UNITED STATES
DEPARTMENT OF AGRICULTURE

In the Matter of:	)	
	)	
INTERNATIONAL PLANT PROTECTION	)	
CONVENTION (IPPC) STANDARD ON	)	
PLANT PEST RISKS ASSOCIATED	)	Docket No.: 01-061-1
WITH LIVING MODIFIED	)	
ORGANISMS (LMOs)	)	

Pages: 1 through 99

Place: Washington, DC

Date: August 23, 2001

HERITAGE REPORTING CORPORATION
Official Reporters
1220 L Street, NW, Suite 600
Washington, D.C.
(202) 628-4888

THE UNITED STATES DEPARTMENT OF AGRICULTURE
APHIS PUBLIC MEETING

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Thursday,
August 23, 2001

Conference Room 1D11
USDA Center at Riverside

4700 River Road
Riverdale, Maryland 20737

The meeting in the above-entitled matter was convened, pursuant to Notice, at 10:07 a.m.

BEFORE: ANISSA CRAGHEAD
Moderator

PARTICIPANTS:

PANELISTS:

CATHLEEN ENRIGHT
Director, Biotechnology Issues
PIM, PPQ, APHIS

NARCY KLAG, PIM, PPQ, APHIS

JOHN GREIFER

QUENTIN KUBICEK

PARTICIPANTS (continued):

PRE-REGISTERED SPEAKERS:

PETER JENKINS
Center for Food Safety

MICHAEL HANSEN
Consumers Union

LEAH PORTER
American Crop Protection Association

PRE-REGISTERED SPEAKERS (continued):

FAITH CAMPBELL
American Lands Alliance

PRE-REGISTERED PARTICIPANTS (via telephone):

RICHARD CAPLAN
U.S. Public Interest Research Group

BETH BURROWS
The Edmonds Institute

DAVID GUYER
Syngenta Seeds

MARK CONDON
ASTA

KENT SWISHER
ASTA

PRE-REGISTERED PARTICIPANTS (in person):

MARK LEARN
Hogan & Hartson

RICHARD O'BLEINSTEIN
Defenders of Wildlife

JESSICA FERRUZZI

P R O C E E D I N G S

(10:07 a.m.)

MS. CRAGHEAD: This is a public meeting to discuss the recommendation for the development of a standard concerning the plant-pest risks associated with living modified organisms, LMOs, under the International Plant Protection Convention. The IPPC is recognized as the international, standard-setting body for international plant-pest issues by the World Trade Organization.

My name is an Anissa Craghead, and I've been asked by the deputy administrator for PPQ to be the moderator for today's meeting. The panelists for today's meeting are Dr. Cathy Enright, to my right, director of biotechnology issues and phytosanitary issues management, plant protection, and quarantine. Cathy is the person responsible for coordinating the federal government process for addressing LMOs under IPPC.

And to Cathy's right is Mr. Narcy Klag, program director for international standards development and issues under the North American Plant Protection Organization. Narcy coordinates the development of U.S. Government positions for a range of IPPC issues and is here to answer questions related to IPPC in general.

The purpose of today's meeting is to provide you with background on the issue of LMOs as they pertain to IPPC

and to give interested persons an opportunity to present their views on the recommendation for the development of an IPPC standard concerning the plant-pest risks associated with LMOs. Notice of today's meeting was published in the Federal Register on July 27, 2001.

The format for today's meeting will be as follows. After I complete my remarks on the procedural aspects of the meeting, Dr. Enright will provide you with background information on the issue of LMOs under IPPC and update you on what's happened on this topic since our last public meeting, which was on March 8th of this year.

After Dr. Enright's presentation, persons who have registered to speak will be given an opportunity to speak in the order that they registered. After each speaker completes his or her remarks, panelists will have the opportunity to provide clarification or additional background information if needed and appropriate to the topic of this meeting. If time permits, persons who have not registered will be given an opportunity to speak once all registered persons have spoken.

Today's meeting is scheduled to end at noon. Should registered speakers' presentations take us over the noon conclusion time, we will remain longer to accommodate their statements. Alternatively, we may conclude before noon if all persons who have registered to speak have been

heard, and there are no other persons who wish to speak.

Four people are registered to speak at today's meeting. I know we have some people by phone. Does anyone who is on the line right now by phone want to speak, give a prepared statement? Can you hear me by phone?

A PARTICIPANT: Yes. Can we reserve the right to ask questions? We're not there. We can't see if it's possible to ask questions. In the last meeting like this there was some facility to ask questions, and I found it quite useful.

MS. CRAGHEAD: I think that would work out fine. Sure, you can ask questions.

All comments made here today are being recorded and will be transcribed. The court reporter for today's hearing is Wallace Farmer, who is associated with Heritage Reporting Corporation in Washington, D.C. Detailed information on obtaining a copy of the transcript for today's meeting is available at the registration table, which is right over there.

I will call each person who has registered to speak. Before beginning, please come and sit in that chair, pick up that microphone, state and spell your first and last name for the court reporter, and tell us who you are affiliated with. If you're on the phone, please tell us who you are, state and spell your last name, and then every time

subsequently that you speak please let us know who you are so that the court reporter can record who you are.

If you read a prepared statement and have an extra copy with you, please give me that extra copy at either the beginning or end of your remarks. Any oral statement presented or written statement submitted at today's meeting will become part of the public record. If a speaker's comments do not relate to the stated purpose of today's meeting, which is to present comments or questions on the recommendation for an IPPC standard concerning the plant-pest risks associated with LMOs, I will ask the speaker to focus his or her comments accordingly. In addition, I expect everyone to show respect to speakers and give speakers your full attention.

Please sign the attendance sheet, which is also located on the registration table, before you leave today. After Dr. Enright's presentation I will call the first registered speaker. Cathy, it's all yours.

MS. ENRIGHT: Thanks, Anissa, and thank everyone for coming today. At the March 8th meeting I recalled for everyone what had happened in the runup to the April meeting of the Interim Commission on Phytosanitary Measures. That's the ICPM, the governing body of the IPPC. So today I'm going to begin where I left off March 8th. If we need to come back to events that occurred before the March 8th

meeting or before the April meeting of the ICPM, I would be happy to clarify or recall the background for you.

In April, as I said, the IPPC's Interim Commission on Phytosanitary Measures -- that's the ICPM, the governing body of the IPPC -- recommended that an international standard be completed by April 2004 to address the plant-pest risks associated with living modified organisms, or LMOs.

As the first step toward development of an LMO standard, the ICPM requested that an open-ended, expert working group be convened to produce a detailed specification or an outline for an LMO standard. The expert working group is scheduled to meet September 10th through the 14th at FAO headquarters in Rome under the terms of reference that were printed in the Federal Register notice for today's public meeting. I'm not going to repeat those. The specification developed in September will then be considered at the next meeting of the ICPM in March of 2002.

As discussed at our March 8th public meeting, the decision to consider an IPPC standard for LMOs was the result of requests from a number of IPPC member countries in 1999 for guidance in evaluating the plant-pest risks associated with LMOs and also from the subsequent recommendations made in June of 2000 by a meeting of an IPPC working group formally charged with considering the need for

an LMO standard.

Our goal in the IPPC exercise is to develop substantive guidelines for the assessment of plant-pest risks associated with LMOs; in other words, to set out information requirements, assessment criteria, and risk-mitigation measures that countries may want to consider as they make decisions regarding the importation and use of transgenic organisms.

Your comments today will help us prepare for the September meeting at the IPPC and will also help to inform our approach to the overall LMO standard development process. Before we hear from the first speaker, I would like to draw your attention to an effort that will parallel and perhaps serve as a model for the IPPC LMO standard. As noted at the March 8th public meeting, the United States has begun to address the plant-pest risks associated with genetically engineered organisms at the regional level with Canada and Mexico under the North American Plant Protection Organization, or NAPPO.

In this draft NAPPO standard we have focused first on transgenic plants and have divided the draft standard into four modules based on the intended use of the transgenic plant. The first two models of the draft NAPPO standard should be available on the NAPPO Web site, www.nappo.org, by the end of next week, after which those

modules will be available on our APHIS Web site, which is there for you at the back of the room, for a 60-day, country-comment period. And we would appreciate your reviewing those modules, and we look forward to receiving your comments on them. Thank you.

MR. HANSEN: Hi. My name is Michael Hansen -- I have two questions -- from Consumers Union of the U.S. I have two very brief questions. One is, is the Web site, www.nafo.org?

MS. ENRIGHT: Nappo.org

MR. HANSEN: Nappo. And the other question was, since I was not at the March meeting -- it was probably covered there -- could you tell me who the countries were in 1999 that requested the development of the standard?

MS. ENRIGHT: John, would you?

(Off microphone.)

MS. ENRIGHT: India.

MR. HANSEN: India. Five countries. Most of them from the south, developing countries?

MR. GREIFER: And then that led on to others.

MS. ENRIGHT: So what John Greifer has just said is that the initial impetus for guidance stemmed from a request by India and several other developing countries, and then that led to increased support for guidance from a number of developing countries. And I believe, John, at the

March 8th meeting you had recalled that Latin America had joined that request for guidance as a whole at that time. Is that correct?

MR. GREIFER: It may be worth noting that the interest stemmed from developing countries who did not have the capacity at that time in terms of assessing risk, pest risk, for what appeared to be an increasing volume and amount of traffic and trade in products that they needed to have that ability.

MS. CRAGHEAD: Okay. Our first registered speaker is Peter Jenkins.

MR. JENKINS: Thank you. Thanks for having this meeting. I'm Peter Jenkins. I'm an attorney and policy analyst with the Center for Food Safety and International Center for Technology Assessment in Washington, D.C. We appreciate your taking public input on these issues, and I think this is a really useful forum to share ideas about the ways in which LMOs present traditional sorts of plant-pest risks and the ways in which perhaps they don't and the ways in which those risks might not be appropriately considered within an IPPC context.

Let me give you a copy of a written comment we submitted that's got a lot of detail, and I won't go through all of this. I'm just going to summarize a few points from it. I sent you that by e-mail. Attached to that comment

with respect to this particular forum is also the comment that we submitted about a month ago to a similar forum, which was set up for considering APHIS's position with respect to IPPC as far as this new environmental-impact standard that is similarly being developed. So I think the two issues are related, that is, ways in which IPPC's competence should be expanded, should be extended and recognized in broader areas and ways perhaps in which it shouldn't.

So the gist of our written comment, though, is that, and let me preface this by saying that I was a little bit upset that I didn't hear you mention the other international body that needs to be considered with respect to this issue, which is the CBD, sort of up-and-coming, Cart-in-hand Protocol on Biosafety, which, of course, has primary competence to issue LMO standards.

This is going to be your challenge, it seems to me, is to define those areas which the IPPC should be addressing and those areas which really belong to the Biosafety Protocol to address. We've tried to go through in detail in our comment areas in which your exercise, as you called it, might be a useful thing.

And don't get me wrong. I'm not criticizing this process as a whole. In fact, I think it's great. I think that what we need to see is greater cooperation between

these international agencies that may have some overlapping jurisdiction in some areas. It's not uncommon in the federal government to see overlapping issues of competence and jurisdiction. Of course, you have to iron those out.

