

1 SUPPLEMENT TO ISPM NO. 11
(Pest Risk Analysis for Quarantine Pests)

2 PEST RISK ANALYSIS FOR LIVING
3 MODIFIED ORGANISMS

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6 The hearing in the above-entitled matter
7 was held on Thursday, September 25, 2003 at the
8 United States Department of Agriculture, 4700 River
9 Road, Riverdale, Maryland 20737 before Louisa B.
10 McIntire-Brooks, Notary Public.

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12 APPEARANCES:

13 MATTHEW RHOADS, Hearing Officer

14 TERRI DUNAHAY, Panel Member

15 NARCY G. KLAG, Panel Member

16 JOHN GREIFER, Panel Member

17 REBECCA BECH, Panel Member

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21 REPORTED BY: Louisa B. McIntire-Brooks, RPR, CSR

1 PROCEEDINGS

2 MR. RHOADS: Good afternoon, everyone, and
3 welcome to the Animal Plant Health Inspection Service
4 Meeting to discuss the development of a standard for
5 pest risk assessment of living modified organisms under
6 the International Plant Protection Convention.

7 The International Plant Protection
8 Convention, or the IPPC, is recognized as the
9 international standard setting body for plant health
10 issues by the World Trade Organization agreement on the
11 application of sanitary and phytosanitary measures. My
12 name is Matt Rhoads. I'm a regulatory analyst for
13 APHIS's regulatory analysis and development staff.
14 I'll be the presiding officer for the meeting today.

15 The panelists for today's meeting are
16 Dr. Terri Dunahay, Director for International Policy
17 Issues in Biotechnology Regulatory Services here at
18 APHIS. Terri is responsible for coordinating the
19 federal government process for addressing living
20 genetically modified organisms under the IPPC. She
21 also represents the United States on the biotechnology

1 panel of the North American Plant Protection
2 Organizations known as NAPPO. NAPPO is in the process
3 of developing regional guidance for the importation and
4 release into the environment of transgenic plants for
5 NAPPO member countries.

6 Also on the panel are Mr. John Greifer,
7 Director of APHIS Trade Support Team and Nancy Klag,
8 Program Director for International Standards
9 Development and issues under NAPPO. John and Nancy
10 coordinate the development of U.S. government positions
11 for a range of IPPC and NAPPO issues.

12 The fourth member of the panel is
13 Ms. Rebecca Bech, Associate Deputy Administrator of
14 Biotechnology Regulatory Services. She'll be able to
15 address questions regarding the U.S. regulatory process
16 for risk assessment of LMOs and the relationship to the
17 work ongoing in the IPPC.

18 Somebody just joined us on the phone?

19 MR. RITCHIE: This is Bobby Ritchie with
20 FAS.

21 MR. RHOADS: Someone else just joined us on

1 the phone?

2 MS. BURROUGHS: Yes. My name is Beth

3 Burroughs with the Edmunds Institute.

4 MR. RHOADS: Do you and Mr. Ritchie or Ms.

5 Burroughs plan to make a statement today?

6 MS. BURROUGHS: No, I do not.

7 MR. RHOADS: The purpose of today's meeting

8 is to solicit public comment and discuss the draft

9 standard for pest risk assessment of living modified

10 organisms in development under the IPPC.

11 The Federal Register notice announcing this

12 meeting was published on August 21st and there are

13 extra copies of the notice out on the registration

14 table. The draft standard of pest risk analysis for

15 LMOs is currently available for country consultation and

16 copies are also available on the registration table.

17 Comments on the draft document are due to

18 the Secretariat by October 1st and we will be taking your

19 comments into consideration as we finalize our

20 response. Two previous public meetings have been held

21 on this topic. The first in March 2001 was to solicit

1 input on the role of IPPC in the assessment of
2 potential plant pest risk from invasive species and
3 from LMOs.

4 The second meeting in August 2001 provided
5 an opportunity for input on specifications for the LMO
6 standard. Transcripts of both these meetings are
7 available at the APHIS website. A copy of the meeting
8 transcript for today will also be made available on the
9 APHIS website, shortly after the -- probably about a
10 week from today and a copy will also be available at
11 the APHIS reading room in Room 1141 of USDA South
12 Building. That room is open from 8:00 a.m. to
13 4:30 p.m.

14 As Presiding Officer, I will announce each
15 registered speaker that has requested to make a
16 statement. Before commencing your remarks, please
17 state and spell your name for the benefit of the court
18 reporter. After the conclusion of all the registered
19 speakers, we'll open up the floor for questions and if
20 anyone has any additional statements.

