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Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development **03-Oct-2008**

English - Or. English

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

ENV/JM/BIO/M(2008)2
For Official Use

Working Group on the Harmonisation of Regulatory Oversight in Biotechnology

DRAFT SUMMARY RECORD OF THE 21st MEETING OF THE WORKING GROUP ON HARMONISATION OF REGULATORY OVERSIGHT IN BIOTECHNOLOGY

English - Or. English

JT03251919

INTRODUCTION

1. The 21st meeting of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology was held 25-26 June 2008 at the OECD Headquarters in Paris. The meeting was chaired by Sally McCammon (United States) and attended by delegations of member countries, observers from non-member countries (Argentina, Chile, Philippines, the Russian Federation and Slovenia) and BIAC. A complete list of participants is included as Annex IV to this report.

ADOPTION OF DRAFT AGENDA

2. The main objectives of this meeting were to: i) take note of the outcomes of the special meeting on LLP and discuss the feasibility of a project on this topic; ii) agree to the programme of work for 2009-2012 and; iii) agree to a strategy for proceeding on existing projects. The draft agenda was adopted without amendment.

ADOPTION OF THE SUMMARY RECORD

3. The Working Group adopted the draft summary record of the 20th meeting without changes [ENV/JM/BIO/M(2007)2].

REPORT FROM THE SECRETARIAT

4. The Secretariat presented a progress report on developments in its work since the last meeting of the Working Group [ENV/JM/BIO(2007)10]. Amongst other things, it mentioned a special meeting of the Working Group on Low Level Presence (LLP), which had been held at OECD Headquarters in Paris, 14-15 April 2008. As a result, three potential approaches/ outputs to work on LLP were identified in the report of this meeting [ENV/JM/BIO/M(2008)1] for further consideration in the 21st meeting of the Working Group. The aim of this special meeting was to assist the Working Group in deciding whether and how to move forward with a project.

5. The Secretariat also noted that it had developed a system to exchange information with the FAO database and OECD's Product Database which will be able to import information on food safety assessment from the FAO International Portal on Food Safety, Animal and Plant Health (IPFSAPH), while exporting information on products in return.

6. A new project proposed at the 20th meeting [ENV/JM/BIO(2007)17] to construct a web-based database on information of research projects on the environmental risk/ safety of transgenic organisms (a subset of OECD BioTrack) was recommended to be put "on hold" for the present.

CURRENT DEVELOPMENTS IN MEMBER COUNTRIES – *Tour de Table*

7. The Working Group was updated on the regulatory developments and related activities by all delegations including observers from non-member countries and BIAC. The Working Group was encouraged to include website links in their submissions, when appropriate. A summary of those interventions, forwarded to the Secretariat in electronic form, is found in Annex III to this report.

PROGRAMME OF WORK 2009-2012 (Part I)

Introduction to the Draft Programme of Work 2009-2012

8. The discussion on the draft Programme of Work (2009-2012) was held in two parts. As an introduction to the Draft Programme of Work 2009-2012 [ENV/JM/BIO(2008)6] (Part I), the Secretariat went through the content of the draft. It was mentioned that this draft had been influenced by the results of the priority-setting exercise [ENV/JM/BIO(2007)18] as well as the discussions in the 20th meeting of the Working Group, but that the content is basically similar to the current Programme of Work. In particular, the Working Group was invited to note the proposal to change its name to the Working Group on Environmental Safety Aspects of Biotechnology to ensure that the title clearly reflects its focus on environmental risk/ safety assessment.

9. It was noted that this document must be forwarded to the Joint Meeting of the Chemicals Committee and the Working Party for Chemicals, Pesticides and Biotechnology by mid/ late September. It was also mentioned that this issue would be revisited later in the 21st meeting (Part II) when the Working Group would be invited to comment on the draft at that time.

SPECIAL MEETING ON LOW LEVEL PRESENCE (PART I)

Report on the Special Meeting on Low Level Presence

10. The Chair reported on the results of the special meeting on Low Level Presence (LLP) held 14-15 April 2008 [ENV/JM/BIO/M(2008)1] and [ENV/JM/BIO/M(2008)1/ADD1]. The Chair went through the content of the meeting summary and directed the focus of the Working Group to the three refined approaches that were derived from the special meeting as its significant outputs. The Working Group was invited to revisit this item later in the agenda when the Working Group would consider the feasibility of undertaking a project on LLP.

SPECIAL WORKING GROUP DOCUMENTS: OVERVIEW

Current Biology Consensus Documents on Plants: Schedule for the Drafting and Review

11. The Chair mentioned that this document *Current Biology Consensus Documents on Plants: Schedule for the Drafting and Review* [ENV/JM/BIO(2008)2] was drafted according to the action item of the 20th meeting of the Working Group to show the current status of projects for developing biology consensus documents. It was pointed out that reference to the status of the project, *Module III (General Information Concerning Agronomic and Environmental Aspects of the Cultivation of Genetically Modified Herbicide Resistant Plants)*, is missing from this document.