But I think in particular where there is a positive synergy that's developed in this dialogue is with respect to capacity building to ensuring that countries like India and other developing countries do have the capacity to address both traditional sorts of non-LMO plant-pest risks and LMO sort of uniquely LMO risks. And as you know, it may be the official same line people looking at both risks.

And to the extent that the IPPC and Biosafety Protocol can cooperate and assist developing countries in the capacity to look at both sorts of issues, that's great. To the extent that there is dialogue between the two bodies and the parties and the secretariats to both groups, that's great. To the extent that you all officially recognize each other's competence, we support that.

But where we run into problems is the idea that the IPPC's body that you are talking about, this deliberative body that's getting together in September, is going to be laying out in great detail what the LMO risks might be. If you consider risks beyond sort of traditional plant-pest risks and invasive-species-type risks that the IPPC is used to dealing with, and I tried to lay out some of

the distinctively LMO-type risks that really belong to the Biosafety Protocol in the comment. And I hope you recognize those, and I'm sure this is going to be an interesting discussion because I don't think the IPPC either has the capacity or the interest to really jump in and start getting into all of the technical detail on LMO risks. Maybe they do. I don't know. They have got enough problems already without jumping entirely into the whole LMO-risk field.

I just listed a few that I think are clearly beyond IPPC competence, and those include the concept of unstable, inserted genes in LMOs that might jump from species to species, which is not a negligible risk in some cases. It seems to me far beyond IPPC sorts of issues, although it might conceivably be considered by some definition to be plant-pest risks. Similarly, this concept of genetic contamination of organic and non-GMO crops might be considered a plant-pest risk, but really it's the sort of risk that is clearly within the Biosafety Protocol competence to develop.

Gene flow from LMOs to wild relatives, protection of centers of crop origin from LMO contamination, issues deal with how to address resistance management for protected plants such as BT corn, resistance management. You could call that a plant-pest risk, but really it's the sort of broader biosafety issues that the Biosafety Protocol was set

up to address, not the IPPC.

And then, of course, there's issues related to allergenicity or toxicity of LMOs, such as the Starling disaster, which you clearly don't want to get involved in, and so on. So we put those in the comment with some support for the fact that these issues are not trivial, and they need to be recognized as serious risks that belong to the Biosafety Protocol.

Let me try to finish up here. I'm rambling a bit. These issues come up at the federal level, too. It's not just an international situation. They couple up at the federal level, too. How do we divide competencies between the agencies?

Let's take the example of one critter, a genetically engineered mosquito, which is happening. There is research on genetically engineered mosquitoes, and they might present two sorts of risks. They could present an animal-disease risk and a human-disease risk, and at the federal level we divide the analysis of those risks amongst the appropriate agencies, where USDA APHIS looks at the animal-disease risk, particularly VS and your biotechnology groups. Bob Rose is here. He looks at those sorts of risks. And as far as the human-disease risk, APHIS stays out of it, and that belongs to the Public Health Service, DHHS. The same sort of division of issues has to occur on

this topic.

So, again, the agencies should recognize each other's competence, encourage cooperation and so on, but don't step on each other's toes. That's the gist of the comment, and I'm glad to answer any questions or anything. Thank you.

MS. CRAGHEAD: Thank you. The next registered speaker is Michael Hansen.

MR. HANSEN: Hi. My name is Michael Hansen, and I'll spell it. It's H-A-N-S-E-N, just in case. And I'm representing Consumers Union and the Consumer Policy Institute of the U.S. And I guess we just have a few comments we would like to make. They are sort of along the lines of what Mr. Jenkins said.

We do think it is a positive first step that this meeting is being held and that there is some consideration between the IPPC and the Convention on Biological Diversity. And in terms of them working together, I noticed that there was a meeting in Thailand in February where the secretariats for both sort of got together and talked about developing a detailed standard specification.

We have some of the same concerns that the Center for Food Safety does, and I think one of the first things the U.S. should recognize is, yes, there probably are parts of the plant-pest risk that are appropriate for the

international, for IPPC to cover because it does have international standing. But I think there does need to be an explicit recognition that the environmental issues raised by genetically engineered plants or LMOs are wider than just plant-pest risks.

So while it might be appropriate for the IPPC to develop this standard, they should realize that there are environmental implications that are outside of the plant-pest risks. So that means they wouldn't be taking the whole ball where they would be saying these specifications will deal with all risks of LMOs. It would just be for the narrow, plant-pest-associated risks, the risk that they might become a weed or be invasive, those characteristics.

But some of the other considerations that people have, some of the instability of transgenic organisms, the horizontal gene transfer -- some of those may overlap if the traits being moved do have an impact on or bear on plant-pest risks, but others of them really don't.

And so I think that the U.S. and these agencies should realize that the universe of environmental effects is larger than just the plant-pest risks and that both the CBD and IPPC should carve out and say, okay, these are the parts that are appropriate for IPPC, and these are the parts that are appropriate for CBD. And I think that needs to be done in consultation with the secretariats from both getting

together.

However, I do notice one thing that might be useful in terms of the issue of genetic contamination, is I noticed in the pest-risk analysis that has to be done for plant pests under the IPPC there is all of this consideration of economic impacts. Now, some people have brought up the concern with transgenic organisms that if they have an impact on centers of diversity, some of those impacts you can't necessarily put into an economic number. What kind of value do you put on contamination, for example, of teosinte in Mexico with transgenic genes? There is a question of what its ecological impact could be, but there is also -- it's really hard to put any kind of monetary figure on that.

So that's why some people were concerned that if you just focus on economic considerations, you will lose things, but on the pro side, with the economic considerations, since that's one thing that's very well worked out under the IPPC, that might be a way to move forward for the marketing aspects because one thing that's unique about engineered plants is since there is now a global trade, and there are countries that want GE-free products or products with no detectable GE contamination, then that means for countries that are not growing transgenic organisms, if they decide to import some, then

the gene flow that will happen when these crops are planted in those countries to neighboring crops that are not engineered could have a negative economic impact and prevent either their movement in international trade or prevent them from being labeled as non-GMO. So that's an economic impact that I think might be something appropriate for the IPPC to look at under the pest-risk-analysis standard.

Now, I realize that that's a little bit of the stretching of the concept -- well, probably not really because normally what they are thinking is that you bring in some plant that's not native, and it escapes and, I guess, causes competition with some crop, thereby causing an economic damage. Well, I think we need to start considering with engineered crops that general flow does a very similar thing, just from a strictly economic sense because rather than in a biological sense this plant pest coming in and displacing crops so you can't physically sell them and having an economic impact that way, the way engineered crops have an economic impact is simply through pollen flow and through the movement of these transgenes into nontransgenic crops.

So that might be one thing that I think should be looked at in more detail, since there is this whole strong economic-analysis part of the plant-pest risk, that's one thing that I think should be dealt with at the open-ended,

expert working group, is to lay out the economic considerations more fully in doing a pest-risk analysis for the entry of a transgenic organism. And you are going to have to start changing or modifying other things because I noticed here that when you look at plant-pest risks, they talk about how you have to look at the risk of movement, and that's basically just based on the biological characteristics of the organism.

But with transgenic organisms, that's not really true because you will have humans who will be wanting to plant those when they get approved for use in a country, so the mechanism of spread won't be based just on the biological characteristics of the plant, but they are based on humans sort of trading them and moving them. So I think it will entail sort of an expansion of your traditional pest-risk analysis, but I think it can be done.

And so, in sum, I would like to say we do support moving forward with this open-ended, expert working group meeting and with the development of a standard, but the most important things are I think there has to be a recognition, number one, that not all environmental impacts of transgenic plants, or LMOs, are plant-pest impacts.

Plant-pest impacts are a subset environmental impacts of all of the environmental impacts of LMOs. And I think this meeting should work out in conjunction with CBD

what the appropriate universe is of the plant-pest risk for the LMOs, develop a standard based on that, and then explicitly say that the other areas should be dealt with by CBD, and further, we would like to see a strengthening or a further development in the pest risk assessment that needs to be done, a fuller development of using the economic considerations for the unique sort of economic impacts that LMOs can have via gene flow. Thank you very much.

MS. CRAGHEAD: Thank you for your comments. Our next registered speaker is Leah Porter.

MS. PORTER: Good morning. My name is Leah Porter, and I represent the American Crop Protection Association. We welcome the opportunity to be part of this meeting. We have written comments, which I'll just read excerpts from.

We welcome the opportunity to comment on the development of an international standard concerning the plant-pest risks associated with living modified organisms, or LMOs. We encourage APHIS's participation as part of the expert working group under the auspices of the International Plant Protection Convention, IPPC, given IPPC's recognition by the World Trade Organization.

As the IPPC's Interim Commission on Phytosanitary Measures commences its work, we would like to emphasize the following. Evaluation of all LMOs should follow a

science-based, transparent, and timely risk-assessment paradigm.

An LMO should not be assumed to be a plant pest unless the risk assessment, one that utilizes IPPC standards or an endorsed equivalent, concludes that phytosanitary consideration is merited. A discussion of LMO or products of modern biotechnology within the ICPM standard-setting efforts must be within the context of seeds for planting purposes. A discussion of LMOs or products of modern biotechnology within the ICPM standard-setting efforts must avoid the incorrect notion that seeds that are derived using modern biotechnology are by definition plant pests.

A discussion of LMOs, products of modern biotechnology within the ICPM standard-setting efforts, must appropriately assess benefits and potential environmental impacts within a science-based framework.

Transboundary or international movement of seeds derived using modern biotechnology should use the existing invoicing system, with the necessary changes rather than requiring a phytosanitary certificate for each shipment. Once an importing country has conducted a required risk assessment on a transgenic event and granted approval, transboundary shipments should not require approval of the importing country prior to each shipment.

Thank you for giving the American Crop Protection

Association the opportunity to comment.

MS. CRAGHEAD: Thanks very much for your comments. Our final registered speaker is Faith Campbell.

MS. CAMPBELL: Thank you. My name is Faith Campbell. I'm with American Land Alliance, an environmental organization that represents grassroots groups across the country. We also appreciate the opportunity to be here. We were unable to participate at the March meeting.

American Land urges APHIS to ensure that the IPPC proceeds with great caution in exploring development of an international standard for LMOs, and I was not happy to hear of the 2004 goal. I think that's far too earlier.

First, you must carefully coordinate with the CBD, as everyone else has said this morning, or virtually everyone else, and that is going to take some negotiation and working not just between the two secretariats, but among the parties and among the various agencies within each government that is party to one or both of these measures. It's not going to be that easy to develop true cooperation on this issue.

Second, I think the IPPC lacks expertise in many of the crucial components of a truly science-based evaluation of LMOs. The IPPC's current risk-assessment process is already under criticism, certainly by me and scientists with whom I work, and explicitly in the

invasive-species area by the IUCN guidelines on invasive species and those under consideration by the CBD parties. And if these risk-assessment criteria are inadequate for invasive species, as I and others believe, they surely will be inadequate for LMOs. So I think there is a need for much caution and considerably broader consultation and rethinking of the whole process.

I recommend that the IPPC base any LMO standard on the conclusions drawn by the Royal Society of Canada in the report it issued in January. There is a reference in my written statement to that report. The Royal Society recommended that commercial use of any LMO be deferred until after testing of the specific GE line in six areas: the genome, the transcript, the protein, the metabolite, the health impacts, and the environmental impacts.