21 At this point, Terri Dunahay will provide

1 some background information on the development of the
2 LMO standard in the IPPC and discuss U.S. views on this
3 document. After Dr. Dunahay's presentation, persons
4 who are registered to speak will be given their
5 opportunity and we'll take it from there.

6 MS. DUNAHAY: If I just speak from here,
7 can everyone hear me or do I need to go to the mike?

8 MS. BURROUGHS: It would help the people on
9 the phone if you would go to the mike.

10 MS. DUNAHAY: Thank you, Matt, and I want
11 to thank everybody for coming in today or for calling
12 in for this meeting. I apologize for the inconvenience
13 because of the hurricane last week, but I appreciate
14 everyone's persistence on this.

15 As Matt said, I'd like to begin by
16 providing some background on the development of the LMO
17 standard within the IPPC. As you know, and as Matt
18 has said, the IPPC is an international treaty that's
19 aimed at promoting international cooperation to prevent
20 the spread of plant pests. The IPPC is strictly
21 focussed on phytosanitary or plant health risks. The

1 scope of the work covered by IPPC includes not only
2 agriculture, but also the protection of natural flora
3 and plant products and it includes both direct and
4 indirect damage by pests, including weeds and invasive
5 species.

6 The process for development of an LMO
7 standard under the IPPC began in 1999. At the request
8 of a number of IPPC member countries, a working group
9 was established to explore the role of the IPPC in
10 addressing plant pest concerns associated with LMOs and
11 with invasive species. The working group met in June
12 of 2000 and agreed on the need for further guidance
13 under the IPPC with respect to LMOs and invasive
14 species. For LMOs, the working group agreed that the
15 plant pest risks associated with LMOs fall within the
16 scope of the IPPC mandate to protect plant health.
17 They also agreed that the mechanisms for analysis and
18 management of plant pest risks under the IPPC are
19 appropriate for assessing and managing plant pest risks
20 that may be posed by LMOs. The working group
21 recommended development of a standard under the IPPC to

1 address pest risks associated with LMOs that may not be
2 addressed by other IPPC standards. The U.S. supported,
3 and continues to support, the recommendation for
4 development of an LMO standard under the IPPC.

5 The recommendation from the June 2000
6 working group was presented to the ICPM, and that
7 stands for the Interim Commission on Phytosanitary
8 Measures, which is the governing body of the IPPC, and
9 that was in April of 2001. The ICPM then recommended
10 that an LMO standard be developed under the IPPC for
11 completion by April 2004. And open-ended expert
12 working group was convened in September of 2001 to
13 draft specifications for the standard which were
14 adopted by the ICPM in March of 2002.

15 A working group met in September of last
16 year, 2002, to draft the LMO standard based on those
17 specifications. The working group was directed to take
18 into account the following points: 1) Consideration of
19 existing procedures and standards for pest risk
20 analysis; 2) Identification of relevant standards and
21 methods for the evaluation of phytosanitary risks

1 presented by LMOs; and 3) The development of a standard
2 that is clear and easy to understand and that provides
3 comprehensive guidance on pest risk analysis for LMOs.

4 In addition, the working group was charged
5 with developing the standard as a supplement to an
6 existing standard, and that standard is ISPM-11, and
7 ISPM stands for International Standard for
8 Phytosanitary Measure. ISPM-11 provides guidance on
9 pest risk analysis for quarantine pests, and just to be
10 clear, I want to define a quarantine pest. It's
11 defined as a pest of potential economic importance that
12 is not yet present in the area, or if it is present and
13 not widely distributed, it is being officially
14 controlled. The United States disagreed with the
15 development of the standard as a supplement to ISPM-11
16 and supported, instead, the development of a
17 stand-alone standard. We believe the stand-alone
18 document would be easier to use by phytosanitary
19 officials who might be unfamiliar with the
20 who might be unfamiliar with the types of risks that
21 could be posed by LMOs. Our concerns about the format

1 of the document were noted in a report from the ICPM
2 meeting in 2002 and it was noted that the format would
3 be reconsidered following development of the standard.

4 A working group consisting of seven experts
5 met in Ottawa in September 2002 to draft the standard.
6 The working group included one representative from each
7 FAO region as well as representation from the
8 Convention on Biological Diversity, the Cartagena
9 Protocol on Biosafety, the Global Invasive Species
10 Program, and Canada was present as host country.

11 Although the United States and Canada make up the North
12 American region under FAO, it was agreed by the
13 Executive Committee of the North American Plant
14 Protection Organization, or NAPPO, that North America
15 would be represented by NAPPO at the IPPC working
16 group. Mexico is the chair of the NAPPO Biotechnology
17 Panel and they represented NAPPO in Ottawa. The draft
18 that was produced by this expert group is the document
19 that's currently under consideration that we're
20 discussing today.

