# *Plenary Session Q&A*

Moderator:
Anthony M. Shelton
*Cornell University*
*Ithaca, NY*

*Dann Okoth (Nairobi, Kenya):* I'm a journalist from the same country as the current Nobel Peace Prize holder, environmentalist Wangari Maathai. This question is directed to Dr. Rodemeyer. Perhaps I should get some information to take back to Wangari Maathai on environmental conservation. How can GM help us conserve our environment? Thank you very much.

*Michael Rodemeyer:* You'll hear more about that in the next few days from people who are working on some of those applications. But certainly, one of the arguments, for example is in forestry. If we can develop ways to meet the needs of populations for timber and wood products from more intensively managed plantations, harnessing genetics to make those trees more appropriate for those uses, then we can begin to take some pressure from the destruction of natural forests, which is clearly an issue in many countries in the developing world. So that's certainly one part of the issue. *Bt* crops potentially reduce the use of insecticides and drought resistance has the potential to conserve scarce water resources. There is a number of possible environmental applications that could be of benefit in the developing world.

*Roger Beachy:* I think you can't avoid the obvious. By increasing food yields per acre you also reduce the pressure to require more land. I listened recently to the governor of one of the states in Madagascar where very fine centers of biodiversity are in operation, and he was lauding the efforts of agencies, including the US government and the United Nations, for working with his state for conservation, although it was a very small piece, about 380 hectares. He said, "You know the problem is that our farmers grow cassava that are severely diseased, causing continuous need for more and more land. Can you help us get disease-resistant cassava so we don't have to do that?" It's a continuing challenge in these economies—struggling to maintain this vast wealth of important biodiversity along with food production. While we are considering value-added traits, such as plant-made pharmaceuticals, there is the expectation that our food needs will be met. Not instead of, but on top of.

*Okoth:* In Kenya, we don't have regulations in place to govern the agricultural biotechnology sector. It's in parliament, but the legislators keep turning it around every other year. Hopefully soon they will be able to debate and decide what to do. In terms of biotechnology research we are very well established, but the regulation part of it is dragging us down. I hope very soon they will formulate laws to regulate this and this economy will be on the way.

*Oyeley Olukayode (Lagos, Nigeria):* I don't know whether to classify this as a question or an observation. In Nigeria we have the problem of bush burning and I think we are losing species of potential economic importance. Are there ways through biotechnology application and and regulation to conserve species that are at risk of extinction through bush-burning?

*Rodemeyer:* Part of the response to that is similar to what we've said before. Most of the diversity exists in unmanaged and natural areas, and to the extent that you save that habitat by doing agriculture and forestry in other places, you help take the pressure off development of those areas. That's one answer. But there is a broader question—and this is certainly not something that I'm an expert on—of trying to identify and save, for example, seeds and other resources, creating a biological diversity type of inventory. Certainly others have tried to ensure that there is a "savings bank," so that those genetic resources are at least available. But there is larger debate. Are we trying to preserve these things in place or are we trying to simply preserve them as germplasm for future development?

*Beachy:* In African countries where we've had discussions *vis-à-vis* biosafety, there was confusion between the importance of having biodiversity solved before implementing biosafety regulations. The issues are very separable. You are talking about agriculture in one case and biodiversity in the other, and the issue is not biotechnology's impact on biodiversity. The question is, "Is agriculture affecting biodiversity?" And sometimes in countries where a scientist is not placed at the head of the regulatory agency, then other influences, other externalities and philosophies, enter the regulatory process from the standpoint of the environment that are not based in science. Our concern is, as science is respected at high levels in all countries, so science should make an informed impact on policies. That's the challenge that we see in Africa. There's concern that biodiversity is so important—and it really is—but the issue is biodiversity and agriculture, not biodiversity and biotechnology. Although those are very separable they are too often confused, and that stops countries from making decisions with regard to biotechnology. We heard that over and over and over at the Montreal Cartagena Biosafety Protocol meetings. These are important issues, but separable, and need to be dealt with differently.

*Milt Zaitlin (Cornell University, Ithaca, NY):* Dr. Rodemeyer, I'm not quite as comfortable as you are with your assertion that food system fears won't carry over to these PMPs. I mean, let's face it, the objection to bioengineered food is not based on science and is not always based on risk. There are activist organizations that are very effective in combating…[audio

lost]…rice and Anheuser Busch is a good example of that.