Regulators must rely on data from empirical studies rather than assumptions based on hypotheses, and countries should be encouraged by the IPPC and others to subject their analyses to peer review and to take care to avoid conflict of interest within the regulatory agency. These studies must evaluate each genetic line, again, in the context of the ecosystems, whether managed, such as agricultural, or natural, into which the introduction is proposed or into which it might slip as a result of being intentionally introduced into one or the other. A crop

introduced into a managed ecosystem can have impacts on nearby natural systems, and no analysis is adequate without looking at those.

Now, some may consider these studies duplicative, but I don't think they are, and we also need to look at the risks from pleiotropic effects, and that is one area where I see very little attention domestically, and I would assume that would follow in the international arena as well.

Such detailed studies are called for, according to the Royal Society of Canada, whenever there are some scientific data, although incompletely, contested, or preliminary, or plausible scientific hypotheses or models, even though contested, that establish a reasonable, prima facie case for the possibility of serious harm, and there is significant uncertainty.

An underlying principle here is that we need to do a better job of managing the risks associated with this new technology than we did the risks, for example, with chemical pesticides. We don't want to be in the same situation 50 years from now of trying to clean up after ourselves because we weren't adequately careful beforehand.

Now, I believe these principles point to an IPPC standard that encourages each country to consider the potential risks and benefits from its own ecological and social perspective before deciding whether to allow

importation. It allows countries to require would-be importers of LMOs to conduct or pay for the relevant empirical studies on which this assessment must be based but recognizes countries' differing abilities to adopt and enforce regulations.

I would like to emphasize this. Regulations written on the assumption that everyone is going to behave correctly are unrealistic. Regulations that assume that regulatory bodies will find out quickly that something has gone wrong are unrealistic. Regulations that assume that mistakes can be cleaned up afterwards are borderline unrealistic or perhaps not even borderline. All of these factors need to be considered, and any IPPC standard needs to put that warning in place, I believe.

And, finally, I join Mr. Jenkins in calling for a real emphasis on technical and financial assistance in helping countries develop their capacities. I don't think any country, including this country, has an adequate capacity, but 150 other countries have severely worse capacities than ours, and nothing is going to work right if that isn't improved.

Potential negative impacts from GE organisms or LMOs include, but are not limited to, escape of the gene from the crop into other related species, the impacts of inserted pesticides on food webs and ecosystem processes,

the repercussions of pests developing resistance, enhanced invasiveness of the LMO or its relatives in both natural and managed systems, and certainly study of this issue in natural systems lags far behind the study in managed systems, the impacts of other genetically induced changes, and the environmental impacts from management technologies, such as sterility and increased use of herbicides to control LMOs and prevent their escape.

Again, all of these potential risks need to be evaluated for each line in the context of each environment in part because of the risks from pleiotropic effect, and these evaluations must occur before the LMO is approved for use, not as some adaptive management process afterwards.

I concur with a remark made a little earlier about the great risks of introducing LMOs into centers of origin or diversity for the particular kind of crop that is being dealt with, and I think the IPPC needs to highlight that and work very hard on that problem.

In short, I think that this whole process is going to take a lot longer than two or three years. It should take longer than two or three years, both because of the requirement for dialogue and the many unanswered questions that need to be addressed. Thank you.

MS. CRAGHEAD: Thank you. That's the end of our list of registered speakers. Does anyone have a prepared

statement that they would like to give?

MR. SWISHER: Yes. The American Seed Trade.

MS. CRAGHEAD: We'll go with the phone.

MR. SWISHER: Okay.

MS. CRAGHEAD: Can you state and spell your first and last name and give your affiliation before you start your comment, please?

MR. SWISHER: Sure. This is Kent Swisher, K-E-N-T S-W-I-S-H-E-R, with the American Seed Trade Association, and we have also provided written comment as well. Can you hear me okay?

MS. CRAGHEAD: Yeah.

MR. SWISHER: Okay. I'll proceed. The American Seed Trade Association, or ASTA, appreciates the opportunity to provide comments today on the development of international standards concerning the plant-pest risk associated with LMOs. In general, ASTA cautiously endorses such standards, development processes under the auspices of the IPPC. Where one or more international agreements exist covering various areas, we believe that existing international organizations and mechanisms should be used wherever possible instead of the establishment of new organizations or procedures or both.

The objectives and mechanisms of the IPPC and of other international treaties can coexist and complement each

other. At the same time, we also want to emphasize that duplication should be avoided whenever possible.

By way of background, founded in 1883, ASTA is one of the oldest trade organizations in the United States. Its membership consists of around 900 companies involved in seed production and distribution, plant breeding, and related industries in North America. Its mission is to enhance the development and premovement of quality seed worldwide.

Many of ASTA's members, large and small, are engaged in research-and-development activities designed to enhance the quality, variety, productivity, and availability of agricultural seeds. Some of this research involves the use of molecular and other techniques for genetic modification. Although the industry still relies heavily on traditional breeding methods, such as hybridization, to produce new plant varieties and to otherwise accomplish desirable genetic changes, the Association remains committed to the development and commercialization of all genetically altered plants that comply with applicable federal and international laws and regulations.

ASTA and its members have a long-valid relationship with organizations involved in implementing the IPPC, a multilateral treaty developed in 1952. ASTA has cooperatively worked for many years with bodies such as regional plant-protection organizations in the development

of standards and other criteria to prevent the spread and introduction of plant pests on plants and plant products and promote measures for their control.

IPPC, therefore, can be the appropriate forum for the development and application of harmonized, phytosanitary measures and the elaboration of international standards. The IPPC's scope is to, and I quote from Article 1.1, "common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote measures for their control."

This broad nature of IPPC's mandate governing plants is not limited to cultivated plants, and protection is not limited to direct damage from pests. The coverage of the IPPC includes weeds and other articles that have indirect effects on plants. The scope of the convention, therefore, already applies to the protection of wild flora that make an important contribution to the conservation of biological diversity.

A particularly important aspect of the IPPC is that it involves a collaboration with other organizations to avoid duplication and encourage harmonization for the implementation of obligations of other instruments.

Given this overall mandate, it is not surprising to us, and, indeed, it may be appropriate, that IPPC address plant-health issues that might be presented by LMOs or other

products of modern biotechnology that fall within the scope of the IPPC. Indeed, existing national mechanisms and other structures for phytosanitary measures can perhaps help serve as a model for developing approaches for managing risks associated with LMOs and other products of modern biotechnology. It is our view that the plant-pest risks associated with LMOs can fall clearly within the scope of the IPPC, as do invasive species and quarantined pests. On the other hand, not all seeds that may be considered LMOs are necessarily plant pests or pose plant-pest issues.

One of the main reasons why we cautiously endorse the use of IPPC mechanisms is that IPPC plays a key role in trade. It is recognized by the World Trade Organization in the Agreement on Application of Sanitary and Phytosanitary Measures as a source of international standards for phytosanitary measures affecting trade. Since phytosanitary measures, by their very nature, may result in restrictions on trade, the WTO-SPS agreement specifies which factors should be considered in the assessment of risks involved, thus reducing the possible arbitrariness of phytosanitary standards and ensuring consistent decision-making.

Phytosanitary measures to protect the health of plants must be based as far as possible on the analysis and assessment of objective and accurate scientific data. In other words, countries must establish SPS measures on the

basis of an appropriate assessment of the actual risks involved. The WTO-SPS Agreement also encourages the government to select those measures that are not more trade restrictive than required to meet a particular health objective.

The adoption of IPPC's standards in accordance with the WTO-SPS Agreement, therefore, can help ensure that phytosanitary and other standards are not abused for protectionist purposes, resulting in unnecessary barriers to international trade. Thank you.

*(Tape 1B)

MS. CRAGHEAD: Does anyone else have a prepared statement they would like to give at this time?

MS. BURROWS: I have a few remarks I would like to give. This is Beth Burrows on the phone.

MS. CRAGHEAD: Okay. Are they questions or remarks?

MS. BURROWS: Remarks.

MS. CRAGHEAD: Okay. Go ahead, Ms. Burrows. Will you state and spell your name and give your affiliation, please?

MS. BURROWS: My name is Beth, B-E-T-H, Burrows, B-U-R-R-O-W-S. I'm with the Edmonds Institute, a

public-interest, nonprofit group in Edmonds, Washington, and, I believe, the only speaker of whom I'm aware who has participated actively in the negotiations of the Biosafety Protocol of the Convention on Biological Diversity. The Edmonds Institute is especially happy to hear so much concern with science-based measures and so much concern with economic considerations subsequent to the introduction of LMOs into ecosystems.

In some respects, this represents a new direction for the United States. Having recently returned from discussions in Cuba under the auspices of the CBD on biosafety capacity building, it was noted by many of those in the Third World that they were actively seeking help in biosafety capacity building.

And so the Edmonds Institute is especially happy to hear that the United States is so concerned to raise the capacity of others in biosafety and hopes that this implies that the United States will give much greater investment, certainly than was evident at the meeting in Havana, in biosafety capacity building in the Third World so that, hearing my colleague from the American Crop Protection Association and others, so that we will not have unscientific or lack of competence in science decision-making made under IPPC.

We note, and agree with our colleagues, that it is

very important that whatever transpires in the discussion here be coordinated with the CBD. However, the Edmonds Institute would recommend that this not be composed of merely inviting the two secretariats to get together. As I'm sure everyone there is aware, the Biosafety Protocol, as are the rules that we are discussing here today, is still under negotiation to a large extent as it moves toward a moment in time when it may be implemented. I would hope that the United States would continue to send a fuller delegation to those deliberations so that we may not at the end wind up with two bodies with different competence in biosafety and no agreement as to how to settle their disagreements.

We would invite everyone to notice that both our moving processes and both often occur in different ministries, which creates an even greater role for the United States not only to raise capacity throughout the world in environmental ministries, but also in agricultural ministries. And we hope that the United States, with its great concern for science-based assessment, will take up that challenge, lest we simply force countries to leave out LMOs altogether because of lack of ability to make a science-based decision.

Finally, we welcome very much the discussion focused on economic considerations, and we hope that this

will mean a new sign that the United States is prepared to support in the CBD and other places socioeconomic considerations in the decision making around biosafety. Thank you very much for arranging to have phone connections so those of us in other places can access this meeting, and we look forward to your further deliberations.

MS. CRAGHEAD: Thank you for your comments. Any other prepared statements, remarks? Okay.

Before we start with questions, I just want to remind you of something that I said in the opening remarks, that is, the panelists will provide clarification or additional background information. Okay. So if there are any questions, please come up to the hot seat and talk into the mike.

MS. BLAUSTEIN: Thank you very much for this opportunity. My name is Rich Blaustein, B-L-A-U-S-T-E-I-N, and I'm a consultant to Defenders of Wildlife. I follow the CBD and alien-species issues.

I have just a question for Dr. Enright. I read the transcript for the meeting in March, and that was before the April ICPM meeting, and I went through the report of the ICPM. I wasn't here for the March meeting, but I read the transcript, most of it, because I just heard about the meeting recently. And in the April report there is quite a bit that's relevant, but strongly so would be Appendix 13,

which would be the statements of the ICPM exploratory, open-ended Working Group on the Phytosanitary Aspects of GMOs, Biosafety, and Invasive species.