12. The Working Group was invited to take note of this document and comment on the schedule for producing the documents. There was no comment on this document at the meeting but it was agreed that comments on this document, if any, would be submitted to the Secretariat subsequently (Annex I, Item 2).

Guide for Preparation of Biology Consensus Documents

13. The Chair noted that to improve the process for drafting and review of biology consensus documents, it was agreed at the 20th meeting of the Working Group to make use of the document, *Consensus Documents on the Biology of Plants: The Process for Drafting* [ENV/JM/BIO(2007)8], as general Interim Guidance and to finalize guidance for authors for the 21st meeting using the general interim guidance as a basis. The Chair emphasised that the resulting document *Guide for Preparation of Biology*

Consensus Documents [ENV/JM/BIO(2008)5] had been developed with the main objective of improving the efficiency and quality of the first drafts of consensus documents prepared by lead countries.

14. The Working Group was invited to comment on the draft and consider it for declassification as a companion text to two previous publications prepared by the Working Group: (i) *An Introduction to the Biosafety Consensus Documents of OECD's Working Group for Harmonisation in Biotechnology*; and (ii) *Points to Consider for Consensus Documents on the Biology of Cultivated Plants*. Certain delegations requested a further period for reviewing this document. As a result, it was agreed that comments on this document, if any, would be submitted to the Secretariat subsequently (Annex I, Item 3).

Project Development and Management in Future Issues in Harmonisation and Micro-organisms

15. The Chair indicated that the objective of this document *Project Development and Management in Future Issues in Harmonisation and Micro-organisms*[ENV/JM/BIO(2008)3] is to assist the development of a more structured and efficient process for completing projects related to issues in harmonisation and micro-organisms. The Working Group was invited to take note of this document and comment on the schedule and process for producing the documents.

16. In addition, it was emphasised that because issues in harmonisation are very significant, they should be given a high priority and that this management process is valuable as an aid in planning and completing projects, taking into account resource constraints. It was also agreed that comments on this document, if any, would be submitted to the Secretariat (Annex I, Item 2).

FACILITATING HARMONISATION

Environmental Considerations for Risk/ Safety Assessment for the Release of Transgenic Plants

17. The Chair invited the delegation of Canada, as the lead country, to provide an oral progress report on this project. The delegation of Canada outlined the history of this project by referring to the original draft operational plan [ENV/JM/BIO(2007)7] as a starting point. Reference was also made to an annotated outline complied as a result of the meeting of the Steering Group held in Helsinki in August 2007, as well as discussions at the 20th meeting of the Working Group.

18. The delegation of Canada indicated its intention to draft a new concise and annotated outline by the end of August 2008. It would share this with the Steering Group for further discussion via teleconference. The Chair noted her appreciation for the efforts of the lead country in spearheading this significant project. The proposal of the lead country was agreed (Annex I, Item 4). The Chair indicated that it would be desirable for the Steering Group to agree on the annotated outline so that, if possible, the first draft of a document could be provided for the next meeting of the Working Group.

Molecular Characterisation

19. The Chair invited the delegation of Canada as the lead country to provide an oral progress report on this project. Canada explained that much progress has been achieved to date so because the Steering Group had prepared a first draft [ENV/JM/FOOD(2007)3] according to the Operational Plan [ENV/JM/BIO(2004)5]. A number of useful comments had been received as a result. However, Canada also noted that this is a joint project of the Working Group and the Task Force for the Safety of Novel Foods and Feeds, and that it is important to consider how best to facilitate discussion between the two bodies so as to finalize this project.

20. In this context, the Chair mentioned that the Bureau had discussed how to best advance this project and a "face-to-face" special meeting of the Steering Group might be held to resolve any

outstanding issues. The Chair also added that if this special meeting is held, it will be necessary first to identify the specific issues that need to be resolved and for the two Bureaux (of the Working Group and Task Force) to work together to accomplish this. It was agreed that a joint Bureaux discussion would be held as soon as possible to move this project forward (Annex I, Item 5).

Atlantic Salmon

21. The Chair invited the delegation of Norway, as one of the lead countries, to provide a progress report on this project. Norway gave a brief overview of the first draft [ENV/JM/BIO(2008)4]. The United States, one of the other lead countries, noted that it would complete the missing part IV of the draft by the end of July and that once comments on this draft have been submitted, the Steering Group could focus on revising the draft.

22. In regard to the first draft, the Working Group was invited to focus their comments on broader issues (for example, identify points not yet addressed in the text) rather than on editorial ones (Annex I, Item 6).