*Shelton:* Michael, it would be good if you state what the example is. I'm not sure everyone in the audience knows about rice and Anheuser Busch.

*Rodemeyer:* A company called Ventria is developing a transgenic rice to produce a number of proteins, including lactoferrin. There was opposition in California from conventional rice growers and they made an agreement with the University of Missouri, to carry out some field trials there. There was opposition from environmental consumer groups and, interestingly, from food companies and other producers. It's not that people are concerned about the safety of the protein that is developed from the pharmaceutical plant. The concern is over how to protect the food supply. Until there is some additional guidance on what those standards are going to be, there will be a clash. Some in the food industry and others have called for a ban on the use of pharmaceuticals produced in any food crop, to preclude adventitious presence in the food chain. On the other hand, some say that these proteins are ubiquitous and it makes no difference whether they get into our cornflakes or not. But that decision hasn't been made yet, and that is part of the problem.

*Beachy:* This is an issue of marketing not an issue of safety. Riceland is a major buyer of rice in the delta—in the Mississippi region and throughout Arkansas and Missouri and other growing areas—and the question is who buys their rice? Well, if it's Kellogg and Kellogg said that there might be accidental mixing, whether it's safe or not is not the issue. It's a marketing issue because somebody in another company can say, "We grow our rice elsewhere, therefore, ours is not mixed." Whether the contamination is 0.001% or 0.1%, it becomes marketing, not safety. We certainly don't want to be glib and think that the future for value-added traits will be smooth. It won't. We've heard for the last 20 years, "Just bring us a consumer product and the consumers will approve GM crops." I think that's a red herring and meant to put us off, meant to make us all feel like we are on the right track. I'm cynical at this point, after 20 years of agbiotech and still not getting new products out very often. You have to be ready for every eventuality. There are so many products in development that are in great states of readiness that aren't coming to market. There is such great fear of bringing things into foods. I must say I was very pleased to hear Michael's positive leaning because that is not what I expected. I'm hopeful, but I wouldn't say I'm optimistic.

*Neal Stewart (University of Tennessee, Knoxville, TN):* I've often wanted to ask this question but I've always hesitated and especially now that we've had such heavy stuff —bush burning and people starving. Well anyway, this is it. We are always thinking about benefits of, potential benefits of biotechnology in products. What about just fun stuff? For example, flowers with novel fluorescent traits or bioluminescence or just new colors? There was a company that spun out of Carnegie Mellon a few years ago that had bioluminescent squirt guns. So I guess my question is, "Would consumers actually need benefits if something was fun?" A genetically modified golf ball that would fly a thousand yards?

*Rodemeyer:* Now you're talking benefits!

*Stewart:* But that would not necessarily be very safe, especially if I was hitting it. Are there any scale effects of risks and benefits that we apply to food vs. nonfood and then just frivolous stuff that is fun?

*Beachy:* Remember that regulatory agencies no longer capture on just outcome, they now capture based upon method of production. That's the major challenge. We're not regulating product, we're regulating process. As long as that's the overriding consideration, then a golf ball that is locatable with a radio beam because of genes or luminescence will be regulated by those agencies and the cost goes up as a consequence. So, I think it gets back to this issue of rationalization of regulation. There is a way to rationalize and so far we've been in a reactive mode listening so much to every potential doomsday scenario in response to every product that comes out that we keep imposing more regulations. And so a few years ago the cost for a new product was a million dollars, then it went to five, now its twenty so what will it be in 5 years unless you bring regulation under rationalization?

*Stewart:* Of course, unless it's a zebra fish—then there's no regulation, right?

*Rodemeyer:* Right. But the glowfish is, in fact, partly the answer to your question. I am unaware of any protests or consumer or environmental or ethical issues with response to having a genetically modified aquarium fish.

*Beachy:* Yet they were banned from certain counties in California.

*Rodemeyer:* Well, except for California; maybe that's an outlier. But it's an interesting story. From consumers, from the public, I've heard absolutely nothing and I have talked to the folks who make this thing and they say they've heard very little.