There is much in that annex that should be encouraging, calling for the IPPC working together with the CBD. Of course, there is the standard talk of the secretariats working together and consulting. But, for example, in alien species there is a recollection of Article 8(h) by the IPPC. And I will further mention a specific one that caught my interest. Number 32 of Appendix 13 recommends the ICPM work with the CBD and other relevant bodies to develop and deliver appropriate programs that meet the needs of countries in regard to common areas of interest.

My question is, in the context of this report, this appendix, what's the impressions of the process of clarification in relationship, and what can we expect on the calendar in the next year, clarification for some of the points raised from some of the earlier speakers, too?

MS. ENRIGHT: Thank you for your question. I was going to come back to this issue of consultation. We recognize that in order for an LMO standard under the IPPC to be credible and be worthwhile and have some utility for countries, that the IPPC and the CBD, or the ICCP, as it is now, the Interim Commission for the Cartagena Protocol, are

going to have to consult. It's expected that at this September meeting two of the bureau members of the ICCP, the Interim Commission on the Cartagena Protocol, will be in attendance. So we're not at all thinking that this is the IPPC going it alone. That would be foolish.

One of the reasons, in addition to the fact that there is the Cartagena Protocol out there -- it hasn't entered into force, but steps being made with regard to its implementation. We have that agreement, and we will all have to operate under that agreement. But we also are very well aware that ministries of agriculture are now aware that they will be in many, many countries responsible for implementing the obligations under the Cartagena Protocol.

Although they may not have had a primary role in their countries in the negotiation of the protocol, ministries of agriculture have existing mechanisms and systems to deal with in this case phytosanitary issues related to LMOs, and the onus is going to be on them to adopt or amend those mechanisms so that they can implement the appropriate obligations under the Biosafety Protocols.

So there has got to be a synergy there between, as Ms. Burrows was saying, the CBD and the IPPC, but also within country, and we don't have an impact on that, but ministries of environment and ministries of agriculture. I think those two things are a given for us.

MR. BLAUSTEIN: Can I ask? September will be the --

MS. ENRIGHT: Oh, the calendar. I'm sorry. You asked for future. What we would expect, then, under the IPPC, and I'm sorry about all of the acronyms -- I think we could do better -- the IPPC, the International Plant Protection Convention, the specification will then go to the March meeting of the ICPM, the interim governing body of the IPPC.

MR. BLAUSTEIN: March ICPM 2002.

MS. ENRIGHT: Right, 2002. That will be the next step for the IPPC process. And with regard to Dr. Campbell's concern about the calendar, that is a target date, and all of the activities under the IPPC are given target dates so that they can be put on the work plan. We certainly would agree with you that we wouldn't want to rush a standard through just to meet a deadline. That wouldn't be helpful to anyone.

With regard to the Biosafety Protocol process, I would expect, and I can't speak for the bureau, but I would expect that the bureau attendees at the September meeting will report back to -- here we go again -- the ICCP meeting in Nairobi the first week of October. And so the consultative statements that I expect to come out of the September meeting I expect would be considered by those

attending the October meeting of the ICCP. And I don't know what -- I know it's very confusing -- I'm sorry. But I would expect the ICCP then to respond to the report that will come from the September meeting, the specification.

So with regard to chronology, the Biosafety Protocol part, interested groups will have a chance to react to the September meeting before the IPPC member countries will. That will be the chronology.

MR. BLAUSTEIN: If I can just add, the fact that there is a November meeting on environmental impact standard for invasive species, that is going to be kept discrete from this.

MS. ENRIGHT: Yes. That's correct.

MR. BLAUSTEIN: Okay.

MS. ENRIGHT: With regard to how that came about, and for those of you who weren't at the March meeting or haven't followed all of the dialogue, the increased profile of environmental concerns, the increased profile of living modified organisms, member states in the IPPC wanted further guidance on both of those issues, the environmental concerns that may be specific to invasives as well as the environmental concerns that may be specific to LMOs, recognizing that the IPPC has to operate within its scope, so we are limited to plant-pest risks.

We're not going to try to go out. That's out of

our mandate and out of our scope. We wouldn't go beyond that. Countries came seekIng further guidance in their assessment processes under each those umbrellas. Let me just make one clarification on your comments about economic importance. If you look at the current PRA -- how this came about, I'm still not quite clear, but economic consequences, the assessment of economic consequences, includes environmental consequences that may be of a nonmonetary nature. And I know that the IPPC is working to make that more clear, that "economic" just doesn't mean monetary consequences, but it includes nonmonetary, noncommercial consequences.

So with regard to the current status of the IPPC, countries have the ability or have the authority, if you will, under the IPPC to perform a risk assessment for invasive species and to perform a risk assessment for LMOs should they wish. However, they don't feel as though they had enough guidance.

What questions do we ask? What do we require from an applicant? What are the risk-assessment criteria that we may want to be looking at under each of these umbrellas that we don't look at under our traditional plant-protection quarantine operations? So for that reason these two processes were begun, one, the one you're speaking about, the environmental risk-assessment standard, which will meet

in November, and then the separate -- it met in August. Right. And it will meet again in November? No. That's the standard committee. I'm sorry. It met in August. The environmental risk-assessment group met in August.

So in November that work will go to the IPPC Standards Committee for review. Not finalization, just review, just as an update as to how far they got in August. And then the other process is then the risk assessment for the LMOs.

MS. CRAGHEAD: Can you grab the mike from where you are?

MS. CAMPBELL: Yes. This is Faith Campbell again. Countries seeking guidance; I understand why they are seeking guidance, and I think some international guidance would probably be useful. But guidance from the IPPC is not advice. It becomes the standard that the SPS agreement enforces, and that is what worries me because advice, particularly at this early stage of IPPC competence in both the environmental area and LMOs, will suddenly become the standard that every other country either has to follow or it has to come up with a very good explanation why it's not following, and that's what bothers me. You had better do it right because it's going to become international law, and I don't think in either one you're going to get there in two years.

MS. CRAGHEAD: Thank you. Are there other questions? Should we go to the phone? Okay. A question from the phone.

MS. BURROWS: Well, the phone has a couple of questions. Why doesn't Dr. Hansen give his question, and then I will know when he is done to give mine?

MS. CRAGHEAD: Okay. Thanks.

MR. HANSEN: This is Michael Hansen from Consumers Union again. The question I have relates to the meeting in September. Do we have a list -- two questions about that. Can we get a list of who is attending, number one; and number two, are they going to permit any observers? Is this a closed meeting, or will they permit any observers to attend?

MS. ENRIGHT: As far as I know, there isn't a list of participants. When I last spoke with the secretariat, they had a very informal list. Europe had not put forth any names yet. It's down time across the Atlantic right now. So they are expecting to have participation around 50 or 55 people. I don't know whether there will be available on the FAO IPPC Web site a list of participants. I certainly don't have one that I'm able to give you one. Probably not. It is an open-ended meeting.

Now, that means that if you would like to participate -- I'm not the FAO secretariat or the IPPC

secretariat, but my understanding of "open ended" means that if you would like to participate, you should contact the secretariat and tell them of your interest. At the meeting that we had in June 2000, observers were present, and they made presentations when they were called upon or when they felt the need to make a remark.

MR. HANSEN: So that would entail just getting in touch with Nick Van DeGraff, then. Okay. Thanks.

MS. ENRIGHT: You're welcome.

MS. BURROWS: This is Beth Burrows again from the Edmonds Institute. Two questions, one a further clarification to the question Dr. Hansen asked. Is it possible for Dr. Enright to make available to at least those at this meeting a list of the pertinent meetings that will be occurring? It occurred to me as she was listing various meetings that I was becoming confused as to which meeting was which, and it would be extremely helpful to know which meetings will be coming up and to have some list available, perhaps even on a Web site would be fine. That's my first question.

MS. ENRIGHT: Sorry for the delay, Dr. Burrows. I'm just checking with Narcy, who coordinates our Web site, to see if he could put it on there, put the list of meetings on there, and, yes, he can. He will make that available.

MS. BURROWS: Great. And also in the case of

meetings that are open ended, since not all secretariats have the same rules about the meaning of "open ended," at least that's my understanding -- some require accreditation to the body, and some do not -- if you could further put on the calendar who to contact if you want to go to the meeting.

MS. ENRIGHT: Okay.

MS. BURROWS: I would appreciate that. Thank you.

My second, and this is a question to the whole committee and maybe to people not on the committee but who will read the report of this meeting, again, to capacity building. When the United States took up this challenge that was offered it by your report in response to the requests of countries, were there also moves in the United States to find funds to enable these countries to raise their capacity to do the kinds of assessment we will be advising them about, whether we advise them rightly or wrongly, completely or competently?

It's not simply a matter of issuing a booklet, here is how you do it. It requires a body of science and training that may not, as I think Dr. Campbell noted, may not be available in the appropriate ministry that is addressing this. Is the United States prepared to help these countries raise their capacity in biosafety by investing in their infrastructures, or are you advising them

to do so?

MS. ENRIGHT: Dr. Burrows, John Greifer is coming over to the microphone.

MR. GREIFER: Let me try to as best answer the question. We do have ready resources deployed around the world, APHIS does with its foreign service, and these are plant-animal health specialists that do provide technical assistance. And so we often don't always get the credit we should for a lot of that work that we do overseas. It tends to be right now more traditional, the issues. We don't have folks out there really that are as up to speed as we would like them yet to be able to be providing technical advice and assistance directly on LMO issues.

As far as the IPPC goes, this is a major, major topic, capacity building. And, of course, the question always becomes, are the resources available for that? The IPPC operates on a shoe string budget right now. We're doing what we can to try to direct more attention to the important activities that the IPPC plays, not only in plant protection in a traditional sense, but also in some new, contemporary issues, such as LMO invasive species, et cetera.

So we're working on trying to draw more attention not just within our own government, but also with other governments as well because the decisions about directing

FAO resources or resources with some of these other organizations, not a U.S. decision. It's going to be one of working with other countries to agree on certain priorities about how some of that international money needs to be spent.

The first, just as a matter of, I think, the important work that we're doing with IPPC is to try to develop a diagnostic tool so that countries have a manner in which to identify their real needs so that once money does become available, if it becomes available through various sources, that we are not just throwing money without having a clear idea of what specific needs these countries have.

Over the past two years, the New Zealand government put up money to develop a diagnostic tool for countries to self-assess themselves in the plant-quarantine, plant-protection area. And so part of that diagnostic tool does include trying to assess their strengths or their weaknesses in terms of being able to assess pests. They have the ability also to look at LMO products as well.

Right now, the emphasis is on trying to get this diagnostic tool in place, get it completed. It's being piloted with several developing countries to see if it's a useful way for countries to determine what their true needs are.

So we have a long way to go. The

capacity-building issue is not unique to the IPPC, and probably the biggest challenges in front of us are going to be, as is obvious, is really going to be the question of resources.

MS. BURROWS: I don't know if it's proper for me to make a remark in response to an answer to a question I asked. I need the chair's advice.

MS. CRAGHEAD: A quick remark, I suppose, would be appropriate.

MS. BURROWS: In the context of the Biosafety Protocol, it was noted, particularly by developing countries, that putting rules into place before people have the capacity to implement those rules or to understand how those rules will affect them in their own countries is extremely problematic.