21 The U.S. government is still in the process

1 of developing our comments, finalizing our comments, to
2 the IPPC secretary with respect to the draft IPPC
3 standard. But, I'd like to give you an overview of our
4 main concerns and what will likely be the important
5 elements of our position.

6 First, the U.S. strongly supports the
7 adoption of science based risk assessment guidelines
8 for LMOs under the IPPC. We believe this is the
9 appropriate forum for international guidance on the
10 determination of the pest risk potential of LMOs and we
11 think the expert working group that met last year made
12 a commendable effort in preparing the draft document.
13 We are concerned, however, that the current document
14 does not provide clear, easy to use and comprehensive
15 guidance for phytosanitary officials who may need to
16 evaluate the potential pest risk of an LMO to be
17 imported into their country. The format of the current
18 draft document is very confusing. The new language
19 related to LMOs has been inserted as boxed text into an
20 existing standard, ISPM-11. The format of the
21 supplement has never been clearly defined and it's

1 difficult to tell what that final document will look
2 like, would look like, or how the guidance for pest
3 risk analysis under ISPM-11 relates to phytosanitary
4 risks that might be posed by LMOs. We believe the
5 draft standard could be improved significantly by
6 modifying and reformatting the document to clarify the
7 applicability of ISPM-11 to risk assessment of LMOs and
8 to ensure the guidance provided in the document is
9 clear and technically accurate.

10 We agreed with the conclusion from the
11 working group that not all LMOs will present
12 phytosanitary risk. LMOs are likely to be organisms,
13 such as corn, that are not traditionally considered to
14 be pests, but that may present a new risk as a result
15 of the modification. We believe there is a need for
16 clear guidance to determine if an LMO presents a
17 potential plant pest risk before consideration of these
18 organisms as potential quarantine pests under ISPM-11.
19 Any LMO not determined to pose a phytosanitary risk
20 would not require further consideration under ISPM-11
21 beyond the quarantine pest risk analysis performed on

1 the non-LMO counterpart of that organism.

2 Guidance on determination if an LMO is a
3 potential pest is presently contained in Section 1.1.5
4 of the draft standard. This is new text that was
5 developed by the working group. We believe that
6 Section 1.1 .5 is critical in providing new useful
7 guidance for risk assessment of LMOs under the IPPC.
8 However, the inclusion of this section within the
9 current ISPM-11 text makes the document confusing and
10 unwieldy. We plan to recommend that the document be
11 reformatted so that the lengthy discussion of
12 determination of pest risk potential of an LMO in
13 Section 1.1.5 is moved to an Appendix. Moving this
14 language to an Appendix and including a referral to the
15 Appendix in the ISPM text would streamline the document
16 and reinforce the conclusion of the working group what
17 all LMOs to not present an inherent phytosanitary risk.
18 We also plan to provide recommendations for specific
19 revisions to Section 1.1.5 focussed on technical
20 accuracy and completeness based on our experience in
21 the area of LMO pest risk assessment.

1 In addition, we plan to recommend that
2 revisions to the proposed text within ISPM-11 focus on
3 new criteria specifically needed to perform risk
4 assessments for LMO pests not covered by IPPC's
5 traditional pest risk assessment procedure. The focus
6 of the risk assessment for LMO pests must be on direct
7 or indirect risks to plants or plant health.

8 So, what is the next step in the process?
9 As I mentioned, comments are due to the IPPC Secretariat
10 by October 1st. We plan to finalize our comments
11 following this meeting for transmission to the
12 Secretariat, taking into consideration comments
13 received previously or at this meeting, and if you do
14 have comments, if you could, get them to me by tomorrow
15 night. That would be great, because I've got to
16 finalize this next week. Our comments and those from
17 other countries will be compiled by the Secretariate
18 and sent to the Standards Committee for their meeting
19 in November of this year. The Standards Committee will
20 revise the document based on the comments received
21 during the country consultation process. If they

1 believe the document meets the specifications of the
2 standard, and that the comments can be incorporated,
3 they will forward the document to the Commission for
4 adoption at the ICPM meeting next March. If they find
5 the document does not meet the criteria in the
6 specification, or if the comments are too technical or
7 lengthy, the Standards Committee can recommend that the
8 document be returned to the working group for further
9 work.

