ACCESS TO PESTICIDES AS A SOURCE OF TRADE DISPUTES

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The authors are to be congratulated for offering up an interesting, lively and relevant paper on an important topic for this conference. Most of the comments they make on agricultural chemicals can also be applied to the animal health products industry where I work every day. After all, herbicides, insecticides, fungicides, antibiotics, parasiticides and vaccines are all highly targeted killers of organisms of one sort or another. In a sense, selectively killing undesirable plants, fungi, insects, bacteria and viruses are all similar processes. Concerns over potential collateral damage to harmless non-target organisms (including, but not limited to, plants, insects, bacteria, food consumers, dogs and cats) and to the environment are the basis of regulation, whether done by the likes of the Environmental Protection Agency (EPA) or the Food and Drug Administration (FDA).

The viewpoint offered here is from someone engaged in the day-to-day animal health business in Canada, the United States and Mexico, and my objective is to enlarge the scope of the differences among the three countries that need to be recognized as part of this conference. Unless stated otherwise, my comments apply to both the crop protection and animal health industries.

GOVERNMENT REGULATIONS

One thing that separates agricultural chemicals and animal health products from agricultural commodities is that both these markets are heavily influenced, some would say dominated, by government regulations. Companies must first prove to a government agency that their products are safe, effective and of an acceptable quality and purity before they can even be offered for sale. This is very different from food and feed made from GRAS (generally regarded as safe) materials. However, as the au-

thors point out, standards of safety, efficacy and quality are not absolute, leading to substantial debate over what is "acceptable risk". The authors point out that the product regulatory systems of the three NAFTA countries evolved over a long period of time and along different paths to get to where they are today. Reconciling the differences in the systems will not be easy, and in fact may not even be possible, or even desirable for that matter.

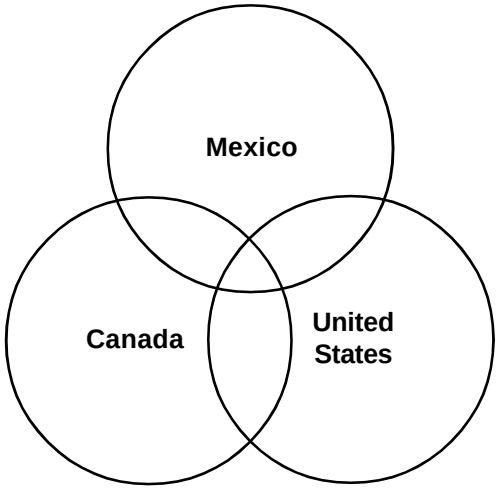
Also, there are other important differences that need to be incorporated into the discussion. Not only are each country's technical regulations for products and product use different, but the entire legal and social framework in which business takes place is diverse, and from my observations has a major impact on both pricing and product availability (for example, what can be registered and what can not).

From an industry point of view, the regulatory authorities in all three NAFTA countries have become more conservative in registration decisions over the past few years. This is particularly true for animal health products where the U.S. FDA has approved only one new drug for food animal use in the last three years. Fewer new products, and the lack of incentives for minor use registrations pointed out by the authors, is leading to reduced producer choice in general. Fewer choices means both less competition and increased use of "second-best" products.

HARMONIZING STANDARDS AND RULES

These considerations bring up a major issue with the concept of harmonization. In a debate over what standards are to be applied there is a real risk that the regulatory authorities of each country will insist on the maintenance of the most restrictive standard for each area of regulation. This could result in either the loss of currently registered products, or some very significant expenses for bringing product regulatory packages up to a more restrictive harmonized standard. A Venn diagram (Figure 1) can be used to illustrate this concern. With each circle representing a set of regulatory standards, the easily agreed standards are represented by the small

Figure 1: Non-Harmonized Regulatory Standards.



triangular area at the intersection of the three sets. Symbolically, and in practice, this set is small relative to the full set of tri-national regulations.

My hypothesis is that the intersection would contain, for the most part, the most restrictive of the entire sets of each country. If this were correct, such an outcome would lead to sharply higher registration costs, fewer new products, the loss of existing products, and virtually no new products for minor uses.

One example of this phenomenon from the world of animal health is BST. BST has been registered in Mexico and the United States for about a decade, but Canada has refused the application. The basis for the Canadian action was a different interpretation of the risk to dairy cows. Would harmonization force the Canadians to register BST? Not likely in my opinion. There are many other examples of different product registrations, some of which the authors allude to in their paper. Canada is also the only country among the three with a milk production quota system, also a source of considerable trade friction. I would propose that the differences we see are the result of very different attitudes regarding the dairy industry, not

just technical or economic arguments over the merits of BST or quotas. My point is that it will be difficult to have any regulatory authority adopt a more lenient standard based on an international panel's recommendation.