I would hope that the United States will not push to get a rule in place before the biosafety capacity of those whose jobs it will be to implement it in their country is high enough so that that implementation is something that is, to use earlier remarks, science based and capable. Thank you.

MS. CRAGHEAD: Thank you. I would just like to interject, because I didn't do it earlier, that John Greifer is the director of APHIS's trade-support team. There was a question on this side of the room. Thank you for waiting.

MR. KUBICEK: I'm Quinton Kubicek, K-U-B-I-C-E-K, with DuPont, and I have a request and a question. The request comes from what seems to be a need for transparency, and that was Michael Hansen's original question earlier in the day reminded me of it. But at the March meeting we could only recall a couple of countries that were asking for this LMO standard. I recall India being one. The other one couldn't be recalled, but it also seemed to have been made -- the requests for these seem to have come more from hallway conversations rather than official intervention.

So in today's meeting it seems like this number of countries, from what seems to be personal anecdotal recall, seems to increase. So perhaps my request is that the minutes of these meetings that are held also be put in addition on the Web site so that we could independently look at them. I realize that many of the minutes may not be available, but rather than depending on personal anecdotal recall, if we could have the minutes, or if they are available, then we could independently assess the number of countries that are asking for these things or their positions. And obviously, if there are hallway or even bathroom conversations, obviously those aren't official minutes, but neither they should reflect the minutes.

And my question is -- Narcy, I presume this would be for you -- it was mentioned that for the NAPO standard to

be a 60-day comment period. The question is, will it also be the same 60-day comment period for Mexico and Canada, and if not, will that comment period be longer or shorter for each of the countries?

MR. KLAG: You're referring to the standard we posed on the Web site.

MR. KUBICEK: The one that's coming up.

MR. KLAG: Yeah. The country consultation period is the same for all of the countries, yeah. And once that's completed, then we take the comments and review them, and we incorporate them if possible or when necessary and then try to move toward a final standard.

MR. KUBICEK: No. I understand that. The question was whether a 60-day for both Mexico and Canada.

MR. KLAG: That's right. Yeah. As far as the first comment on the minutes of the proceedings of the meeting, they are posted on the IPPC Web site. You can obtain them there. Of course, that's the official minutes from the meeting. It's, I guess, the consolidation of what the members decided on, so it doesn't go into detail on who brought what up exactly and who supported what. It's just what the final outcome is.

MS. CRAGHEAD: There was one other question on this side. Did you want to ask it?

A PARTICIPANT: It's answered.

MS. CRAGHEAD: It's answered. Are there any other questions?

(No response.)

MS. CRAGHEAD: On the phone, any other questions? No?

MS. BURROWS: No.

MS. CRAGHEAD: Great. Well, thanks very much for coming today. We really appreciate all your comments, and we hope you have a really good day. Thanks for coming.

(Whereupon, at 11:25 a.m., the meeting was concluded.)

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STATEMENT OF KENT SWISHER

The American Seed Trade Association (ASTA) is providing these comments in response to the Federal Register notice announcing a public meeting to solicit views on the development of international standards concerning the plant risks associated with LMOs. 66 Fed. Reg. 39136 (2001). In general, ASTA cautiously endorses such standards development processes under the auspices of the IPPC. Where one or more international agreements exist covering various areas, we believe that existing international organizations and mechanisms should be used wherever possible, instead of the establishment of new organizations or procedures, or both. The objectives and mechanisms of the IPPC and of other international treaties can coexist and complement each other. At the same time, we also want to emphasize that duplication should be avoided whenever possible.

By way of background, founded in 1883, ASTA is one of the oldest trade organizations in the United States. Its membership consists of about 900 companies involved in seed production and distribution, plant breeding, and related industries in North America. Its mission is to enhance the development and free movement of quality seed worldwide. Many of ASTA's members, large and small, are engaged in

research and development activities designed to enhance the quality, variety, productivity, and availability of agricultural seeds. Some of this research involves the use of molecular and other new techniques for genetic modification, although the industry still relies heavily on traditional breeding methods such as hybridization to produce new plant varieties and to otherwise accomplish desirable genetic changes. The Association remains committed to the development and commercialization of all genetically altered plants that comply with applicable federal and international laws and regulations.

ASTA and its members have a long and valued relationship with organizations involved in implementing the IPPC, a multilateral treaty adopted in 1952. ASTA has cooperatively worked for many years with bodies such as the regional plant protection organizations in the development of standards and other criteria to prevent the spread and introduction of plant pests of plants and plant products and to promote measures for their control. IPPC, therefore, can be the appropriate forum for the development and application of harmonized phytosanitary measures and the elaboration of international standards.

The IPPC's scope is to secure "common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote measures

for their control ..." (Article 1.1). This broad nature of the IPPC's mandate governing plants is not limited to cultivated plants, and protection is not limited to direct damage from pests. The coverage of the IPPC includes weeds and other articles that have indirect effects on plants. The scope of the Convention therefore already applies to the protection of wild flora that make an important contribution to the conservation of biological diversity.

A particularly important aspect of the IPPC is that it involves the collaboration with other organizations to avoid duplication and encourage harmonization for the implementation of obligations of the other instruments. Given this overall mandate, it is not surprising to us,a nd indeed it may be appropriate, that the IPPC address plant health issues that might be presented by LMOs or other products of modern biotechnology that fall within the scope of the IPPC. Indeed, existing national mechanisms and other structures for phytosanitary measures can perhaps help serve as a model for developing approaches for managing risks associated with LMOs and other products of modern biotechnology. IT is our view that the plant pest risks associated with LMOs can fall clearly within the scope of the IPPC, as do invasive species and quarantined pests. On the other hand, not all seeds that may be considered LMOs are necessarily plant pests or pose plant pest issues.

One of the main reasons why we cautiously endorse the use of IPPC mechanisms is that the IPPC plays a key role in trade. It is recognized by the World Trade Organization (WTO) in the Agreement on Application of Sanitary and Phytosanitary measures (the WTO-SPS Agreement) as a source of international standards for phytosanitary measures affecting trade. Since phytosanitary standards, by their very nature, may result in restrictions on trade, the WTO-SPS Agreement specifies which factors should be considered in the assessment of risk involved, thus reducing the possible arbitrariness of phytosanitary standards and ensuring consistent decisionmaking. Phytosanitary measures to protect the health of plants must be based as far as possible on the analysis and assessment of objective and accurate and scientific data. In other words, countries must establish SPS measures on the basis of an appropriate assessment of the actual risks involved. The WTO-SPS Agreement also encourages governments to select those measures that are not more trade restrictive than required to meet a particular health objective.

The adoption of IPPC standards in accordance with the WTO-SPS Agreement therefore can help ensure that phytosanitary and other standards are not abused for protectionist purposes, resulting in unnecessary barriers to international trade.

Cordially yours,

Dean Urmston

Executive Vice President

STATEMENT OF PETER T. JENKINS

The Center for Food Safety (CFS) is pleased to submit comments on the development of an international standard concerning the plant pest risks associated with living modified organisms (LMOs). CFS is a nonprofit, membership organization established in 1997 to address the increasing concerns about the impacts of our food production system on human health, animal welfare, and the environment. We believe it is vital that the IPPC's approach to LMOs mesh well with the Convention on Biological Diversity (CBD) Cartagena Protocol on Biosafety. The parties and secretariats of both international laws clearly seek better coordination.

Background.

To some extent, LMOs represent a distinctive subset of the issues pertaining to introduction of non-native, potentially invasive pests. The nested relationship of these topics has been repeatedly recognized. The Expert Consultation on IPPC-CBD Cooperation specifically stated "... some LMOs have the potential to be invasive species." Here are the words of the President of the General Assembly of the UN announcing this year's theme for International Biological Diversity Day as "Biodiversity and Management of

Invasive Alien Species":

While it is a fact that non-native animal species may be harmful to land and crops, there are still controversies and differences of opinion. Genetically engineered species are another cause for concern. Today, we already know of examples where genetically engineered species pollute the germplasms of the indigenous ones with dire consequences.

The IPPC standard on plant pest risks should acknowledge that two types of LMOs may exist:

1. LMOs that in their nonmodified form were recognized plant pests. A good example is the current USDA APHIS effort to release (for biological control purposes) a genetically modified version of the pink bollworm, a major cotton pest. In general, the modification of such species may increase, decrease, or not affect the pest risk presented by their release.
2. LMOs that in their nonmodified form were <u>not</u> recognized plant pests but whose status may have changed. A good example is herbicide-resistant canola, the genetic modification of which increased the weediness of the plant,

as an unwanted and difficult-to-eradicate volunteer. Again, in general, the modification of such species may increase, decrease, or not affect the pest risk presented by their release.

To the extent that a proposed LMO movement or release prevents invasiveness issues that may impact the environment, we note that the IPPC has a separate ongoing process to prepare an expanded "environmental impact standard" in coordination with the CBD. Each of the concerns that CFS expressed in its earlier comment (attached) related to that new environmental impact standard also apply to potentially invasive LMOs. We further note that standards for both nonmodified invasives and potentially invasive LMOs. We further note that standards for both nonmodified invasives and potential invasive LMOs must address prevention of both intentional and unintentional introductions.

The parties and secretariat to the Biosafety Protocol are the bodies of acknowledged primary competence to elaborate specific LMO standards, which they are expected to do in the future in full coordination with the IPPC. Various LMO risk issues are far removed from the pest/invasive species areas of IPPC competence, such as gene "jumping," resistance management for pesticidal crops, and

so on (discussed below). Specific IPPC standards related to these LMO issues would not be helpful, even though they might be conceptualized as "plant pest" issues in some senses. Such IPPC standards would cause confusion and would not come from the body of greatest expertise. Further, the parties, obligations, information mechanisms, and other procedures differ widely between the Biosafety Protocol and the IPPC, such that each should draft the standards most within its area of competence, even though the coverage of the laws overlaps somewhat.

Specific Recommendations

The following points address the five announced topic areas of the proposed IPPC standard. Each of these recommendations is consistent with the report of the April 2001 ICPM meeting (at paragraph 34), and each reinforces the sensible ICPM goals of avoiding duplication and encouraging harmonization with the Biosafety Protocol.

"1. Identifies the plant pest risks associated with LMOs/products of modern biotechnology."

Rather than seeking to list in detail or characterize the IPPC view of all LMO risks, the IPPC LMO standard should state that a major subset of the risks presented by LMOs correspond with the pest/invasive species risks already addressed in existing IPPC standards or in the ongoing development of the expanded environmental impact

statement.

"2. Identifies elements relevant to the assessment of these plant pest risks."

Consistent with the point made above, the IPPC standard should not address risk elements of LMOs beyond the major subset of risks that coincide with pest/invasive species risks presented by nonmodified species. The standard should indicate reliance on the Biosafety Protocol to identify other risk elements, to be done in the future in consultation with the IPPC.

"3. Considers existing international regulatory frameworks and guidelines."

Here, of course, the standard should positively reference the Biosafety Protocol as the appropriate primary source for LMO standards beyond the pest/invasive species risks discussed herein.

"4. Identifies areas within pest risk analysis standards and other international standards for phytosanitary measures that are relevant to the phytosanitary aspects of LMOs/products of modern biotechnology."