10 One additional point that I would like to
11 make concerns the relationship of the IPPC LMO standard
12 to the Cartagena Protocol for Biosafety. As you know,
13 the Biosafety Protocol entered into force on
14 September 11th of this year. The Protocol is an
15 international treaty under the U.N. Convention on
16 Biodiversity that provides a framework for the safe
17 transboundary movement of LMOs that could have an
18 adverse impact on biodiversity. There have been some
19 concerns expressed about whether the IPPC or the
20 Protocol is the appropriate forum for the development
21 of risk assessment guidelines related to importation of

1 LMOs.

2 We do not believe these two are mutually
3 exclusive. Under the protocol, decisions to import
4 LMOs for environmental release must include a
5 scientific risk assessment. The Convention on
6 Biological Diversity and the IPPC have agreed to
7 cooperate on the development of risk assessment
8 guidelines that can be used to facilitate decision
9 making under the Protocol. Representatives from both
10 the Convention on Biological Diversity Secretariat and
11 the Bureau of the Intergovernmental Committee of the
12 Biosafety Protocol were participants in the expert
13 working group that drafted the LMO standard under
14 consideration. Additionally there is a memorandum of
15 understanding that is close to being finalized between
16 the Secretariats of the CBD and the IPPC noting the
17 agreement to cooperate in the development of risk
18 assessment guidelines for LMOs. The LMO standard in
19 development in the IPPC should be helpful to
20 phytosanitary officials who may need to make decisions
21 regarding importation of LMOs under new domestic

1 regulations for compliance with the Protocol.

2 Finally, another concern that has been

3 raised is that the focus of the IPPC is too narrow to

4 be relevant for the Biosafety Protocol. The mandate of

5 the IPPC is the protection of plant health and includes

6 consideration of plant pest risks, not only to

7 agriculture, but also risks to plant biodiversity

8 including risks to both cultivated and noncultivated

9 plants and natural flora, habitats ecosystems. In May

10 of this year, the IPPC Commission adopted the

11 Environmental Supplement to ISPM-11 which is reflected

12 as new language within the text of the standard and is

13 part of the document under review here. And that's

14 included in the unboxed text in that document. The

15 purpose of this environmental standard was to clarify

16 the relationship of the IPPC and ISPM-11, particularly

17 with respect to the environment beyond managed

18 ecosystems, and to more clearly address pest risks that

19 could be posed by plants themselves. For example,

20 weeds and invasive species. So, while we recognize

21 that an LMO standard in the IPPC will not address all

1 issues that may arise under the Biosafety Protocol, we
2 continue to support the development of an LMO standard
3 under the IPPC as the appropriate forum for the
4 assessment of potential risks to plant health from
5 LMOs.

6 So, I think I'll close there and return it
7 back to Matt. Thank you.

8 MR. RHOADS: Thanks, Terri. Any comments
9 from the rest of the panel? Then at this point, we'll
10 call the first registered speaker, Ms. Jane Earley.

11 MS. EARLEY: I'll go to the podium.

12 MR. RHOADS: Please.

13 MS. EARLEY: Thank you. I'll do my best to
14 respect the process here. Unfortunately, that's going
15 to mean reading most of my prepared statement which is
16 both general to the general issues, and I also have
17 specific comments on the text.

18 So, I'm presenting these comments on behalf
19 of the Corn, Soy, Cotton Coalition. It's composed of
20 the Corn Refiners Association, the American Soybean
21 Association, the National Oil Seed Processors

1 Association and the National Cotton Council. We
2 appreciate the opportunity to comment on ISPM-11 on
3 pest risk analysis for living modified organisms.
4 This is a particularly timely amendment to
5 ISPM-11, we believe, since the Biosafety Protocol
6 became effective on September 11th. We anticipate that
7 these amendments to ISPM-11 will substantially help to
8 enable countries to implement the protocol with respect
9 any risks to plants and the environment posed by
10 genetically modified commodity crops. Since this is
11 our focus, our comments will be limited to issues posed
12 by IPPC pest risk analysis as it is applied to LMO
13 commodities.
14 Our comments are both general and specific.
15 Generally we believe that while the
16 Biosafety Protocol technically extends to areas other
17 than those that are reasonably related to the risks
18 posed to plants and the environment, IPPC risk analysis
19 would under normal circumstances be appropriately used
20 to ascertain the degree of risk to plants and the
21 environment and to take appropriated protective

1 measures in most situations arising under the Protocol.
2 This is a science based regime that has existed for
3 many years and that has credibility and acceptance
4 worldwide.

5 Countries that have ratified or are
6 preparing to ratify the Biosafety Protocol must now be
7 prepared to implement it. This means that they must
8 have procedures in force via legislation or other legal
9 instruments to implement the many provisions of the
10 Protocol including those dealing with crops intended
11 for food, feed and processing, or FFPs. The Protocol
12 itself does not provide detailed guidance at this point
13 as to many specific measures that must be taken with
14 respect to FFPs because relevant issues remain to be
15 worked out among the parties.