LLP (Part II): Discussion of the Feasibility of a Project on this Topic

23. The Chair opened the discussion by inviting the Working Group to make comments on (amongst other things) the three refined approaches/ outputs to future work on LLP that had been identified as a result of the special meeting on LLP [paragraph 38, ENV/JM/BIO/M(2008)1] held 14-15 April 2008. These three refined approaches are as follows: incorporate LLP issues into the Environmental Considerations (EC) document; prepare an LLP document in parallel with the EC document; and draft a general risk assessment document incorporating LLP issues. In the ensuing discussion, there was a wide range of comments to the approaches as well as a number of related issues.

24. Some delegations stressed the importance of the project on Environmental Considerations (EC) and expressed concerns that progress might be delayed by attempting to incorporate LLP issues into the text of that document. The lead country of the EC project, Canada, took the view that it would not necessarily take much work to incorporate factors related to LLP issues into the EC document. However, others maintained that the LLP issue deserves a distinct treatment as compared with other projects of the Working Group, including the EC document.

25. It was also suggested that the Working Group could take an approach to LLP issues that is similar to the way in which the Codex Alimentarius Commission addressed the topic in its plant guideline focusing on food and feed safety. In this case, LLP issues were covered as an annex to the main document. However, it was pointed out that the Working Group should take into account the fact that its EC document is still in the process of development and is not the environmental equivalent of the Codex plant guideline. Whereas the Codex plant guideline had been completed before the discussion on LLP took place within the Codex.

12. 26. It was recalled that the Working Group had developed not only neutral science-focused documents such as the consensus document on the biology of plants and traits but also documents that focused on other types of issues either as supplements to previously prepared documents or as guidance documents. Two documents were cited as good examples: the *Module II document - Herbicide Biochemistry, Herbicide Metabolism and the Residues in Glufosinate-Ammonium (Phosphinothricin)-Tolerant Transgenic Plants* [ENV/JM/MONO(2002)14] and *Guidance Document on Methods for Detection of Micro-organisms Introduced into the Environment: Bacteria* [ENV/JM/MONO(2004)7]. The former focuses mainly on the metabolism of the herbicide as well as metabolites and residues in genetically modified plants and is a supplement to the previous published document, *Consensus Document*

on General Information Concerning the Genes and their Enzymes that Confer Tolerance to Phosphinothricin Herbicide [ENV/JM/MONO(99)13]. The latter is a stand-alone document which specifically focuses on detection methods of transgenic micro-organisms. So, these two examples indicate that the Working Group is not strictly limited in the types of projects that it might undertake related to assessment of the products of modern biotechnology.

27. Other approaches were suggested. It was noted that four guidance documents on micro-organisms had been prepared (or were under preparation) in parallel. With this precedent in mind, the Working Group could prepare an LLP document in parallel with EC document.

28. It was further noted that a document on LLP should be stand-alone and independent of EC document because EC deals with broad scientific issues in environmental risk assessment. While an LLP project will address scientific aspects, it might also have implications for trade issues and risk management. Therefore, it might be difficult to exclude such issues, at least from the discussions.

29. The Chair went on to invite the Working Group to discuss an approach that the Working Group makes a general risk assessment document incorporating LLP issues. This approach arose from the idea that it might be time to revisit and revise some of the earlier principles on risk assessment agreed at OECD. In discussing, the Chair noted that work on LLP issues should not give the impression that this was a substitute or short cut for normal risk assessment for approval. Some countries pointed out that a project for a general risk assessment document would be quite ambitious and tremendous work would need to be undertaken for its completion. However, in this context, a number of delegations noted that it might be more acceptable (and less controversial) to treat LLP within the context of risk assessment as a whole. This would ensure that the focus of project remained within the normal scope of work of the Working Group.

30. Some countries stressed the importance of information sharing among authorities, in relation to LLP incidents. This would be significant because an authority addressing an unauthorised event might not have sufficient official information.

31. It was noted that the experience of countries in addressing LLP issues should be captured. Case studies that indicate what happens when countries are faced with a LLP situation, including how risk assessment is approached and experience relied upon; practical approaches to dealing with LLP; actions taken to bring the situation into compliance; and how risk assessment has been used to inform risk management were mentioned.

32. It was noted that much of the discussion had involved LLP in seeds. This is because LLP in seeds might have greater impacts on the environment due to propagation in fields. However, some delegations stressed the need also to consider LLP in commodities. In response to this opinion, BIAC, the original proposer of this project, mentioned that it had made a proposal on LLP in seeds but it would support the idea that LLP in commodities could be covered. It was agreed that whether and how LLP in commodities would be treated, LLP in seeds would be considered first.

33. In summary, the Chair concluded that the Working Group regarded a project on LLP as feasible but more work would be necessary to bring a more refined proposal to the Working Group. There was wide interest in capturing country experiences and enhancing information sharing. In fact, it was agreed that the Bureau would develop a more specific project proposal on LLP for the 22nd meeting (Annex I, Item 7).