*Beachy:* In the case of green roses—that's also been a nonoffender. The blue rose, I suspect, would be the same.

*Rodemeyer:* One of the reasons I distinguish between food products and nonfood products—I'm not aware of any efforts to boycott blue jeans that have been made from—

*Beachy:* Patagonia did it.

*Rodemeyer:* Well you're right, Patagonia maybe. There's no reason that you couldn't launch exactly the same campaigns against fabric that you launch against food and this is one of the reasons that I argue that this may be different because it's not food. So that makes me a little bit more cautiously optimistic about these applications.

*Henry Miller (Hoover Institution, Stanford, CA):* There's an interesting historical example that melds agriculture and the last question—fun aspects of biotech—and that's the old example of *Pseudomonas syringae*, the old ice-minus organism, that was field tested to prevent frost damage. Now, for those of you who don't recall, frost is promoted on plants by an ice-nucleation protein that is in *Pseudomonas syringae*. And so scientists at the University of California devised a mutant that lacked the gene for the ice nucleation protein and found that, indeed, it did have some protective effect. Now, the regulatory aspect of this is interesting. EPA in its wisdom decided that frost is a pest and so this deletion mutant of *Pseudomonas syringae* is a pesticide, and they regulated it as a pesticide. As a result, although it was shown to be effective in field trials, ultimately it was never commercialized because it would have to be registered as a pesticide. Now, what gets us to the last questioner is that the wild-type *Pseudomonas syringae*, which is ice-plus, is used in snowmaking equipment at ski resorts. It's sprayed into the air and there are skiers all around. And what's interesting about it is that if somebody using recombinant DNA techniques made an overproducing mutant, that would be regulated by USDA and/or the EPA at the cost of tens of millions of dollars for registration. This is the kind of thing that Roger is talking about—the need for rationalizing regulation. Currently, it makes no sense. It's extremely destructive. It limits the number of experiments that can be done, it limits what gets into the pipeline, it limits what gets through the pipeline and it raises the cost ultimately for anything that does manage to get through.

*Ralph Hardy (NABC, Ithaca, NY):* You were talking about the regulatory process. We have a number of people from foreign countries here that do not yet have regulatory processes. What sort of guidance might you give them, and just as a lead off to that, I might suggest the Canadian system vs. the US system. The Canadian system regulates on the basis of novel traits. The US system regulates on the basis of process. In the US system we can use ionizing radiation—all sorts of things that can be produce massive changes in genomes—that require no regulation, but if its by a molecular process it does. In the Canadian system if it's a novel trait, it doesn't matter how you got there, it requires regulation. So, I'd be interested in your comments on that and as an add-on question, you've described one way of getting containment of genes, could you assess where the other processes, like the Daphne Preuss synthetic chromosome and chloroplast modification, fit into accomplishing the same end point?

*Rodemeyer:* Well Ralph, I think you've just thrown the entire agenda off if you want to open up what the regulatory system should look like. The initial point is that the administration, back in 1986, made a decision that we were going to regulate biotechnology using existing laws, and I would argue that part of the problem is that by having to shoehorn the review under our existing laws, we don't have an optimal system in place. Everyone was concerned that if Congress enacted a new system it would be worse than what the regulators could invent on their own. So, I'm not sure I have any great wisdom to share with you about our own system. There is no question that the regulatory system has done

pretty well with respect to the crops that are out there today. I don't think there are any major environmental issues. There are certainly no health issues. The issue that we have tried to raise is: is the system ready for the new kinds of products that are coming along? And as I said, given the nature of novelty, every time you get a new issue, regulators are going to want to ask new questions. I'm not sure there's a magic bullet. There have been arguments that we should have a system with minimal or no regulations. But—and I'm probably going to get a lot of disagreement on this—the reason that we have acceptance of biotechnology in this country is largely because people have confidence in the institutions that regulate it. That's one of the differences between us and Europe. I think no regulation would be a mistake because the people wouldn't have confidence in the technology. You have to have a rational system that's based on science and on actual risk. There's no magic bullet.