16 However, Article 3 of Annex III of the
17 Protocol governing Risk Assessment provides that Risk
18 assessment should be carried out in a scientifically
19 sound and transparent manner, and can take into account
20 expert advice of and guidelines developed by relevant
21 international organizations.

1 We also believe that it's in the interest
2 of all parties, as well as countries that do not intend
3 to ratify, but that have significant FFP trade that may
4 be affected, to find Biosafety Protocol implementation
5 options that are WTO consistent. As IPPC guidelines
6 are specifically referenced in the WTO's agreement on
7 sanitary and phytosanitary measures, we believe that
8 IPPC risk analysis procedures would be a good option
9 for use by countries preparing to implement the
10 protocol. Countries signatory to the Protocol
11 currently have laws on their books that implement their
12 IPPC obligations and they have experience with IPPC
13 procedures. These laws currently allow importing
14 countries to take measures to protect against the
15 introduction of genetic material as well as plant
16 pests.

17 In our view, the IPPC covers protection of
18 plants from pests and disease, a mandate that
19 encompasses virtually all the concerns, except for
20 perhaps human health posed by the Biosafety Protocol.
21 Specifically we believe that ISPM-11 already authorizes

1 plant pest risk assessment for LMOs, but regard the
2 amendment of ISPM-11 to deal specifically with plant
3 risks posed by biotech plants as most welcome.

4 While we would have preferred a separate
5 text to accomplish this task, we are satisfied that the
6 amendments to the present text provide interim guidance
7 that could perhaps be published separately as guidance
8 for the introduction of LMOs under the Biosafety
9 Protocol under the circumstances and conditions noted
10 in the preamble to the text.

11 Now, we have specific comments as well on
12 1.1.5, determining the potential for an LMO to be a
13 pest.

14 This section states that, "There may be no
15 evidence indicating that genetic modifications relating
16 to the physiological traits have significant quarantine
17 risks, and therefore, those types of LMOs require no
18 further consideration." It also lists, among factors
19 that may result in need subject an LMO to stage 2 of
20 the PRA, "Lack of knowledge about a particular
21 modification event."

1 We find these two guidelines to be somewhat
2 contradictory, but believe they can be reconciled by
3 amending the lack of knowledge bullet to read, "Lack of
4 knowledge about a particular modification event based
5 on potential for risk and similar modification events."

6 The section also contains two lists of
7 factors: Those that would be used to justify a
8 conclusion to subject an LMO to stage 2 of the PRA and
9 those that would justify a conclusion that an LMO is
10 not a potential pest and/or requires no further
11 consideration under ISPM-11. We believe that for
12 purposes of consistency and clarity, the order of the
13 factors could be reversed, i.e., the no need coming
14 before need, and the lists should be made symmetrical
15 with the same or similar considerations appearing in
16 each.

17 Under 1.3.1, previous PRA, the disclaimer
18 that PRA may constitute only a portion of the overall
19 risk analysis is well taken. But, it might be helpful
20 in this context to include reference to other
21 guidelines that could be used to determine whether

1 other risks are present. We anticipate that virtually
2 all LMOs will fall out of the process at this stage.
3 In other words, they won't be considered pests. So,
4 guidance at this point referencing the requirements of
5 the Biosafety Protocol might also be helpful.

6 2.2.1.2, probability of the pest being
7 associated with the pathway at origin.

8 This text adds as a factor, "For LMOs, the
9 role of identity preservation system should also be
10 considered." We find this too vague and would suggest
11 it be amended to state that, "The effectiveness of the
12 handling and distribution system for the LMO in
13 controlling any risks identified by the risk assessment
14 should also be considered."

15 3.1, level of risk.

16 This text adds to ways to express an
17 acceptable level of risk "For LMOs, the acceptable
18 level of risk may also be expressed by comparison to
19 the level of risk associated with similar or related
20 organisms." We believe that this should be a primary
21 way of expressing a level of risk for an LMO and would

1 substitute may with should in most circumstances.

2 3.4.1, options for consignments.

3 This text allows for LMOs measures that

4 may include -- that, "may include procedures for

5 provision of information on the phytosanitary integrity

6 of consignments -- e.g., tracing systems..." We

7 believe that this text is too vague and could be taken

8 to imply that the procedures for provision of

9 information will substitute for the information itself.

