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Position Paper

CropLife International Position on Harmonization

Historical Background

The early interests in harmonization were led by the Food and Agriculture Organization of the United Nations (FAO). A 1975 FAO Ad Hoc Government Consultation on Pesticides in Agriculture and Public Health recommended that FAO establish an international consultation to analyse and discuss the basis for harmonizing the requirements for registration of pesticides in different countries. The motivation for harmonization at this time was the concern that the differences in registration requirements between countries would increase the cost of new pesticides, inhibit their development, and/or limit their availability.

In line with this recommendation, FAO established the FAO Committee of Experts on Pesticide Specifications, Registration Requirements and Application Standards. Two Ad Hoc Government Consultations were held in 1977 and 1982, but, by the time of the second consultation, the emphasis had shifted toward registration procedures and effective national control of pesticides at the expense of some of the focus on harmonization.

Another "distraction" to the harmonization effort came about as a result of concerns about pesticide use in developing countries, which do not have the infrastructures necessary to register and control the use of pesticides. These concerns led to the development in 1985 of the FAO International Code of Conduct on the Distribution and Use of Pesticides. The FAO Code recommends responsibilities for all stakeholders involved in the development, registration and use of pesticides. Then, in 1989, Prior Informed Consent (PIC) was incorporated into Article 9 of the Code on Information Exchange. Extensive resources were required by FAO to assist governments to understand PIC and to develop the infrastructures necessary to implement PIC in their countries, which utilized resources otherwise available for harmonization.

In 1991, member governments of the Organization for Economic Cooperation and Development (OECD), together with several international organizations, NGOs and industry, strongly agreed on the need for harmonization of registration data requirements, test guidelines and the evaluation of registration data. In response to this recommendation, OECD established the Pesticide Forum, renamed the Working Group on Pesticides in 1999, to work in the following areas:

- Harmonization of data requirements, testing methods, and hazard assessment;

- Facilitate sharing work among Member countries to register new pesticides and re-register older products; and,
- Facilitate information sharing among Member countries on risk reduction approaches.

The OECD Working Group on Pesticides has been working in these areas of harmonization, but its philosophy is very different from that of CropLife, in terms of final objectives. CropLife questions if the OECD Working Group will ever achieve harmonization to the degree CropLife is proposing in the discussion below.

In addition to the international programs discussed above, it should also be pointed out that regional cooperative efforts in harmonizing registration requirements and procedures for pesticides have been established in the US, Canada and Mexico through the North American Free Trade Agreement (NAFTA); in Central America and Panama for the Central American Common Market; in the southern cone of Latin America through the MERCOSUR agreement; in Asian countries through the Regional Network on Pesticides in Asia and the Pacific (RENAP); and, more recently, in the European Union.

Discussion

The FAO Expert Consultations in 1977 and 1982 established several principles regarding harmonization, which CropLife International strongly supports. These are:

1. The principle that the registration process is essentially predictive regarding the fate and effect of pesticides, and is, therefore, based on the concept of extrapolation. There was a consensus that this is a valid concept, although it is certainly more reliable with closely related species.
2. The principle of transportability of data, that is, that laboratory data are universally applicable, and there is no need to duplicate experimental work. Field tests can be extrapolated on a regional basis, and sometimes even more broadly, e.g., field dissipation tests from a temperate region can be extrapolated to tropical regions, because the effects of higher temperatures and humidity are well understood.
3. The principle of a step-wise, or phased, registration system, so that a registration is granted to an extent commensurate with the availability of data. This is the principle followed in the granting of experimental permits and emergency exemptions.
4. The principle of risk management and mitigation, that is, if the risk from the use of the pesticide as proposed in the original registration submission is too high, measures to reduce the risk to an acceptable level may be agreed and introduced, rather than having the registration

submission rejected outright.

5. The principle of protection of proprietary data, that is, the data of the original submitter should not be used for the purpose of evaluating and registering a product of a submitter who does not own the data and has not been given permission to use the data by the owner.

In addition to these guiding principles from the FAO expert consultations, CropLife International, in its association with the OECD program on harmonization, has expressed support for three additional principles:

1. Harmonization must reduce the time from submission of a registration package to a decision on that registration.
2. Harmonization must provide a measurable financial benefit in data generation, e.g., by eliminating unnecessary duplication of testing.
3. Harmonization must permit increased co-operation among regulators in order to achieve the benefits listed above.

On this basis, harmonization of pesticide registrations within the OECD Harmonization Project has been supported in the past by CropLife International. CropLife has suggested that harmonization within the Project is best achieved by building from harmonized basic blocks to larger harmonized pieces. This is best exemplified by the following list of building blocks:

1. Common/core data requirements form the base.
2. These requirements need to be supported by common guidelines and protocols for studies which fulfil each of the requirements.
3. Studies carried out according to agreed OECD guidelines and having common quality criteria for accepting study reports must be mutually accepted by governments.
4. Data reviews carried out by different governments, either jointly or by sharing the work by reviewing different sections of the dossier, should be accepted by all governments involved in the general harmonization effort.

CropLife International must point out that it does not support the harmonization globally of the risk assessment required for granting registrations, nor the registration decisions which are made as a result of such assessments. The common data package must be supplemented with unique national data, most of which is product-related, rather than being related to the active ingredient. The national studies are key to the national risk assessments, and, as a result, the national registration decisions. In addition, national registration decisions are influenced by risk/benefit assessments and socio-economic considerations, both of which are unique to a particular national situation.