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## *Plenary Session 4—Governmental Regulatory Aspects*

Q&A

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Dana Carroll (University of Utah): Dr. Shearer, how long does it take for the regulatory process to be completed in Canada?

Heather Shearer: It depends very much on the complexity of the file—sometimes quite quickly if it's something we are familiar with and if the package is well presented by a more experienced proponent. With first-timers it can take a bit longer just because they are not so familiar with our process and requirements. Also, it depends on the length of our queue; right now it's very short. At times we have questions about a product and require more information. It may take some time for them to get back to us with the answers. There can be a back and forth.

Carroll: What's the range?

Shearer: Twenty months is the average. The range—I would say, as a rough guess, probably twelve to twenty-four months would be fairly typical.

Perry Hackett (University of Minnesota): Given that large companies have no real incentive for making large changes in the *status quo*, is it realistic to expect that small companies, which do want to make significant changes in the areas that you regulate, really have a chance to do so with the current regulations?

Shearer: I'm an optimist. I'm going to say *yes*, and it's not because of the advocacy of a large or small company, it's honestly coming out of the regulators ourselves. We are

motivated to make this system efficient. Now, there's a lot of inertia there. It's a big system, there is interconnectedness around the globe. We interact with lots of other countries. Political considerations impinge when you want to change a law or how you regulate. There is difficulty, but we are motivated internally to make this system work, and it is possible for small companies to work with our system. Some successful applicants have been small companies.

Joachim Schiemann: The answer for Europe is clearly *no*. Requests to place a single event on the European market cost somewhere between 15 and 50 million euros. The regulatory burdens in Europe are so high, and it is so cost-intensive to provide the data, that small and medium-sized companies are completely excluded; they can do it only in cooperation with the big five or six. This is really a problem because Europe still has a lot of small and medium-sized breeding companies with varied genetic backgrounds. There is broad biological variability within these small and medium-sized companies, which are active and productive, but are excluded due to the high burden resulting from using the new technologies.

Neil Hoffman: In the United States, I would say *maybe*. Early on there was success with papaya, but there has been little success since then. However, if we are successful in revising the regulations the way we would like to, I think it would be possible again.

Alexa Schmitz (Boyce Thompson Institute): We've talked a lot about how we regulate products before they are released. Most of what I have heard is determining their safety prior to release. To what extent do we regulate how those products are used once they are released to farmers. Are companies responsible for making sure that protocols for proper use are put into action?

Schiemann: The European regulation provides consent for only 10 years. The company can apply for an extension. During these 10 years, monitoring is mandatory. We have so-called *general surveillance* where you have to look for negative effects that cannot be predicted, which is scientifically quite demanding. In some cases we have so called *case-specific monitoring*. Case-specific monitoring is based on imagination that the new trait or the new event might have some negative effects. For example, in the case of *Bt*, it is the emergence of resistance in target organisms. In the case of herbicide-tolerance technology, it's the emergence of weediness.

Hoffman: In the United States, the USDA is not involved in oversight once the product has been deregulated. In the two examples mentioned, insect resistance to *Bt* and weed resistance to herbicide, the EPA is involved. Addressing weed resistance is a new development for the EPA. They have stepped up to the plate to provide oversight of the new 2,4-D product; a number of stewardship requirements are connected with the use of that product—monitoring for weeds that are becoming resistant and developing a rapid response to rectify that situation.

Shearer: In the best Canadian tradition, we do it just like Americans do. In addition, when we authorize a product, we have a condition that, if new information comes to light that may affect the specific use or safety of that product, then the farmer is required to notify us, possibly leading to reassessment or revoking of the authorization.

Robert Millman (MPM Capital): Heather, I have a question stimulated by your presentation on Canada about allergens. In any new event—any new engineering or editing event—where you are deleting a protein you could be creating new epitopes. How is that being addressed in Canada and the United States?