10 It's not the procedure that should be the focus of the

11 measure, but whether it is adequate, whether it is

12 followed and whether it's been effective. We would

13 suggest as alternative text, "measures to obtain

14 information on the phytosanitary integrity of

15 consignments," and omit mention of any specific kind of

16 information system.

17 3.4.2, options for preventing or reducing

18 infestations in the crop.

19 This text lists several options for

20 preventing or reducing infestations in the crop. We

21 believe that these are good options, but note that they

1 may not be exhaustive as the technology continues to
2 evolve.

3 3.5, phytosanitary certificates and other
4 compliance measures.

5 This text provides that "information on
6 phytosanitary certificates regarding LMOs should only
7 be related to phytosanitary measures." We support this
8 statement, but note that further documentation
9 requirements implementing the Biosafety Protocol under
10 Article 18.2a may be forthcoming, and urge that if such
11 documentation requirements begin to parallel or
12 conflict with those required under the IPPC, that those
13 Biosafety Protocol requirements defer to those
14 negotiated in the IPPC. This would most likely be
15 appropriate under Section 4.1.

16 This concludes my comments. Thank you.

17 MR. RHOADS: Thank you. Are there any
18 other folks who are present who would like to make a
19 prepared statement? Anyone on the phone who would like
20 to make a prepared statement? Okay. At this point, I
21 open up the floor. We'll start with folks who are

1 actually in the building. Are there any questions for
2 the panelists? Yes, sir?

3 MR. KORWEK: Ed Korwek, Hogan & Hartson. I
4 have a question on new Section 1.1.4. There is, under
5 the subject of phenotypic and genotypic instability,
6 the third paragraph under that, there may be no
7 evidence indicating the genetic modifications relating
8 to physiological --

9 MS. BURROUGHS: This is Beth Burroughs on
10 the phone. I'm sorry to interrupt. Can I please ask
11 the speakers to speak a little more slowly and loudly?
12 Thank you.

13 MR. KORWEK: There is under that paragraph,
14 5 of new 1.1.4, the statement there may be no evidence
15 indicating that genetic modifications relating to
16 physiological traits have significant quarantine risks,
17 et cetera. What is the reference to physiological
18 traits mean?

19 MS. DUNAHAY: I'm not sure where you are.

20 MR. KORWEK: On new section 1.1.4.

21 MS. DUNAHAY: Right.

1 MR. KORWEK: It looks like it's page seven.
2 There is the subcategory, phenotypic and genotypic
3 instability, at the bottom. Number 5.

4 MS. DUNAHAY: Actually, it's 1.1.5?

5 MR. KORWEK: Yes. I am sorry. That is
6 correct. And then there is the paragraph underneath
7 that that starts, there may be no evidence -- this is
8 on page eight, indicating that genetic modifications
9 relating to physiological traits have significant
10 quarantine risks, and therefore, these types of LMOs
11 require no further consideration. I'm inquiring what
12 is the meaning of physiological traits.

13 MS. DUNAHAY: This is the text that came
14 from the working group, and so we can just interpret
15 what they mean by that. I think our recommendation is
16 going to be to delete that section because I don't
17 think we agree with that. My understanding with that,
18 from the way that is written, is they would say
19 something that was -- that there could be modifications
20 that, per se, you could exclude a whole set of
21 modifications. And I'm not quite sure what

1 physiological traits they're talking about in
2 particular. Maybe they mean oil concentrations or
3 changes in oil concentrations, and you can just exclude
4 those, per se, from a risk assessment process to
5 determine if an LMO is a pest. And the way that we do
6 our own risk assessments here in the U.S. is we would
7 at least take a look at it to see whether something
8 about adding that new trait could cause the organism to
9 now become pest like.

10 So, I think our recommendations, and I
11 don't have copies of my modifications in front of me,
12 but I think we would recommend that that section be
13 deleted. That would not be appropriate.

14 MR. KORWEK: That paragraph?

15 MS. DUNAHAY: Just that line. That line.

16 MR. KORWEK: Okay.

17 MS. DUNAHAY: But, as I said, you know, we
18 don't have any further clarification as to what the
19 working group was thinking when they drafted that text.

20 MR. RHOADS: Any other questions?

21 Mr. Korwek? Or anyone else in the room before we go to

1 the phone?

2 MR. KORWEK: Yeah.

3 MR. RHOADS: Please.

4 MR. KORWEK: Ed Korwek again, Hogan &

5 Hartson. I did mention to you, Terri, off the

6 record --

7 MS. BURROUGHS: I'm sorry. I can't hear --

8 MR. RHOADS: We're trying to keep you

9 close. This is Ed Korwek from Hogan & Hartson.

