

GLOBAL HARMONIZATION OF PESTICIDE REGULATION: GREATER TRANSPARENCY OF THE RISK ASSESSMENT PROCESS IS A PREREQUISITE

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Global harmonization of regulation for pesticides is an obvious good thing. If a consensus process for approving safe uses of pesticides for all countries could be developed (although certain local options would still likely be needed), all four interested parties — consumers, farmers and other users, regulators, and pesticide manufacturers — would benefit. For consumers, the result would be increased confidence in safer pesticides, a more diverse diet, and a healthier environment. For farmers, the result would be an increased availability of critical tools for crop protection with increased productivity, profits and trade. For other users — for example, in public health protection — the technology to control disease vectors will advance.

For regulators, the result would be an increased global collegiality, a leveraging of multiple resources, expertise and mutual support, and a general increase in confidence that the best science available is being used. For the pesticide industry, the result would be a vastly simpler risk assessment and registration process, as the snarl of hundreds of national regulatory agency requirements becomes simplified. The potential cost relief for new pesticide development would be enormous.

Of course, this vision can only be realized if a consensus can be achieved amongst the four parties. This is not going to be easy. The vision itself may not be universally shared, because mutual distrust is so deeply ingrained. What seems like a good idea to one — certainly industry has been in the lead in supporting harmonization — is likely to be immediately suspected by one or more of the others.

What is the path toward consensus? We must begin by searching for common assumptions and values amongst the parties. There is one fundamental value that we can build upon: that pesticide risk assessment must be based on *science* — at least, the best science available.

Hold on; I think I can hear derisive laughter. Industry and the regulators will splutter that this is exactly what they are trying to do, what am I on about? Greener consumers will rise up in outrage: has not science (or the lack of it) always been used as an excuse to defer regulatory action? Worst of

all, nearly everybody not privy to the inner workings of the regulatory process has developed a suspicion that regulatory science seems strangely pliable — conclusions bend in the direction of whichever side applies the most pressure.

So perhaps it is more accurate to say that everyone agrees “in principle” that science is the truth source for regulatory decisions. In practice, there is a suspicion that science is being manipulated and spun — by the greens, by the regulators, by the industry. Why is this?

There are two critical shortcomings of current national or regional risk assessment procedures which lead to mistrust of the science being done.

1. *Confidential (unpublished) industry studies done via negotiation with individual regulatory systems are not science because they are not peer reviewed by the community of science.* Actually, the studies I have seen have usually been competent and sometimes brilliant. And I am not suggesting that regulators are not competent to review the studies. But the most basic requirement of science is peer review by the *whole* scientific community. Neither the industry scientists doing the studies nor the regulators reviewing them know everything! The current system of confidential studies, though driven by intellectual property considerations, lends itself to suspicion of bias in results (impossible to avoid without peer review) and distrust of the system by the two uninvolved parties: public and agriculture. Publication of the details of every study done for the registration of a pesticide will be the best possible evidence that those doing risk assessment have nothing to hide.
2. *There are basic scientific needs which the current system cannot address.* There are public pesticide safety concerns which are applicable to broad classes of pesticides, but are too complex, ill-defined and expensive to be addressed by the current systems — not least because it is inequitable to demand this from individual companies or even consortia of companies. Examples include spray drift, dissipation and sampling study protocols, volatilization as a dissipation route, climate zones, foliar residue fate and transport, aging of soil residues, synergism (or antagonism) of multiple residues, spray and runoff buffers, monitoring methodologies, effects of formulation inerts, atmospheric transport, and conceptual models. A

¹ This subject has previously been presented at meetings of the Pesticides Formulators Association Of India (PFAI), Bangkok; 2005; the British Crop Protection Council (BCPC), Glasgow (2006); the Agrochemical Division of the American Chemical Society, Chicago, 2006; and the 7th International Workshop on Crop Protection Chemistry and Regulatory Harmonization, Beijing, 2007.

transparent and public global pesticide regulatory reporting system will allow *public* analysis and participation in the science. This will have the immediate beneficial effect of revealing to the public the extent of the elaborate testing that is done. It will also almost certainly reveal gaps and unresearched concerns. More importantly, a transparent system will allow the science to be nourished and synthesized by the studies already done. We will learn from what has been done and will not have to repeat it. And a perspective from those not quite so close to the work is often beneficial! An international, prioritized “larger issue” research program could be defined, and perhaps a globally-funded virtual or brick-and-mortar research institution founded, funded, perhaps, by an assessment on global pesticide sales combined with public funding.

Not only will transparency lead to more *harmony*, it will greatly aid regulatory *harmonization*. Clearly, there are real differences to be resolved between developed-nation systems, but the greater disparity is with less developed countries. Non-access to regulatory data and information from developed regulatory systems, and a lack in less developed countries of the capacity to organize and analyze such data for local needs, are the most important hindrances to harmonization between developed and less developed

countries. Access to all regulatory data and methods currently in place will not automatically harmonize systems – but it is a necessary first step. Authoritative sources which describe the suite of studies and data and their interpretation as done by national or regional systems and their variability, and provide the data for the pesticides which are registered in those systems, will provide the state of the art for anyone to see. Guidance for implementation in less developed countries – the translation of risk assessment systems from one country to another – will still be needed, but the information needed will be there.

Consider the possibility of developing a single global registration that provides use of a pesticide anywhere it is safe to use. Think of a risk assessment that is done in the full light of public oversight, which facilitates use of the product in any country. Think of a global standard of worker safety, dietary exposure assessment, and ecological risk management. Of course, national sovereignty will still apply, but if the entire system, including its national components, is transparent, regimes will not wander too far from global standards, nor will they need to. The crucial issue of intellectual property can be dealt with by international treaty. Besides, how can someone steal your data if their use is public? The resulting system would enhance trade, the science of pesticide risk assessment, global pesticide safety, and the image of pesticides.

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