility properties.



Without a doubt the noisier workshop participants, these macaws, which are native to South and Central America, were eager to learn more about crop protection.

Lecturers and participants also discussed the impact of pesticides on water quality, including effects on aquatic organisms, humans, and livestock. Water monitoring has indicated the presence of trace concentrations of both highly persistent and more degradable pesticides in natural water areas adjacent to agricultural fields. For example, monitoring of irrigation return waters near the Palo Verde National Park area of Costa Rica displayed low ppb (μg/L) levels of both insecticides and fungicides. Similar observations of low concentrations of pesticides in both irrigation and natural waters have been reported from the fruit and vegetable areas of Mexico, the banana-growing areas of Central America, and the soybean and grain growing areas of Brazil.

The importance of effective water management in mitigating pesticide entry into natural areas was also emphasized. The movement of residues from agricultural areas following sprinkler/flood irrigation compared to the lack of detections where drip irrigation was employed was particularly noteworthy. Lecturers also stressed the need for accurate and reliable data from well-designed studies for regulatory compliance purposes and for determining the effectiveness of exposure mitigation practices. It was generally recognized that regional cooperation would be beneficial for implementing systematic monitoring of surface water residues from pesticides and other contaminants. Important quality control aspects for both chemical and biological monitoring of residues were highlighted (# 1999-017-1-600), including the establishment of monitoring objectives, design of sampling frequency and procedures, secure sample handling and preparation procedures, laboratory analysis using appropriate methods and procedures (e.g., accredited labs), and reporting of results with appropriate limits.

Finally, with respect to establishment and interpretation of limits for pesticide residues in water, conclusions and recommendations of a recently completed IUPAC project were highlighted. Key considerations include defining the purpose of the standard and type of water to which the standard will apply, explaining publicly and transparently the rationale for each limit, and developing analytical methods with limits of quantitation that can match concentrations relevant to biological effects. Arbitrary adoption of water standards from other regions without consideration of the basis or rationale for such standards could result in little real benefit to advancement of environmental and human health protection in the Latin American region.

Ecological risk assessment involves consideration of the inherent toxicity of a pesticide as well as the magnitude and likelihood of exposure. Although simple toxicity or hazard classification systems are available and may be suitable for purposes of handling, storage, and transportation, these may be entirely inadequate and subject to misuse for purposes of environmental evaluation and regulation when not considered within the context of a full risk assessment. The importance of exposure considerations in determining potential harm was perhaps first well recognized some 500 years ago:

"All substances are poisons: there is none which is not a poison. The right dose differentiates a poison and a remedy." — Paracelsus, Swiss philosopher and medical expert (1493–1541)

A number of schemes have been developed, primarily in the United States and Europe, for supporting the regulatory evaluation of ecological risk posed by pesticides. Generally, these schemes involve tiered approaches whereby screening levels requiring limited data are used to identify those products and crop/use scenarios for which more detailed, data-intensive assessments are required. A recently initiated IUPAC project (# 2004-011-1-600) provided initial insight into how screening-level or comparative approaches may be employed as a first step in the pesticide evaluation procedure, particularly in countries where there are significant evaluation resource limitations. The EU's tiered approach to ecological risk assessment, involving standardized fate/exposure scenarios to represent different climatic/geographic areas across a region, was also highlighted. What made this approach particularly interesting for the Latin American situation was the collaborative manner, involving both government and industry, in which the FOCUS (FOrum for the Coordination of pesticide fate models and their USe) scenarios were developed. This might be a good model for Latin America to follow since the region has yet to achieve consensus on ecological risk assessment methods.

Finally, preliminary conclusions of an IUPAC project on environmental implications for the use of genetically modified crops (e.g., insecticide resistant and/or herbicide tolerant) were reviewed (# 2001-024-2-600). Such crop protection technology has growing importance in many parts of the world, including the soybean- and grain-growing areas of Argentina and Brazil, which together contain around one-fourth of the world's transgenic crops. Genetically modified, disease-resistant rice and banana varieties are currently under investigation in Central America. In general, data predict genetically modified crops are likely to have less environmental impact than traditional pest management practices.

Residues and Human Exposure

The topic of pesticide residues and human exposure was also included in the workshop. Latin America is an important agricultural producing and exporting region, and food safety considerations are of growing importance in today's regulatory arena. Mexico's vegetable and fruit exports to the USA, the worldwide export of bananas and other tropical fruits from the Central American and Andean countries, and the grain, soybean, meat, and fruit exports of Brazil, Argentina and Chile to the USA and EU are all major components of the increased international trade in agricultural commodities observed during the past 20 years.

The primary means of local management of pesticide residues in food is via establishment of maximum residue limits or MRLs:

Maximum residue limit (MRL) "Maximum concentration of a residue that is legally permitted or recognized as acceptable in, or on, a food, agricultural commodity or animal feedstuff as set by Codex or a national regulatory authority." (IUPAC 1996)

These MRLs are set to reflect the good agricultural practice (GAP) of a particular country or region, and when residues are present at or below the MRL, this is an indication that GAP has been followed. Most of the countries in Latin American, even those that may establish their own national MRLs, defer to the internationally harmonized MRLs established by Codex when it comes to the regulation of pesticide residues in imported foods. These Codex standards are specifically established to promote fair practices in food trade by ensuring that all relevant GAPs of producing countries are considered in establishing the MRLs. The suitability of these Codex standards for consumer protection is evaluated using chronic and, where appropriate, acute dietary intake assessment methods developed, in part, based on the recommendations of IUPAC. It should be noted that MRLs are *not* health standards per se, but are established based on GAPs and are evaluated for consumer safety. Thus, when an MRL in a food commodity is exceeded, it should not necessarily be viewed as a health concern, but primarily as an indication that GAP may not have been followed.

Monitoring results from tests on both locally produced and imported agricultural commodities in the EU, Japan, and the USA, generally show the vast

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