10 MR. KORWEK: I did mention to you, Terri,

11 off the record, but I'll say it for the record, that I

12 know notice that a lot of the standards that are being

13 added through boxed text do seem to repeat some of the

14 prefatory language that already appears in the

15 standard. I find that redundancy to be a little

16 irritating, to say the least, not to mention that one

17 wonders why it's being added if it's essentially

18 already there. And I hope that that format, sort of

19 objection, is taken into account through some of the

20 government's comments that you will be making.

21 MS. DUNAHAY: Yes. We will. We find it

1 very confusing too, and as I said in my earlier
2 comments, it's not clear to us what supplement means in
3 terms of what the final document would look like. The
4 supplement for the environmental standard, and Nancy
5 might be able to add some clarification on the way this
6 happened, but the supplement to the environmental
7 standard when it was circulated at the consultation
8 also included new language as boxed text. Then when it
9 went back to -- I think it went to the commission -- is
10 that right, Nancy? The commission told the standards
11 committee, you need to just incorporate that language
12 so it makes sense. And so they took that language and
13 incorporated it into the text of ISPM-11 and
14 essentially ended up with the revision of ISPM-11.
15 It's not clear that that's what they intend for the LMO
16 standards. So, it's very unclear to us what the final
17 document would look like. And so when we drafted our
18 comments, we tried to make clear that the formatting is
19 an issue and it needs to be really clear what the final
20 document will look like, and that we did note when
21 there were significant redundancies where they said,

1 you need to do this for all plants and you need to do
2 the same thing for LMOs. And it didn't make sense.
3 So, I think in terms of clarity and technical accuracy,
4 we're going to make those sorts of comments. Is there
5 anything you wanted to add on that, Nancy.

6 MR. KLAG: No, not really.

7 MR. RHOADS: Any more questions from the
8 room?

9 MR. KORWEK: One more.

10 MR. RHOADS: Sure. Please.

11 MR. KORWEK: Ed Korwek with Hogan &
12 Hartson. I do have a question again, which you may not
13 know the answer to, and I think this was alluded to by
14 Ms. Earley's comments, what the role of identity
15 preservation systems is in there to imply in 2.2.1.2.

16 MS. DUNAHAY: I don't have the additional
17 clarification beyond what is in the text.

18 MR. KORWEK: I think our comment would have
19 been again, the same, that that boxed text is very
20 unclear what exactly it means and it needs
21 clarification. It could be a very causative statement,

1 and I think it is, but it's not clear to me what it
2 means.

3 MS. DUNAHAY: I think we would agree that
4 any role for identity preservation would have to relate
5 specifically to a phytosanitary risk and not be just as
6 a marketing type of a tool, but would have to
7 definitely relate to the phytosanitary risk. So, we'll
8 provide some comment on either removing or clarifying
9 that statement.

10 MR. RHOADS: Ms. Earley?

11 MS. EARLEY: Just one point of
12 clarification for the record. This is Jane Earley from
13 the CSCC. Could you describe how the NAPPO Module IV
14 will fit into this ...

15 MS. DUNAHAY: Well, NAPPO Module IV, for
16 those of you who are not familiar with it -- I'll back
17 up. I'll give a little background. Under the North
18 American Plant Protection Organization, we are
19 developing guidelines for risk assessment of LMOs for
20 importation and it's being developed in four modules.
21 The first module is importation for contained use, and

1 the second one is importation for confined release, and
2 the third module is importation for unconfined release.
3 And those three modules, first three modules, are
4 completed. We just finalized the third module and it's
5 currently at the Secretariat, NAPPO Secretariat,
6 for translation and will be adopted by the -- or will
7 be looked at and probably adopted by the Executive
8 Committee in November of this year. The fourth module
9 is for importation for propagative uses only. So,
10 essentially you're importing an LMO plant for food or
11 feed processing only.

12 MR. KLAG: Consumption use only.

13 MS. DUNAHAY: I'm sorry? Consumption use,
14 nonpropagative -- I apologize. Nonpropagative use.
15 That document, to be honest, is -- we have talked about
16 it a lot. We have not begun work on it. The -- all
17 three NAPPO member countries are still in the process
18 of getting our own domestic policies finalized with
19 respect to importation for commodity use only. And so
20 we have not begun work except just in terms of general
21 discussions within NAPPO.

1 Unless the work plan changes under the
2 IPPC, I don't believe the IPPC will be addressing
3 commodities specifically because they would be included
4 under importation under the ISPM-11.