CONSENSUS DOCUMENTS: PLANTS

Completion of Advanced Documents

34. A revised draft of the Consensus Document on ***Cotton*** [ENV/JM/BIO(2002)4/REV5] was presented by the lead country, Spain. It noted that the draft had been prepared in collaboration with the United States and Australia and had taken into account a range of comments from these two delegations. It was agreed that an additional period for comments, if any, would be given to the Working Group before it would be forwarded for declassification (Annex I, Item 8).

35. A revised draft of the Consensus Document on ***Lodgepole pine*** [ENV/JM/BIO(2003)10/REV4] was presented by the delegation of Canada as the lead country. Canada mentioned that the document had revised by incorporating comments from the United States that had not been included in the previous draft [ENV/JM/BIO(2003)10/REV3], which was presented at the 20th meeting of the Working Group. The United States noted its appreciation for the revision and stated that it would have a few minor editorial comments on the draft within a few days. It was agreed that the document would be forwarded for declassification after incorporating these editorial comments (Annex I, Item 8).

36. A revised draft of the Consensus Document on ***Western white pine*** [ENV/JM/BIO(2007)11/REV1] was presented by the delegation of Canada as the lead country. It was mentioned that although the Consensus Document on the biology of Western White Pine had been published, some outstanding issues on the document had to be revisited. The current draft had been prepared by incorporating comments from the Working Group. The United States stated that it would submit some editorial comments within a few days. It was agreed that the document would be forwarded for declassification after the incorporation these editorial comments (Annex I, Item 8).

Update of the Progress on Other Documents

37. The delegation of Spain was invited to make an oral progress report on the ***Banana and Plantain*** document as the lead country. The United States noted that it would comment within six weeks and the revised draft could then be distributed to the Working Group for review with a consideration for declassification (Annex I, Item 8).

38. The delegation of Canada was invited to make an oral report on the ***Black spruce*** document as the lead country. Canada reminded the Working Group that it had been agreed at the 20th meeting that the revised document would be presented at the 22nd meeting (Annex I, Item 8).

39. As the lead country, Canada was invited to make a progress report on the ***Brassica*** **spp.** document. Canada provided the draft document by distributing a compact disc to the Steering Group members because the size of the document is too large to be sent as an email attachment. The Steering Group was invited to make comments on the draft.

40. The Working Group expressed their appreciation for the efforts of Canada in the preparation of this comprehensive draft on *Brassica* spp. In view of the large (electronic) size of the text, the Secretariat agreed to work with its IT department to ensure that the document can be downloaded efficiently from the password protected web site so that comments could be easily be forwarded by delegations. In addition, it was noted that comments to the document, especially from the perspective of the "Points to Consider" document, would be especially welcome. It was agreed that after collecting comments from the Steering Group, a revised draft would be presented at the next meeting of the Working Group (Annex I, Item 8).

41. The delegation of Mexico was invited to make an oral progress report on the ***Cucurbita*** **spp.** document as the lead country. Mexico mentioned that it had provided the revised draft

[ENV/JM/BIO(2005)12/REV2] at the 20th meeting but had not received any comments from the Working Group. Mexico invited the Working Group to review the document and make comments on it. Mexico also proposed that if it did not received any comment, it would like to forward the document for declassification at the next meeting. The Chair not only invited the WG to make comments on the current draft (Annex I, Item 8) but also recommended that Mexico review the current draft to ensure that it is consistent with the "Points to Consider" document and the "Interim Guide for Authors".

42. The delegation of Germany was invited to make an oral progress report on the ***Module III*** document as the lead country. Germany mentioned that it had received constructive comments on the latest draft [ENV/JM/BIO(2004)8/REV3] from a number of delegations. It intended to provide a revised draft for the 22nd meeting. The delegation of Canada proposed to send its comments on the draft (Annex I, Item 8).

43. The delegation of Spain was invited to make an oral progress report on the ***Tomato*** document as the lead country. Spain mentioned that it had received substantial comments on the latest draft [ENV/JM/BIO(2006)5/REV1] from a number of delegations and it will provide a revised draft for the 22nd meeting (Annex I, Item 8).

CONSENSUS/ GUIDANCE DOCUMENTS: MICRO-ORAGANISMS

Completion of Advanced Documents

44. A revised draft of the Consensus Document on Acinetobacter [ENV/JM/BIO(2005)13/REV2] was presented by the delegation of Canada as the lead country. It mentioned that it believed that it would be appropriate for the document to be forwarded for declassification following a short period for a final review. It was agreed that the document would be forwarded for declassification if there are no major comments (Annex I, Item9).

45. The delegation of Germany was invited to make an oral progress report on the ***Horizontal Gene Transfer between Bacteria*** document as the lead country. It noted that the document had been intensively reviewed at the Moscow Workshop of the Sub-Working Group on the Micro-organisms and the document would be completed by incorporating some minor comments. It was also mentioned that the revision would be finished in the next two months and it would then be appropriate to be considered for declassification. The Chair of the Sub-Working Group also added that the document would be well placed for declassification by incorporating the outstanding comments from the United States. It was agreed, therefore, that once the document was revised, it could be forwarded for declassification (Annex I, Item 9).