No other directly relevant pest risk analysis standards exist beyond the IPPC and CBD standards on pest/invasive species risks presented by nonmodified species.

"5. Identifies the plant pest risks associated with LMOs/products of modern biotechnology that are not adequately addressed by existing ISPMs."

Here, the IPPC standard can clarify that the following risks (which might in some conceptualizations be considered as plant risks) lie beyond existing ISPMs and beyond direct IPPC jurisdiction and competence, and rest primarily with the Biosafety Protocol:

- "jumping of unstable inserted genes from LMOs to other species (including possibly humans),
- genetic contamination of organic and conventional crops by LMOs,
- gene flow from LMOs to wild relatives,
- protection of centers of crop origin from LMO genetic contamination,
- herbicide and pesticide resistance management for LMOs,
- allergenicity and toxicity of LMOs,
- modified vectors of plant diseases to the extent they also may vector animal or human diseases,
- sociocultural issues presented by LMOs, and so on.

The U.S. delegation to the IPPC should support the continued synergy presented by these issues. Specifically,

this means the improved dialogue among the parties and secretariats of both agreements and, most positively, the much-needed capacity building for developing countries to respond to "biosecurity" issues defined broadly. Strengthening resources, personnel, and scientific training in developing countries to address LMO risks should improve their capacity to address pest/invasive species risk, and vice versa.

Please contact me if you have any questions regarding this comment. Please provide the opportunity to comment further on the draft standard when it is produced and put me on the list to receive any future communications related to this effort.

Sincerely,

Peter T. Jenkins

Center for Food Safety

Attachment

Ron A. Sequeria, USDA

Daniel A. Fieselmann, USDA

Re: Draft IPPC Environmental Impact Standard

Dear Drs. Fieselmann and Sequeira:

This is to reiterate the remarks I made verbally at the useful public meeting held 7/24, and to add a few related comments. Thank you again for your interest and involvement in making the IPPC mesh with the decisions of the parties to the Convention on Biological Diversity as they implement Article 8(h) on alien species. Better integration is clearly the intent of the Secretariats and Parties to both international laws. International trade is the leading pathway for unwanted invasives, and the IPPC is in a critical position to facilitate the prevention of future plant pests, which may cause further serious economic and environmental harm.

Again, let me stress the importance of referring to the Global Invasive Species Programme (GISP) "Global Strategy," available online on the CBD website at http://www.biodiv.org/doc/meetings/sbstta/sbstta-06/information/sbstta-06-inf-09-en.pdf, as well as to the related International Union for the Conservation of Nature (IUCN) Guidelines for the Prevention of Biodiversity Loss Caused by Alien Species, online at

http://www.iucn>org/themes/ssc/pubs/policy/invasiveEng.htm. The CBD Parties have recognized both GISP and IUCN as appropriate expert bodies whose formal reports and guidelines aid the implementation of CBD Art. 8(h), as the party nations and other international bodies like IPPC develop related standards. Thus, as a rudimentary matter, the environmental standard developed by the IPPC should explicitly and positively reference the GISP strategy and IUCN guidelines, as the CBD parties have done. Again, these diverse, international expert bodies are not equivalent to "the environmentalists," as was suggested at the meeting.

Most relevant to your deliberations are the following sections from the IUCN Guidelines:

Section 5.1 on Principles:

"Intentional introductions should only take place with authorisation from the relevant agency or authority. Authorisation should require comprehensive evaluations based on biodiversity considerations (ecosystem, species, genome). Unauthorised introductions should be prevented.

"The intentional introduction of an alien species should only be permitted if the positive effects on the environment outweigh the actual and potential adverse effects. This principle is particularly important when applied to isolated habitats and ecosystems, such as islands, fresh water systems or centres of endemism."

And Section 5.2 on Unintentional Introductions:

"- Identify and manage pathways leading to unintentional introductions. Important pathways of unintentional introductions include: national and international trade, tourism, shipping, ballast water, fisheries, agriculture, construction projects, ground and air transport, forestry, horticulture, landscaping, pet trade and aquaculture.

"- Contracting parties to the Convention on Biological Diversity, and other affected countries, should work with the wide range of relevant international trade authorities and industry associations, with the goal of significantly reducing the risk that trade will facilitate the introduction and spread of alien invasive species.

"- Put in place quarantine and border control regulations and facilities and train staff to intercept the unintentional introduction of alien species. Quarantine and border control regulations should not be premised only on narrow economic grounds that primarily relate to agriculture and human health, but, in addition, on the unique biosecurity threats each country is

exposed to.

"- Improved performance at intercepting unintentional introductions that arrive via major pathways may require an expansion of the responsibilities and resourcing of border control and quarantine services.

"- Address the risks of unintentional introductions associated with certain types of goods or packaging through border control legislation and procedures.

"- Put in place appropriate fines, penalties, or other sanctions to apply to those responsible for unintentional introductions through negligence and bad practice.

"- Ensure compliance by companies dealing with transport or movement of living organisms with the biosecurity regimes established by governments in the exporting and importing countries. Provide for their activities to be subjected to appropriate levels of monitoring and control."

There are several related specific provisions in the IUCN Guidelines and other provisions on environmental impact assessment, directly relevant to your work, which you should fully consider.

The GISP Global Strategy document represents

advice developed over five years by a team of mostly academic advisors based on numerous international meetings, several broad workshops, and subsidiary publications. The whole Strategy is essential reading for your work, but in particular I recommend Chapters 4, 5, 6, and 7 (especially Strategy elements 5 and 6).

Some other points:

1. A key goal should be to strengthen the legitimacy, from the perspective of the IPPC and the WTO Sanitary and Phytosanitary (SPS) Agreement, of the "clean list" approach to preventing harmful invasions. This approach has been adopted by Australia for weeds (at least), by New Zealand for what I understand to be all introductions, and by various other entities, including some U.S. States for various broad taxonomic groups and even by USDA in some of its quarantine approaches. The point is that this "precautionary approach" of assuming "guilty until proven innocent" is legitimate scientifically for both considering the risks of individual species and the risks of whole trade pathways, such as, for example, all raw wood or all woody plants from China. Your

environmental standard should take care to facilitate this notion, as the environment has suffered terribly in this country and globally from the laissez faire approach of allowing any new species in unless it's on a "dirty" or prohibited list. The dirty list approach is just a big experiment, with U.S. ecosystems as the laboratories. Nevertheless, the clean list approach conceivably could be challenged as a trade barrier under the WTO-SPS Agreement, unless bodies like the IPPC bolster the scientific legitimacy of taking a precautionary approach.

2. The environmental standard will be completely inadequate if it defines plant pests that may already by present in a given nation as limited to those that are subject to "official control programs." Environmental pests are much less likely to receive the funding and attention to be subject to "official control" than "economic" pests are, so you need to make sure that subsidiary and clarifying definitions you use in the environmental standard reflect this. You

should take care throughout your efforts to make sure the definitions and standards are not cramped by traditional agricultural pest notions.

3. Your environmental standard should reflect the fact that old-style, "species by species" or "commodity by commodity" risk analysis may not be adequate to protect the environment from the acknowledged onslaught of new potential invaders carried through vastly increased international commerce and tourism. In view of the substantial uncertainty and risk that may be presented by whole new trade routes, classes of trade commodities, or new transportation and packaging technologies, the standard must be able to accommodate doing risk analysis on a broad "pathway" basis and on the basis of broader taxonomic groups than just species. Good science must remain the basis for making decisions, but the GISP and IUCN documents as well as numerous supporting scientific reports demonstrate that there is a good scientific basis, including new predictive models and decisionmaking protocols, for a

more protective approach.

4. On the particular 5 potential environmental impact topics already identified by the IPPC Working Group, you should add one more as a catch-all for impacts that may occur but may not fall under your 5. The 6th should say, "any other potentially significant environmental impact." Broad provisions like this are appropriate in view of the incredibly diverse array of potential impacts of plant pests on the environment.

5. Let me recommend another useful document on environmental impact assessment related to biodiversity protection, which is really what your task is all about. The White House Council on Environmental Quality (CEQ) oversees the implementation of the National Environmental Policy Act, which, as you know, requires Federal agencies such as USDA to do environmental impact assessment for major actions. In 1993, CEQ issued an official guidance document called: "Incorporating Biodiversity Considerations into Environmental Impact Analysis under the National Environmental Policy Act." (This is

available at the CEQ NEPAnet website, http://tis.eh.doe.gov/nepa/tools/guidance/Guidance-PDFs/iii-9.pdf.)

This report concurs with the significance of the threat of invasives to biodiversity, noting that the concept of diversity contemplates native, not introduced, species. It provides key examples (summarized below) of "weakness in current NEPA practice" related to biodiversity, which also may apply to analyzing invasives prevention and control issues. Let me suggest that you consider these past tendencies of Federal agencies documented by CEQ and that you seek to avoid them as you develop the IPPC environmental standard:

- "Inadequate consideration of 'non-listed' species." Simply relying on governmental lists of threatened and endangered species is unlikely to capture the full scope of the biological diversity that may be affected.
- "Inadequate consideration of

'non-protected' areas." Similar to the issue of listed species, full consideration should be given to important habitat areas that may not be officially designated as protected.

- "Inadequate consideration of 'non-economically important' species." When species that may be affected by a proposal have quantifiable recreational or commercial importance, they tend to get more emphasis in NEPA documents than species whose value is harder to quantify.
- "Inadequate consideration of cumulative impacts." Effects analysis should include the ecosystem or regional scales. Without large-scale consideration and mitigation of harmful impacts, the "ecosystem patterns and

process so important to biodiversity will not be sustained over the long term."

In sum, according to CEQ: "Current NEPA analyses often (1) focus on species rather than ecosystems; (2) address the site scale, rather than the ecosystem or regional scale; and (3) concentrate on immediate short-term impacts, rather than likely future impacts. Because of these weaknesses, major impacts may be missed...". All of these ideas are directly on point to your work and you should explicitly provide in your standard that future analysis of potential environmental plant pests should avoid the pitfalls CEQ has noted.

6. Your final document should include specific encouragement and recommend means for funding for cooperative monitoring by CBD and IPPC of how the member parties are actually performing in implementing Art. 8(h) and the IPPC environmental standard with respect to plant pests. In other words, an annual report on the status and risks of environmental plant pests globally would be

extremely useful in evaluating implementation of both the CBD and IPPC.

Please contact me if you have any questions on the above. Please put me on the mailing list for any future communications related to this effort. I look forward to providing more detailed comments on the draft standard when it is produced.

Sincerely,

Peter T. Jenkins

Attorney/Policy Analyst

OPENING STATEMENT OF ANISSA CRAGHEAD

In April, the IPPC's Interim Commission on Phytosanitary Measures (ICPM) recommended that an international standard be completed by April 2004 to address the plant-pest risks associated with living modified organisms (LMOs). As the first step toward development of an LMO standard, the ICPM requested that an open-ended, expert working group be convened to produce a detailed specification for an LMO standard. The expert working group is scheduled to meet September 10-14, at FAO headquarters in Rome, under the terms of reference that were printed in the Federal Register notice for today's meeting. The specification developed in September will then be considered at the next meeting of the ICPM in March of 2002.

