

CRITICAL ISSUES IN A FUNCTIONAL REGISTRATION SYSTEM BASED ON “EQUIVALENCE”

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Most crop protection products on the market today are post patent pesticides. Therefore, the bulk of pesticide registration requests received by registration authorities around the world will be for generic pesticides. Given that multiple generic manufacturers can request registrations for the same active ingredient, the ratio of registration submissions for generic versions of known active ingredients vs. first time submissions of new chemical entities (NCE's) can easily reach 100:1. Therefore, registration authorities, particularly in developing countries, must become highly proficient at evaluating and registering generic pesticides. The joint publication by FAO/WHO of the *Manual on the Development and Use of FAO and WHO Pesticide Specifications*, aims at providing a reference procedure for the determination of “equivalence” between two Technical Grade Active Ingredients based on the same chemical entity but from two different manufacturing sources or production processes.

The logic behind registrations by equivalence is based on the valid assumption that pesticides that are “equivalent” in their chemical composition will have “equivalent” risk and efficacy profiles. However, the FAO/WHO Manual is not a registration regulation document and many technical details remain to be defined by National registration authorities. Unfortunate decisions regarding key technical definitions of specific parameters and procedures have made registration systems based on equivalence inoperable in many developing countries. The operability of a registration system must be evaluated based on the system's ability to ensure the quality of products reaching the market, as well as its productivity in issuing registrations efficiently without lengthy delays. Numerous countries, including Mexico, Guatemala, South Africa and others, have not been able to register generic pesticides by equivalence efficiently for several years now due to arbitrary barriers to generic registrations. Argentina, the first country in the world to implement a registration system based on the FAO/WHO Manual, has demonstrated that the pragmatic and scientific decision-making process it has implemented since 1999 has maintained productivity in issuing registrations high enough to ensure competitive market prices for farmers, as well as the high quality of products reaching the market. Lessons learned regarding key definitions and procedures that are required to make a registration system based on equivalence operational will be discussed and specific recommendations will be made.