Update of the Progress on Other Documents

46. In the absence of the delegation of Italy, the Chair of the Sub-Working Group on Micro-Organisms was invited to make an oral progress report on the ***Fusarium*** document. It was mentioned that the document should be revised so that it would be consistent with other documents on micro-organisms and that a discussion with Italy should be conducted with a view to completing this document. In response to this suggestion, the Chair of the Working Group invited the Chair of the Sub-Working Group, together with the Secretariat, to work with Italy to undertake this task (Annex I, Item 9).

47. The Chair of the Sub-Working Group on Micro-Organisms was invited to make an oral progress report on the ***Unique Identifier for Transgenic Micro-Organisms***. He mentioned that the Working Group discussed the draft questionnaire for stakeholders to gather their views on the development of the unique identifier at the 20th meeting and that he had received comments from some member countries. He added that a major comment points out that questions related to non-transgenic micro-organisms should be

included in the questionnaire because stakeholders might not necessarily have experience in dealing with transgenic micro-organisms.

48. The Chair of the Working Group appreciated the efforts of the Sub-Working Group for preparing the draft questionnaire. He also stated that the draft questionnaire had been almost finalized through discussions in the informal meeting of the Sub-Working Group held on 24th June 2008. It was agreed that the Secretariat would send the questionnaire to stakeholders when it had been finalized by the Chair of the Sub-Working Group. They would be invited to reply by mid-October (Annex I, Item 9).

49. The delegation of the Netherlands (the Chair of the Sub-Working Group on Micro-Organisms) was invited to make an oral progress report on the guidance on ***Potential Adverse Health Effects of Bacteria***. He mentioned that he had not received any comments on the draft presented at the 20th meeting. He also mentioned that the lead countries, the Netherlands and Canada, intend to prepare a new draft for the 22nd meeting and hope to receive major comments as soon as possible.

50. In response, the United States expressed appreciation for the effort of the lead countries to provide a new draft for the next meeting and mentioned that it has great interest in the content of the document and needs an extended period to prepare comments. After some discussion, it was agreed that the United States would be invited to send comments on this document to the Netherlands by 30th September 2008 and that the Netherlands will prepare the revised document for the 22nd meeting (Annex I, Item 9).

Next Step for the Sub-Working Group on Micro-Organisms

51. As the result of the informal meeting of the Sub-Working Group held on 24 June 2008, the Chair of the Sub-Working Group on Micro-Organisms reported that the Sub-Working Group would discuss by teleconference how to improve the management of the Sub-Working Group including the consideration and prioritization of any of potential new projects. It was agreed that this teleconference would be held in September 2008 (Annex I, Item10).

PROGRAMME OF WORK 2009-2012 (PART II)

Discussion/ Completion of the Programme of Work 2009-2012

52. The Secretariat briefly recapitulated the introduction it had made to the Draft Programme of Work earlier in the agenda.

53. In regard to the proposal for a change in the name of the Working Group, the Chair pointed out that there were good arguments both for and against such a change. This is something delegates might wish to consider in their written comments. The Chair also mentioned that the current Programme of Work 2006-2008 with the existing terms of reference is useful as a reference for the Working Group when considering the proposal for 2009-2012. The Secretariat noted that this document is available on the password protected web site.

54. There was discussion on how to implement the content of paragraph 11 (potential necessity of considering a new generation of traits such as abiotic stress tolerance) in the draft Programme of Work 2009-2012. The Chair noted that there had not yet been any relevant proposals for such projects but that this paragraph would be the basis on which to conduct any such future work during the coming 4 years.

55. In summary, the Working Group was invited to submit written comments to the draft Programme of Work by 12th August 2008 (Annex I, Item 11). It must be forwarded to the parental body, the Joint Meeting, by 24th September. The Joint Meeting will consider the document at its 43rd meeting, 5-7

November 2008. If the Secretariat has difficulty in reconciling written comments from delegations, it will resolve such issues in discussion with the Bureau.

INFORMATION DISSEMINATION AND OUTREACH

Potential OECD Workshop at the 10th ISBGMO

56. The Working Group was updated on the draft Programme on the potential OECD Workshop at the 10th International Symposium on the Biosafety of Genetically Modified Organisms (ISBGMO), which will be held in 16-21 November 2008 in New Zealand [ENV/JM/BIO(2008)7]. The Chair mentioned that the OECD Workshop at the 9th ISBGMO, "BEYOND THE BLUEBOOK, Framework for Risk/ safety Assessment for Transgenic Plants", was very successful because useful information had been provided on how to use scientific information in risk/ safety assessment. The Chair also stated that the International Society for Biosafety Research (ISBR), parent body of the ISBGMO, had asked OECD to hold another Workshop at the 10th ISBGMO.