As discussed at our March 8 public meeting, the decision to consider an IPPC standard for LMOs was the result of requests from IPPC member countries in 1999 for guidance in evaluating the plant-pest risks associated with LMOs, and from the subsequent recommendations made in June of 2000 by a meeting of an IPPC working group formally charged with considering the need for an LMO standard.

Our goal in the IPPC exercise is to develop substantive guidelines for the assessment of plant-pest

risks associated with LMOs; i.e., to set out information requirements, assessment criteria, and risk-mitigation measures that countries may want to consider as they make decisions regarding the importation and use of transgenic organisms.

Your comments today will help us prepare for the September meeting at the IPPC and will also help to inform our approach to the overall LMO standard development process.

Before hearing from the first speaker, I'd like to draw your attention to an effort that will parallel and perhaps serve as a model for the IPPC LMO standard. As noted at the March 8 public meeting, the U.S. has begun to address the plant-pest risks associated with genetically engineered organisms at the regional level with Canada and Mexico under the North American Plant Protection Organization, or NAPPO. In this draft NAPPO standard, we have focused first on transgenic plants and have divided the draft standard into four modules based on the intended use of the transgenic plant. The first two models of the draft NAPPO standard should be available on the NAPPO Web site, www.nappo.org, by the end of next week, after which those modules will be available on our APHIS website for a 60-day, country-comment period. The APHIS website is printed on the handout at the back of the room.

STATEMENT OF LEAH PORTER

The American Crop Protection Association (ACPA) is submitting comments in response to the above-captioned notice published in the July 27, 2001 Federal Register. 66 Fed. Reg. 39136 (2001).

ACPA is a not-for-profit trade organization representing the major manufacturers, formulations and distributors of crop protection, pest control, and biotechnology products. ACPA member companies produce, sell, and distribute virtually all the scientific technology products used in crop production by American farmers.

We welcome the opportunity to comment on the development of an international standard concerning the plant-pest risks associated with living modified organisms (LMOs).

We encourage APHIS's participation as part of the expert working group under the auspices of the International Plant Protection Convention (IPPC), given IPPC's recognition by the World Trade Organization. As the IPPC's Interim Commission on Phytosanitary Measures (ICPM) commences its work, we would like to emphasize the following:

1. Evaluation of all LMOs should follow a science-based, transparent, and timely

risk-assessment paradigm. An LMO should not be assumed to be a plant pest unless the risk assessment (one utilizing IPPC standards or endorsed equivalent) concludes that phytosanitary consideration is merited. A discussion of LMO or products of modern biotechnology within the ICPM standard-setting efforts must be within the context of seeds for planting purposes.

2. A discussion of LMOs/products of modern biotechnology within the ICPM standard-setting efforts must be within the context of seeds for planting purposes.

3. A discussion of LMOs/products of modern biotechnology within the ICPM standard-setting efforts must appropriately assess benefits and potential environmental impacts within a science-based framework.

4. Transboundary (international) movement of seeds derived using modern biotechnology should use the existing invoicing system, with the necessary changes rather than requiring a phytosanitary certificate for each shipment. Once an importing country has conducted the required risk assessment on a transgenic event and granted approval, transboundary shipments should not require

approval of the importing country prior to each shipment.

Thank you for giving the American Crop Protection Association the opportunity to comment.

STATEMENT OF FAITH THOMPSON CAMPBELL, Ph.D.

American Lands Alliance is pleased to submit comments on the development of an international standard concerning the plant pest risks associated with living modified organisms (LMOs). American Lands is a nonprofit organization that works with grassroots environmentalists across the country to protect and restore native forests, grasslands, and aquatic ecosystems.

American Lands calls on the USDA Animal and Plant Health Inspection Service (APHIS) to ensure that the International Plant Protection Organization (IPPC) proceeds with great caution in exploring whether to develop an international standard concerning the plant pest risks associated with LMOs. First, the IPPC must ensure that its approach is carefully coordinated with the Convention on Biological Diversity (CBD) Cartagena Protocol on Biosafety.

Second, the IPPC lacks expertise in many crucial components of a truly science-based evaluation of whether to allow importation of an LMO. Proper risk analyses of LMOs will be complex. The IPPC's current risk assessment process is already under criticism -- explicitly by American Lands and scientific colleagues, implicitly in the guidelines developed by the World Conservation Union/IUCN and under

consideration by the parties to the CBD. The IPPC acknowledges weaknesses in some areas. For example, the IPPC is at only an early stage of developing its own environmental standard -- a partial but vital component of any risk analysis for LMOs as well as for invasive species. It is still unclear how well the draft environmental standard will fill the need (see American Lands' comments on the current draft, which are attached).

For these reasons, any attempt by the IPPC to develop a standard on LMOs must move slowly.

Furthermore, we believe that an IPPC standard on LMOs must differ fundamentally from existing IPPC standards. The IPPC should endorse the Royal Society of Canada's (2001) conclusion that commercial use of any LMO should occur only after the specific genetically engineered line has been thoroughly studied at six relevant levels: genome, transcript, protein, metabolite, health impacts, and environmental impacts. Regulators must rely on data from empirical studies rather than assumptions and subjective judgments based on hypotheses. Furthermore, countries should be encouraged to subject their analyses to peer review and to take care to avoid conflicts of interest within the regulatory agency (Royal Society 2001).

Furthermore, these studies must be conducted on <u>each</u> genetic line of the LMO and in the context of each

ecosystem (managed or natural) into which introduction is proposed. Such apparently duplicative studies are warranted because of the risk from pleiotropic effects. Genetic engineering does not result in the precise placement of a new piece of genetic code into a carefully selected section of the new host's genome. Rather, each insertion occurs at a nearly random location -- resulting in potential differences in the way the gene functions. Furthermore, the remainder of the host's genome is also affected. In short, insertion of a single gene will be accompanied by a range of changes that will, in turn, be affected by the genome of the host, the host plant's developmental and physiological status, and environmental pressures (Royal Society of Canada 2001). Consequently, regulators cannot limit their evaluation of a transgenic variety's potential impacts to those that might arise from the predicted phenotypic characteristics conferred by the transgene chosen for insertion. Instead, officials must empirically assess each genetic line for the potential questionnaires of these pleiotropic effects. The risk of unanticipated and unwanted changes is greater in plant and animal types that have a short history of human breeding.

In the Royal Society's view, studies at the six relevant levels should be undertaken whenever there are some scientific data (although incomplete, contested, or

preliminary) or plausible scientific hypotheses or models (even though contested) that establish a reasonable prima facie case for the possibility of serious harm, and there is significant uncertainty.

These principles point to an IPPC standard that:

- encourages each country to consider the potential risks and benefits of an LMO from its own ecological and social perspective before deciding whether to allow importation and use
- allows countries to require would-be importers of LMOs to conduct or pay for the relevant empirical studies needed to determine the types and level of risk associated with the proposal to import an LMO as well as the effectiveness and environmental impacts of technologies proposed to minimize any risks
- discourages countries from relying on studies done by other countries with different crop systems and ecological countries
- recognizes countries' differing abilities to adopt and enforce regulations
- encourages technical and financial assistance and other mechanisms to help countries

develop their ability to carry out -- or assess independently -- the risk evaluation studies.

The potential negative impacts that must be evaluated include, but are not limited to:

1) escape of the novel genetic material into other plants or animals -- including wild relatives;

2) impacts of inserted pesticidal properties on food webs and ecosystem processes;

3) repercussions of pests' developing resistance to pesticidal properties;

4) enhanced "invasiveness" of the transgenic organism or its relatives -- in natural as well as managed systems;

5) impacts of other genetically induced changes, such as altered lignin content, on food webs and ecosystems; and

6) negative environmental impacts from application of technologies intended to manage the LMO -- including induced sterility and increased use of herbicides.

Again, all potential risks need to be evaluated for <u>each</u> line in the context of <u>each</u> environment which might "receive" the LMO <u>before use is approved</u>. For example,

repercussions of genetic escape are far different in areas that are centers of origin and diversity for the crop species being modified than in areas where the plant is an exotic. Similarly, the food webs and ecosystem vulnerabilities will differ from country to country.

The IPPC standard must encourage each country to do its own review, looking at these and other questions. It must not encourage countries to rely on reviews carried out by other countries with very different ecological considerations.

Further, the IPPC standard must encourage countries to assess realistically their ability to detect and respond to unexpected or unforeseen developments. Some countries will have greater resources and technical capacities than others -- including variations in regulatory agencies' power to ensure that importers and domestic users of the LMO comply with protective management prescriptions, e.g., requirements that they plant refugia to minimize pests' development of resistance to inserted pesticidal properties.

In general, American Lands believes that the IPPC is not now able to develop a detailed standard for risk assessments of LMOs because it lacks expertise in too many areas and it must find ways to coordinate with the different mandates and approaches of the Biosafety Protocol.

If the IPPC proceeds at this time, however, we have identified above some of "the plant pest risks associated with LMOs/products of modern biotechnology" (point 1 from paragraph 34 of the report of the April 2001, ICPM meeting). Under points 3, 4, and 5, the IPPC must specifically reference the Biosafety Protocol and Convention on Biological Diversity.

American Land hopes that the U.S. delegation to the IPPC will actively support increased dialogue among the secretariats and parties to both the IPPC and the CBD. One of the most important steps that both organizations could take is to build the capacity of developing countries to respond to both invasive species and "biosecurity" issues.

ATTACHMENT TO STATEMENT OF FAITH THOMPSON CAMPBELL, Ph.D.

American Lands appreciates that the Animal and Plant Health Inspection Service (APHIS), National Invasive Species Council and the International Working Group of the Invasive Species Advisory Committee held an open public meeting on July 24, 2001. Public input on how environmental impacts are to be incorporated into pest risk assessments is crucial for these elements to be useful, accurate, and credible. Because we were not able to attend the public meeting, we ask that you consider these comments as you prepare for the upcoming meeting of the International Plant Pest Convention's (IPPC) Working Group.

While we value this opportunity to comment, we wonder whether it is timely. The IPPC decision to develop a standard was adopted in June 2000; there is reference to the North American Plant Protection Organization (NAPPO) -- to which the U.S. is also party -- having developed its position in August 2000. The IPPC has scheduled a workshop for August. Why has APHIS waited so long to hold this meeting? The result is that we had only a few weeks to study the current proposal and comment. Furthermore, APHIS provided little information in extending the invitation. We have received, from other sources, a "Background" document -

- but it is unclear how widely this document has been disseminated. Last year, we raised similar concerns regarding tardy provision of opportunities for public comment affecting development of other IPPC standards. APHIS really must improve its compliance with U.S. statutes requiring public comment during development of policies.

American Lands thinks it is entirely appropriate that the National Invasive Species Council and the International Working Group of the Invasive Species Advisory Committee are involved. We have long felt the need for much broader input into U.S. positions on international trade policies that affect management of invasive species. We will except to follow these developments closely.

Formally, incorporating environmental risks into the IPPC (and national) risk assessment process is long overdue. The laxness of international standards for the movement of organisms worldwide has contributed greatly to the alarming numbers introductions. The addition of environmental impacts to assessments of pest risk is a fundamental improvement. However, we have serious concerns as to whether the underlying philosophy of the IPPC's work or the five specific elements will contribute to a significant improvement.