*Beachy:* I agree that we needed regulations early on. That was an important thing to implement. We have built a bigger system than we need and more onerous than necessary because we haven't learned from the last 10 years. I mean a *Bt* gene, the same one put in crop "X" and approved, going into a second crop, or even into another variety by a different transformation event, gets re-regulated as if it's not known before. What's the rationale for that after 10 years of safe use of the *Bt* gene? What's the rationale for limiting some of the use of the virus-resistance technology or some of the anti-fungal technology? The Canadian system regulates the protein product that gives a trait. China seems to have done it in a way that is rational and one that meets their needs. They are looking for ways to reduce the use of agriculture chemicals. So I think China has moved ahead in the regulatory process in a different way. I think Kenya and Nigeria have an opportunity to do it in a different way, learning from what we've done in the last 10 years and what China is moving to. And rather than reinventing the wheel, you start with a knowledge-base after 10 years. And that's what we don't find in countries where the regulation is not in place. Most want to start over from scratch, as if we have never had regulation. That doesn't make any sense. We don't do that when we regulate drugs. Having approved aspirin or Tylenol® in this country, they're acceptable in Kenya because there is a long history of safety.

With regard to how else to control trait flow, this issue of gene-switching versus the artificial chromosomes are apples and oranges and the reason why Daphne Preuss promotes the use of the artificial chromosome is to reduce the likelihood of insertion of the gene at a place on the chromosome where there might be a negative impact. That might be useful in some cases or to move full genes in. So there may be some advantages, but I think they are apples and oranges. They are not the same. There are other ways to get to trait-control. There might be suicide genes where with x numbers of generations you trigger the gene to come back out again. Or you may make expression dependent upon hybridization and if that hybrid outcrosses to something else it won't function. There are lots of ways to do it. I think the one that's the most effective will be one that you can control ultimately with a small molecule.

*Robert Wager (Malaspina University, Naimano, BC):* It seems to me that marketing of fear has been driving policies, to a greater or lesser extent in North America, but certainly to a great extent in international policies. The MOP 1 talks seemed almost totally driven by fear as opposed to science and I'm curious what your feeling is about the MOP 2 talks on the Cartagena Protocol.

*Beachy:* I was there for only 24 hours, which was a long enough time for me to be there. I was there with the Public Research and Regulation Foundation. This is a move that started in Holland and England to try to engage public-sector scientists from all around the world including in Africa, Latin America, Asia, South Asia, Southeast Asia, in the discussion of the impact that the Cartagena Biosafety Protocol has on public researchers like us. What are the impacts and how do they stop innovation? How are they preventing us from doing our jobs? As Ralph indicated earlier, more than 70% of the biotechnology that is known about in the United States is done by his member organizations. If you look in developing countries, far more biotech is done in the public sector at KARI for example, or at universities in Nairobi and Abuja and other places around West, East and South Africa. That's where it's done. Yet lack of understanding of what biosafety is has prevented public-sector scientists from doing their jobs and delivering improved vegetables and grains for their populations. So, for the first time, public-sector scientists were not afraid to speak out, at MOP 2. We had a preliminary meeting at the Danforth Center in March and that group and more were in Montreal to understand the process and make inputs when given the opportunity to do so, to correct some of the misunderstandings. The feeling that I had there—the accusation is—this is a big multi-national way to take charge of food production worldwide, and by George we're not going to have that happen and we're going to put in place regulations to prevent that, while doing so under the guise of preventing transfer of DNA between my country and your country. In the past there was an intention to use the process to listen to the antitechnologist and to block applications of relevant biotechnology around the world. I do agree that that was the goal at MOP 1. I think we've seen a slowdown towards that, and maybe a realization that the public sector has a lot to contribute here. Some of the delegates at the conference expressed surprise that university people are actually doing biotechnology! They didn't know—so that was a learning. We should have been there the last time. The public sector should have been a lot more vocal over the last 10 years than it has. We bear some of the responsibility for how far the Cartagena Protocol has already gone because we've not been there often enough. We haven't spoken out. We haven't made our voices heard. We need to find better ways to get our message across or we'll look a lot like Austria or Switzerland in the next few years. There is a possibility we'll see ourselves slip back.

*Shelton:* Michael, in the title of your talk you used the words "speed bumps." You didn't use "wrong streets" or "crashes," so I'm taking that as an indication of an optimistic future for some of these products. I'd like to thank both speakers. It was a great session.