57. In regard to the draft Programme, it was mentioned that the next potential Workshop would deal with what risk assessors of each OECD member had experienced in risk/ safety assessment. In response to this point, it was pointed out that if the Workshop is being held under the name of OECD, the activities of the Working Group should also be incorporated into presentations in a well-balanced manner. Therefore, it was agreed that the Steering Group would proceed with hosting the Workshop and continue to discuss the program of the workshop.

ADMINISTRATIVE MATTERS

Election of the Bureau

58. The Secretariat explained the process by which the election of the chair and vice-chairs takes place, emphasising that it had held consultations with each delegation. Following these consultations, it was proposed that Sally McCammon (the United States) would serve as Chair, while Hans Bergmans (the Netherlands), Ken-ichi Hayashi (Japan), Marja Ruohonen-Lehto (Finland) and Stephen Yarrow (Canada) would serve as Vice-chairs. The Working Group agreed to this proposal.

Resources

59. The Secretariat introduced the document *Report by the Secretariat* [ENV/JM/BIO(2008)1] and expressed appreciation for financial contributions as well as other types of contributions such as drafting and making input into Consensus Documents, providing consultants for advancing work, hosting meetings and workshops, and sending experts to attend meetings. The Secretariat then emphasised the necessity for member countries to continue to provide extra-budgetary contributions in order to ensure implementation of this programme.

Date of the Next Meeting

60. The Working Group was informed that the 22nd meeting would be held the week of 9th February 2009 at OECD Headquarters in Paris.

ANNEX I

ACTION ITEMS FROM THE 21ST MEETING OF THE WORKING GROUP

Item 1 – Current Development in Member Countries – *Tour de Table*

- Text to the summary record of the 21st meeting will be submitted to the Secretariat by **24th July 2008**. The WG is invited to provide URLs for the documents that were mentioned.
- The WG is invited to send documents to the Secretariat by **29th August 2008** that are thought to be useful when Slovakia considers its biosafety strategy.

Item 2 – Current Biology Consensus Documents on Plants: Schedule for the Drafting and Review as well as Project Development and Management in Future Issues in Harmonisation and Micro-organisms

- Comments on both documents will be submitted to the Secretariat by **29th August 2008**.

Item 3 – Guide for Preparation of Biology Consensus Documents

- Comments on this document will be submitted to the Secretariat by **14th August 2008**.

Item 4 – Environmental Considerations

- A new draft of the annotated outline will be made by Canada by **31st August 2008** for consideration by the Steering Group. There will also be a teleconference with the Steering Group in September.

Item 5 – Molecular Characterisation

- Joint Bureau discussion as soon as possible.

Item 6 – Atlantic Salmon

- Comments to the draft focused on broader issues rather than on editorial ones are expected to be submitted to the Secretariat by **31st July 2008**.

Item 7 – LLP: Feasibility of a Project

- Bureau will prepare proposal for the 22nd meeting.

Item 8 – Consensus Documents: Plants

- Cotton spp.
  - Comments on this document will be submitted to the Secretariat by **22nd August 2008**. If there is no major comment, the document will be forwarded to the Joint Meeting for declassification.
- Lodgepole pine and Western white pine
  - The US will submit editorial comments a couple of days later. After the comments are incorporated, the two documents will be forwarded to the Joint Meeting for declassification.
- Banana and Plantain
  - The US will submit its comments to Spain by **8th August 2008**. Spain will incorporate the comments and distribute the revised draft to the WG for consideration for declassification by **8th October 2008**.
- Black spruce
  - The revised draft will be submitted to the Secretariat by **13th January 2009** for the 22nd meeting.
- *Brassica* spp.
  - The Steering Group will be invited to submit comments on this document to the Secretariat by **5th November 2008**. The revised draft will be submitted to the Secretariat by **13th January 2009** for the 22nd meeting.
- *Cucurbita* spp.
  - The Secretariat will post the current draft on the password protected site. The WG will be invited to review the document and send comments to the Secretariat by **18th November 2008**.
- Module III
  - The revised draft will be submitted to the Secretariat by **13th January 2009** for the 22nd meeting. Canada is invited to send comments to Germany.
- Tomato
  - The revised draft will be submitted to the Secretariat by **13th January 2009** for the 22nd meeting.

Item 9 – Consensus/ Guidance Documents: Micro-Organisms

- *Acinetobacter*

- Comments on this document will be submitted to the Secretariat by **8th August 2008**. If there is no major comment, the document will be forwarded to the Joint Meeting for declassification.

- Horizontal Gene Transfer between Bacteria

  - Germany will incorporate comments that it already received by mid-September and revised document will be forwarded to the Joint Meeting for declassification.