The IPPC bodies and participating countries should accept the leadership of other international bodies that

have considerably greater expertise in evaluating the environmental impacts of exotic or alien species; the IUCN Invasive Species Specialist Group, the Global Invasive Species Programme, and the Subsidiary Body on Scientific, Technical, and Technological Advice (SBSTTA) of the Convention on Biological Diversity. We support the comments submitted by Drs. Mick Clout and Maj. De Poorter of the IUCN ISSG, Defenders of Wildlife, and Peter Jenkins that make extensive reference to the plans and strategies adopted by or under discussion by these organizations. American Lands fully supports the IPPC's following the lead established by these bodies -- at both broad "philosophical" level and more detailed application level. The IPPC should not try to re-invent the wheel.

The plans, guidance, and strategies adopted by the IUCN, GISP, and SBSTTA/CBD are very similar -- and are based on ecological realities. However, these strategies' emphasis on treating every alien species as potentially invasive differs substantially from the species-by-species, commodity-by-commodity approach usually adopted by phytosanitary agencies, including the IPPC. The IPPC should focus its efforts -- both internally and in consultation with the IUCN, GISP, and SBSTTA/CBD -- on resolving ways to adjust the traditional approach to adopt the pathway approach and broad perspective recommended by the expert

organizations. This adjustment presents a challenge. However, it must be done to ensure that an IPPC standard is effective in protecting the environment.

American Lands particularly endorses the warning from Drs. Clout and De Poorter of the ISSG and others about the difficulty and environment and other expense associated with attempts to eradicate or control introduced species. The IPPC must not adopt policy based on a falsely optimistic premise that post-introduction control is an acceptable or workable strategy. The focus must remain on prevention.

A detail under this provision concerns the "trigger" for conducting a risk assessment of an intentional introduction; we support the ISSG in saying that the "trigger" must be the proposal to move a species to a biogeographic region to which it is not native. The risk of escape of any deliberately introduced organism is sufficiently great that the IPPC should not limit environmental assessments to those species <u>intended</u> for release into the environment.

The current "discussion draft" is much too rigid regarding other aspects of the "trigger" for conducting a risk assessment. Requiring potential impacts on officially designated threatened or endangered species sets the bar much too high. It

would be more appropriate to evaluate potential environmental impacts in virtually all cases, using the same scale -- low, medium, or high -- as is applied for the appraisal of economic impacts -- and applying this analysis to the full range of potential environmental effects.

American Lands also fully concurs with the recommendation by Union of Concerned Scientists that the IPPC consult a broader range of scientific expertise. This consultation must be continuous -- and play a role in adjusting other standards, assisting in their application, (re)evaluating threats from both established and newly identified trade pathways, etc.

Because of the lack of previous consultation with experts in biological invasion, and the wide disparities between such experts' advice -- as reflected in the plans and strategies developed by the IUCN, GISP, and SBSTTA/CBD -- and the thinking apparently behind the current "discussion draft," American Lands that the IPPC reject the current draft and start over.

We join the UCA in asking how the environmental evaluation will be incorporated into the overall risk assessment. The standards, once adopted, must be fully integrated into the Guidelines for Pest Risk Analysis (which

we have already noted must also be substantially amended). The various elements of the environmental analysis must be treated equitably with the agricultural or economic factors.

In addition to the challenges the IPPC will face in adapting its customary practices to the fundamentally different scientific consensus on managing invasive species, the treaty partners must also consider how they can work with others to bring about comprehensive, holistic environmental reviews, as recommended by Drs. Clout and De Poorter. Fragmented studies of the separate categories of impacts potentially associated with one pathway is not inefficient, it is likely to result in an incomplete picture and important impacts "falling between the cracks." The IPPC must work with the CBD, Office International des Epizootics (OIE), IUCN, United Nations Environmental Programme, International Maritime Organization, and other players to come up with sensible guidelines. At the same time, we cannot accept lengthy delay in incorporating at least preliminary environmental standards into IPPC guidelines.

Another major challenge will be encouraging regional responsibility when countries contemplate allowing introductions which could then spread to neighboring countries -- again, as recommended by Drs. Clout and De Poorter. At a minimum, the standards should encourage

countries to monitor pest damage in other countries, and to take precautionary action when appropriate, before those pests are either introduced into their own country or are intercepted at the borders.

The IPPC standard on assessing potential environmental impacts will be implemented in conjunction with other IPPC standards, specifically including the standard on "Pest risk analysis for quarantine pests." In comments which American Lands, the Center for International Environmental Law, and Defenders submitted in fall 2000, we pointed out numerous flaws in that standard. The proposed standard for environmental assessments attempts to overcome only one of these problems: the longstanding emphasis invasive species' impacts to economic commodities, such as crops, to the exclusion of environmental damage. Our other concerns remain. We therefore incorporate here by reference our joint letter. By doing so, we hope to encourage the IPPC to avoid repeating the same mistakes in the new environmental standard. We seek to remind APHIS that the standard on "Pest risk analysis for quarantine pests" still awaits revision to bring it into conformity with scientists' guidance re: preventing introductions.

We wish to draw particular attention to both the existing and proposed standards' discussion of reasons for initiating a pest risk analysis. As the IPPC has conceded,

the potential environmental impacts of plant pests that might be introduced via a particular trade pathway have been given too little attention to date. Under these circumstances, many existing PRAs are inadequate -- even without a change in trade patterns. Parties must be encouraged to re-evaluate existing PRAs when there is any indication that they might have overlooked potential environmental impacts.

Meanwhile, we reiterate our longstanding concern re: the narrow definition of "officially controlled." Peter Jenkins, Esq., points out that efforts to contain or mitigate the impacts of environmental pests are particularly likely to fall short of meeting the definition of "officially controlled." As we noted in our earlier comments,

> American agriculture and natural ecosystems are already under assault by up to 4,500 exotic insects and more than 200 exotic plant pathogens. About one-third of the exotic insects are known to have harmful effects, as do 91% of the exotic pathogens (USDA APHIS and Forest Service. August 2000). Between 3,700 and 4,500 exotic plant species are established outside cultivation in the United States and its territories (Kartesz 1999; USDI USGS 1998); at least 500 of these plant

species are already document to be invasive in natural systems.

If the IPPC standards do not allow countries to apply phytosanitary measures at their borders to these established pests and weeds, the standards will fail to provide a meaningful measure of protection to either environmental or economic resources.

Finally, introductions and international movement of genetically engineered or modified organisms also carry the potential to cause environmental impacts. The IPPC is also developing a standard on this matter. The IPPC must ensure that the "environmental" and "GMO" standards are mutually compatible, particularly that the latter affords protection to the environment. In developing the "GMO" standard, the IPPC must consult with the CBD, the parties to which have already adopted the Biosecurity Protocol that addresses specifically this issue.

Thank you for this opportunity to comment on the proposed drafting of an environmental standard by the IPPC. We look forward to working with you and others to ensure that the standard is effective.

MODERATOR'S STATEMENT

Good morning. Welcome to the Animal and Plant Health Inspection Service. This is a public meeting to discuss the recommendation for the development of a standard concerning the plant-pest risks associated with living modified organisms (or LMOs) under the International Plant Protection Convention. The International Plant Protection Convention (or IPPC) is recognized as the international, standard-setting body for international plant-pest issues by the World Trade Organization.

My name is an Anissa Craghead, and I've been asked by the deputy administrator for Plant Protection and Quarantine to be the moderator for today's meeting. The panelists for today's meeting are Dr. Cathy Enright, to my right, Director of Biotechnology Issues and Phytosanitary Issues Management, Plant Protection, and Quarantine. Cathy is the person responsible for coordinating the federal government process for addressing LMOs under IPPC.

Joining Cathy is Mr. Narcy Klag, Program Director for International Standards Development and Issues under the North American Plant Protection Organization. Narcy coordinates the development of U.S. Government positions for a range of IPPC issues and is here to answer questions

related to IPPC in general.

The purpose of today's meeting is to provide you with background on the issue of LMOs as they pertain to IPPC and to give interested persons an opportunity to present their views on the recommendation for the development of an IPPC standard concerning the plant-pest risks associated with LMOs. Notice of today's meeting was published in the Federal Register on July 27, 2001 (see 66 FR page 39136).

The format for today's meeting will be as follows: After I complete my remarks on the procedural aspects of the meeting, Dr. Enright will provide you with background information on the issue of LMOs under IPPC and update you on what's happened on this topic since our last public meeting on this issue, which was on March 8th.

After Dr. Enright's presentation, persons who have registered to speak will be given an opportunity to speak in the order that they registered. After each speaker completes his or her remarks, panelists will have the opportunity to provide clarification or additional background information if needed and appropriate to the topic of this meeting. If time permits, persons who have not registered will be given an opportunity to speak once all registered persons have been heard.

Today's meeting is scheduled to end at noon. Should registered speakers' presentations take us over the

noon conclusion time, we will remain longer to accommodate their statements. Alternatively, we may conclude before noon if all persons who have registered to speak have been heard, and there are no other persons who wish to speak.

Four people are registered to speak at today's meeting. Does anyone joining us by phone wish to give a prepared statement?

All comments made here today are being recorded and will be transcribed. The court reporter for today's hearing is Wallace Farmer, who is associated with Heritage Reporting Corporation in Washington, D.C. Detailed information on obtaining a copy of the transcript for today's meeting is available at the registration table.

I will call each person who has registered to speak. Before beginning, please come and sit in that chair, pick up that microphone, state and spell your first and last name for the court reporter. Especially for those on the phone, please be sure to say who you are affiliated with. In addition, please say who you represent. If you read a prepared statement and have an extra copy with you, please give me that extra copy at either the beginning or end of your remarks. Any oral statement presented or written statement submitted at today's meeting will become part of the public record.

If a speaker's comments do not relate to the

stated purpose of today's meeting, which is to present comments or questions on the recommendation for an IPPC standard concerning the plant-pest risks associated with LMOs, I will ask the speaker to focus his or her comments accordingly. In addition, I expect everyone to show respect to speakers and give speakers your full attention.

Please sign the attendance sheet, which is also located on the registration table, before you leave today. After Dr. Enright's presentation I will call the first registered speaker. Cathy.

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CERTIFICATE OF REPORTER, TRANSCRIBER AND PROOFREADER

APHIS Public Meeting Developmentof LMO Standard
Name of Hearing or Event

01-061-1
Docket No.

Riverdale MD
Place of Hearing

August 23, 2001
Date of Hearing

We, the undersigned, do hereby certify that the foregoing pages, numbers 1 through 99, inclusive, constitute the true, accurate and complete transcript prepared from the tapes and notes prepared and reported by Wallace Farmer, who was in attendance at the above identified hearing, in accordance with the applicable provisions of the current USDA contract, and have verified the accuracy of the transcript (1) by preparing the typewritten transcript from the reporting or recording accomplished at the hearing and (2) by comparing the final proofed typewritten transcript against the recording tapes and/or notes accomplished at the hearing.

9/14/01
Date

Theodore Fambro
Name and Signature of Transcriber
Heritage Reporting Corporation

9/14/01
Date

Anthony Dantley
Name and Signature of Proofreader
Heritage Reporting Corporation

9/14/01
Date

Wallace Farmer
Name and Signature of Reporter
Heritage Reporting Corporation

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