Shearer: In Canada, actually, that is already part of the assessment. Evaluators look for potential allergenic epitopes in the proteins, and, again, that is where we rely on that fallback. If new information comes to light, we need to be told. So, if the evaluators happen to miss something or something unprecedented causes an allergic reaction, that would be a perfect example of a situation where you would want to pull that authorization. That hasn't happened yet and hopefully it never does.

Maria Federova (DuPont Pioneer): Dr. Shearer, if a developer comes up with yet another glyphosate-tolerant corn, made by genome editing, how would you qualify that?

Shearer: Of course, we haven't seen that yet. A policy discussion would have to happen at the time we received such a product. I expect, at the very minimum, there would be a lot of bridging to past data generated for that particular protein. That's something we always encourage in our data submission—if a company has already developed a lot of data around the safety of a protein, they are certainly welcome to bridge to past data that they have submitted. It saves us time and saves them time.

Kay Simmons: Are the advances in DNA editing changing the number or the type of applications that you are now receiving?

Hoffman: I don't think so.

Shearer: Not yet. We have received one. I expect that we will see a lot more from what I've been hearing over the last couple of days.

Simmons: Since we have so many graduate students here, let me ask: how many scientists do you employ in your regulatory agencies?

Hoffman: We have staff of about eighty, and about two-thirds of them are scientists.

Shearer: I can probably count on my fingers how many we have. We are actually a pretty lean organization. Our risk assessors are not dedicated to novel risk assessments by any means. They assess a whole variety, not just genetically engineered foods.

Schiemann: In Europe the decision is made on the European level. For risk assessment, EFSA is responsible, the European Food Safety Authority. EFSA is supported by, I think, ten different scientific panels, one of which is on genetically modified organisms. Twenty-one experts are invited to work on that panel. For 6 years, I have been an expert on the GMO panel of EFSA. We have been meeting at least once a month in Parma in Italy, and the GMO unit of EFSA now consists of about fifteen scientists. That's Europe. You also have to break it down on the level of the member states, and in Germany we are absolutely overdoing it. We have five authorities, all of which are looking at new product placement on the market. All of these authorities have to provide opinions to the central authority, the Federal Office for Consumer Protection, which provides the German opinion to EFSA.

Michael Kahn (Washington State University): Recently, some organic producers have been bringing actions against people who are growing genetically modified alfalfa because they are claiming that cross-pollination is contaminating their crops and making them not organic. Does that constitute a weed under the definition that is being considered?

Hoffman: In terms of what a noxious weed is, we don't consider that as a weed. We consider that actually as a natural event, a cross-pollination, which happens. But in the discussions that can ensue, that is certainly a possibility. We never have considered that—cross pollination and the fact that a GE trait that may go into someone else's field—we have never considered that to be a weed harm, a plant pest or a noxious weed harm.

Shearer: In Canada, once something is approved it is considered to be the same as any other cultivar that's out there. So, if you were growing two cultivars of alfalfa in neighboring fields, no one would raise that as an issue; if it's a GM variety next to a non-GM variety, we stay right out of that. On the organic side, we encourage neighbors to cooperate, but that's about all we have to say about issues around GM. That's a socioeconomic issue. It's not CFA's mandate. But I want to mention one of my favorite topics and give a little plug for one of my favorite NGO organizations. They are called CBAN<sup>1</sup> and their website is at [cban.ca](http://cban.ca) where they have an excellent animation about gene flow in alfalfa. I really have to give them credit. They are a well-informed advocacy group. They ask intelligent questions and they are persuasive. If you watch this short—have a look at it while you are waiting for your plane today, for example—it's educational, it tells you what alfalfa does in agriculture and provides a lot of truthful information. And then it slips a little bit over into spin. But I think if you weren't well informed about the issue it's subtle enough that it sounds very real and very believable and makes a good case for why we should be worried about gene flow and corporations gaining control of agriculture.

Simmons: I'd like to thank the speakers for their services to the research community.

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<sup>1</sup>Canadian Biotechnology Action Network.