5 So, while the work done under NAPPO Module
6 III, we would hope could be used to inform and possibly
7 if there was additional work under IPPC for risk
8 assessment of LMOs to determine plant pest potential,
9 we would hope the work being done under NAPPO could be
10 used to inform that process and as guidance for that
11 process. NAPPO Module IV of the commodities probably
12 would not be moved directly, or would not be applicable
13 directly, for the IPPC unless new work is proposed in
14 the next few years. Does that help?

15 MS. EARLEY: Yes, that helps a lot. I
16 understand there is a NAPPO meeting in October and
17 there will be work on Module IV in November?

18 MS. DUNAHAY: No. That work will be done
19 -- the next step for NAPPO Module IV would be the
20 Biotech Panel. So, the panel members, we have been
21 exchanging e-mails and just some ideas and some draft

1 documents, and the next step will be for us, the panel
2 members, to get together and come up with some ideas
3 and develop a draft among ourselves. I think at the
4 NAPPO meeting in October, there will be a report out of
5 the work by the NAPPO Biotech Panel, but there will not
6 be work done there on Module IV.

7 MR. RHOADS: Any additional comments from
8 the room? Anyone on the phone? We'll turn it over to
9 you for some questions. I'll start with Alexis
10 Ellicott. Do you have any questions?

11 MS. ELLICOTT: I think I'm okay at the
12 moment. Thanks.

13 MR. RHOADS: Sure. Ron Gaskill? Are you
14 still on the phone? Okay. Bobby Ritchie?

15 MR. RITCHIE: No, I'm fine. Thank you.

16 MR. RHOADS: Beth Burroughs?

17 MS. BURROUGHS: No. Although what is
18 always a concern with these kind of issues, we're
19 choosing not to comment here because we find the
20 document much in keeping with Terri Dunahay's comments,
21 not clear and easy to understand. We feel that sort of

1 putting patches on a bad work might later be construed
2 at agreeing that it was good work. I think this is not
3 a clear document. I think it will be very uneasy for
4 people in the field to use. I think it will lead to
5 more scientific disputes and more trade disputes, and I
6 think that needs to be the message taken to the larger
7 body.

8 I apologize for not putting that in formal
9 terms. And so I have no questions because -- where I
10 find continuing confusion, I don't question whether
11 it's my confusion or that of the document. I frankly
12 find it to be that of the document. I commend the
13 people who tried to make it into a silk purse, but you
14 know, as Jim Hightower said, putting sunglasses on a
15 pig doesn't make them prettier.

16 MR. RHOADS: Thank you. Is there anyone
17 else whose come onto the phone who would like to either
18 ask a question or make a statement?

19 MS. PORTER: This is Leah Porter from Crop
20 Life America.

21 MR. RHOADS: We're all clear. Go ahead.

1 MS. PORTER: Actually, I didn't have any
2 comment or statement. I just figured I better speak
3 up.

4 MR. RHOADS: Thank you very much. Is there
5 anyone else on the phone who I haven't named who would
6 like to ask question or make a statement? I'll turn it
7 over one more time. Last chance for folks in the room.
8 If we don't have anything more from the panel, then --

9 MS. DUNAHAY: I guess I would just like to
10 repeat that if anybody does have any written comments
11 that they would like to provide to me, if you can, I'll
12 take them up to the last minute, so if you can get them
13 to me by close of business Friday, that would still
14 give me time to consider them before we finalize our
15 comments and send them to the Secretariate next week.
16 And I really appreciate everyone taking the time again
17 to participate either by phone or by coming down here
18 thank you very much.

19 MS. ELLICOTT: Terri, this is Alexis from
20 American Seed Trade. Did Mark get our comments to you?
21

1 MS. DUNAHAY: Yes. I got Mark's comments.
2 Thank you very much. I had a talk with him yesterday
3 and he sent them electronically. So, thank you,
4 Alexis.

5 MR. RHOADS: At this point, we'll conclude
6 the hearing. Thanks again everybody from coming.

7 (Hearing Concluded)

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1 State of Maryland

2 City of Baltimore, to wit:

3 I, Louisa B. McIntire-Brooks, a Notary

4 Public of the State of Maryland, Anne Arundel County,

5 do hereby certify that the within-named proceedings

6 took place before me at the time and place herein set

7 out.

8 I further certify that the proceedings were

9 recorded stenographically by me and this transcript

10 is a true record of the proceedings.

11 I further certify that I am not of counsel

12 to any of the parties, nor an employee of counsel,

13 nor related to any of the parties, nor in any way

14 interested in the outcome of this action.

15 As witnessed my hand and notarial seal this

16 7th day of October, 2003.

17

18

Louisa B. McIntire-Brooks
Notary Public

19

20 My commission expires:

21 January 1, 2004

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