THE BUSINESS ENVIRONMENT

The legal framework is an important factor in accessibility of chemicals and drugs. The tort law system in the United States is probably the most liberal in the world. I would propose that the carte blanche given to sue anyone over any perceived damage raises somewhat the cost and risk of doing business in the United States relative to most other countries. To what extent are these risks incorporated into pricing and decisions on whether or not to register products with U.S. EPA and FDA versus other countries with less permissive law? Certainly, the risks involved with agricultural chemical and animal health products are potentially large. I don't know to what extent fear of being sued plays a role in the differences we see, but it could be significant. It is also difficult to see how technical harmonization on product standards could address differences in product liability unless tort law is also brought into line.

Another factor is the level of competition, and the effects of that competition on prices. Competition and prices are also very much affected by regulations. In general, the level of generic competition for off-patent products seems to be higher in both Canada and Mexico than in the United States. In part this is because both the U.S. EPA and FDA insist on the same standards for manufacturing of generics as for the original product. In both Canada and Mexico the standards are somewhat different for generics. As a result, we see differences in levels of generic competition that have influences on prices.

I suspect that this may be an important reason for the differences the authors observed in Roundup prices observed by the authors. Roundup just recently (September 2001) came off patent in the United States. It will be interesting to see if in 2002 prices in the United States fall to levels more comparable to those in Canada. Effective entry of alternative generic

glyphosate producers has, in other countries, had a significant effect on pricing.

Distribution margins are also generally higher in Mexico than in either Canada or, particularly, the United States. There are two major reasons for this difference in margins. Though Mexico has made tremendous progress in the past decade, its rural infrastructure is still at a disadvantage, resulting in relatively high transportation costs. For bulky products such as chemicals and feed additives this can be an important factor. Also, the distribution business in Mexico is still fragmented, and does not yet have the economies of scale seen to the north. It would be interesting to have data on distributor margins to see their effects on end-user prices. I know that there are animal health products that are moved through distributors at 5-10 percent markups in the United States, but are 20-30 percent in Mexico and 15-20 percent in Canada.

Although the authors do not mention it, exchange rates can have an important effect on observed prices in local currencies. Manufacturers are often reluctant to make short-term local currency pricing adjustments on imported products in response to exchange rate changes. Since most of the products being compared in this paper are made outside of Canada and Mexico, short term differences in U.S. dollar prices may be in part due to a lack of adjustment to local pricing and a rising or falling exchange rate against the U.S. dollar or other currencies.

I have also noticed that the social basis for doing business is different for Mexico, and other Latin countries, compared to both of the Anglo-centric cultures of the United States and Canada. What effect does this have? In Mexico business is done on a much more personal basis than by their neighbors to the north. The ability to negotiate pricing and other terms of trade is thus much more influenced by whom you know, how well you know them, and to what extent you can use personal ties to alter the effective level of competition. The requirement for personal contact also raises the relative manpower requirements for doing business in Mexico, and this may have an effect on selling costs and manufacturers' margin

requirements. While it may be impossible to quantify, I am convinced that the effects are real and significant.

The authors suggestion that producers be allowed to import products from other countries and observe the label of that country, would result in the U.S. EPA (or FDA in the case of animal health products) allowing uses for which products were not tested. Having worked with both EPA and FDA, I cannot imagine that either agency would be willing to allow producers to be used in a manner other than that which meets U.S. law. Similar comments also apply to both Canada and Mexico. In my mind, the only way that we could envision free cross-border trade would be for there to exist full harmonization, and identical standards and use labels for all three countries. To the extent that local conditions affect product efficacy, this might not be a desirable goal.

CONCLUDING COMMENTS

In summary, cross-border price differences are due to a complex set of forces that boil down to a combination of local intellectual property rights, regulatory, cultural, cost and competitive conditions. From the viewpoint of a private company, the dynamics of individual product pricing are complex, but it all boils down to product value versus cost in the eye of the customer in local markets. As long as there are three countries in NAFTA there will be three markets, and prices and products will be different across the borders.

In my opinion the most telling statement on harmonization that the authors make in the paper is "The most obvious issue is that there may in fact be fundamental differences in levels of acceptable risk among the three societies so that a common MRL is not possible." We have to face the fact that we are dealing with three very different countries with very different regulatory standards that have evolved over time to fit different sets of societal demands.

To try to resolve the technical, regulatory and marketplace differences in a vacuum is to ignore that there are other, very real, differences

that a technical solution might not address. If this is the case, harmonization on one front will inevitably lead to increased friction on another. This broader context for change is, to me, the real challenge to both this conference and the narrower interests of the paper. I fear that only by effectively resolving these broader issues can harmonization result in a set of standards that is not a subset of the most restrictive of each country.