- *Fusarium*

  - The Chair of Sub-working Group and the Secretariat will organise a teleconference or meeting with Italy to complete this document.

- Unique Identifier for Transgenic Micro-Organisms

  - The WG is invited to send the Secretariat e-mail addresses of stakeholders by **4th July**. The Secretariat will send them the questionnaire finalized by the Chair of the Sub-working Group by **18th July**. They will be invited to reply the questionnaire by **15th October**. The Secretariat will send its reminder to them by **22nd September**.

- Potential Adverse Health Effects of Bacteria

  - The US will be invited to send comments on this document to the Netherlands by **30th September**. The Netherlands will incorporate them and send the revised document to the Secretariat by **13th January 2009** for the 22nd meeting.

Item 10 – Teleconference of the Sub-working Group on Micro-organisms

- To discuss how to improve the management of this Sub-working Group, teleconference is planned to be held on **3rd week of September 2008**. The Secretariat will send an e-mail that asks availability of the members on **1st week of September 2008**.

Item 11 – Draft Programme of Work for 2009-2012

- Comments on the draft should be submitted to the Secretariat by **12th August 2008**. The Bureau and the Secretariat will work to complete it by mid-September.

Item 12 – Potential OECD Workshop at 10th ISBGMO

- To be held the **20th November 2008**. The Steering Group to continue work.

Item 13 – Next Meeting

- To be held the **week of 9th February 2009**, OECD Headquarters in Paris.

ANNEX II

Lead Country and Contact Person for Consensus/Guidance Documents

Documents	Lead Country	Contact Parson(s)
Banana and Plantain	Spain	Ms. Lucia Roda: LRoda@mma.es
Black spruce	Canada	Mr. Stephen Yarrow: syarrow@inspection.gc.ca
Citrus	Spain	Ms. Lucia Roda: : LRoda@mma.es
Cotton	Spain	Ms. Lucia Roda: : LRoda@mma.es
Cucurbita spp.	Mexico	Ms. Elleli Huerta Ocampo: Elleli.huerta@semarnat.gob.mx
Tomato	Spain Mexico	Ms. Lucia Roda: LRoda@mma.es Ms. Elleli Huerta Ocampo: Elleli.huerta@semarnat.gob.mx
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Western white pine	Canada	Mr. Stephen Yarrow: syarrow@inspection.gc.ca
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Acinetobacter	Canada	Mr. Jim Louter: Jim.Louter@ec.gc.ca
Horizontal Gene Transfer	Germany	Mr. Jörg Landsmann: j.Landsmann@bba.de
Potential Adverse Health Effects of Bacteria	The Netherlands	Mr. Hans Bergmans: Hans.Bergmans@rivm.nl
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Environmental Considerations	Canada	Mr. Stephen Yarrow: syarrow@inspection.gc.ca
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ANNEX III

Summary of Remarks made by Delegates during the Tour de Table

AUSTRALIA

Australia's *Gene Technology Act 2000* (GT Act) came into effect in June 2001 and has as its objective 'to protect the health and safety of people, and to protect the environment, by identifying risk posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs'. The GT Act establishes a statutory office holder, the Gene Technology Regulator (the Regulator), who administers the legislation with the assistance of the staff of the Office of the Gene Technology Regulator (OGTR).

Australia's inaugural Regulator, Dr Sue Meek, resigned in April 2008. Ms Elizabeth Flynn has been appointed Acting Regulator pending permanent filling of the position.

Approvals made under the Gene Technology Act

Licences issued by the Regulator

Australia's Gene Technology Regulator has issued 62 licences for environmental release (as at 24 July 2008). This includes 10 licences for commercial scale release, including for GM cotton, canola, carnations and a cholera vaccine, after completing comprehensive risk assessment and risk management plans under the GT Act. 16 DIR applications have been withdrawn.

Since the last WG meeting, the Regulator has issued five licences for environmental release. All are for limited and controlled releases:

1 cotton (insect resistant/herbicide tolerant),

2 banana (enhanced nutrition - increased levels of: provitamin A, vitamin E, iron; disease resistance) - 1st banana licences

1 wheat and barley (enhanced tolerance to abiotic stresses or increased beta glucan)

1 wheat (drought tolerance)

There are currently **nine applications for environmental release under consideration**. All are for limited and controlled release:

Sugarcane 1 (altered sugar production)

Cotton 3 (water-use efficiency, water-logging tolerance, altered fatty acid composition in oil)

Ryegrass & Tall Fescue 1 (improved forage quality - altered sugar levels, altered structural components of plant cell walls) – 1st pasture grass application

Torenia 1 (enhanced phosphate uptake)

Maize 1 (functional characterisation of maize genome) – 1st maize application

Environmental release licences issued since June 2001:

Cotton:	32 (6 commercial releases, 26 limited & controlled releases);
Canola:	5 (2 commercial releases, 3 limited and controlled releases);
Indian Mustard:	1 (limited and controlled release);
Canola & Indian Mustard	1 (limited and controlled release);
Oilseed Poppy:	2 (limited and controlled releases);
Sugarcane:	3 (limited and controlled releases);
Pineapple:	2 (limited and controlled releases);
Carnation:	1 (commercial release, placed on GMO Register);
Cholera Vaccine:	1 (commercial release);
Papaya:	1 (limited and controlled release);
Rice:	1 (limited and controlled release;
White Clover	1 (limited and controlled release);
Grapevine:	1 (limited and controlled release);
Bovine Herpesvirus vaccine:	1 (vaccine trial application for a limited and controlled release);
Fowl Adenovirus Vaccine:	1 (vaccine trial application for a limited and controlled release);
Wheat:	4 (limited and controlled releases);
Rose:	1 (limited and controlled release); and
Torenia (flower):	1 (limited and controlled release); and
Banana:	2 (limited and controlled release)

GMO Register

The Regulator placed GM blue carnations on the GMO Register in November 2006. GMOs that have previously been licensed may be placed on the GMO Register if: (a) any risks posed by the dealing are minimal and (b) the Regulator is satisfied that the dealings are sufficiently safe to be undertaken by anyone without the need for a licence. The Regulator will be satisfied that the risks are minimal if the risk estimates of identified risks are low or negligible, or if there are no identified risks. This is the first entry on the GMO Register.

Emergency Dealing Determinations

Emergency Dealing Determination (EDD) is made by the Minister rather than the Regulator.

In March 2008 the Minister made a 6 month extension to an Emergency Dealing Determination (EDD) made in September 2007. The EDD temporarily authorises dealings with genetically modified (GM) vaccines for Equine Influenza (ProteqFlu and ProteqFlu-TE). Import, supply and use of the GM vaccines were also authorised by an Australian Quarantine and Inspection Service (AQIS) import permit and Australian Pesticides and Veterinary Medicines Authority (APVMA) emergency use permit. (These GM vaccines have been approved for use in a number of other jurisdictions including the USA and Europe).

Reviews

Biology documents

The OGTR has recently published several new biology documents and revised a number of existing documents. The production of these documents as a support to risk assessment of GMOs owes a great deal to the example of the OECD consensus documents.

3 New Biology documents: Barley (*Hordeum vulgare*); Banana (*Musa* spp.); Italian ryegrass, perennial ryegrass and tall fescue (*Lolium multiflorum, Lolium perenne, Lolium arundinaceum*);

6 Revised Biology documents: Canola (*Brassica napus*); Cotton (*Gossypium hirsutum* and *Gossypium barbadense*); Pineapple (*Ananas comosus var. comosus*); Papaya (*Carica papaya*); Sugarcane (*Saccharum* spp.) and Wheat (*Triticum aestivum*).

All the biology documents are available on the OGTR website: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1

Risk Analysis Framework and Post release Review

The OGTR Risk Analysis Framework which provides guidance on how the Regulator approaches evaluation and management of GMOs. In November 2007, the OGTR published a revised Risk Analysis Framework, to take account of technical and procedural changes from amendments to the legislation. The Regulator has also recently developed a post release review (PRR) framework for general/commercial releases of GM crops in Australia and the PRR component has now been incorporated into the revised Risk Analysis Framework.

Technical Guidelines

A number of technical guidelines were reviewed in 2007, both as part of the Regulator's ongoing program of review and as a result of amendments to the *Gene Technology Regulations 2001*. All current guidelines

have now been extensively restructured to enhance clarity and consistency and to promote compliance by changing from a prescriptive to an outcomes-based approach.

Combination of the Ethics and Community Consultative Committees

From 1 January 2008, two former advisory committees, the Gene Technology Ethics Committee (GTEC) and Gene Technology Community Consultative Committee (GTCCC) were replaced by one committee - the Gene Technology Ethics Community Consultative Committee (GTECCC). These are the last of the amendments flowing from the 2005/06 review of Act to take effect.

Other international activities

Cartagena Biosafety Protocol

The UN Cartagena Protocol on Biosafety to the United Nations (UN) Convention on Biological Diversity (CBD) entered into force on 11 September 2003.

The objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living genetically modified organisms (LMOs), specifically focusing on transboundary movements. The *Gene Technology Act 2000* (the GT Act) provides Australia with a robust science-based system for regulating 'dealings' with genetically modified organisms (GMOs equivalent to LMOs) to protect the health and safety of people and the Australian environment.

Australia is a party to the CBD but not to the Biosafety Protocol. Australia has no timetable for consideration of accession to the Protocol. However Australia has maintained a keen interest in developments under the Protocol and has actively participated in all its meetings as a non-Party, including the recent 4th Meeting of the Parties in Germany in May 2008.

ISBGMO

Officers from the OGTR have been involved in the planning committee for the 10th ISBGMO to be held in New Zealand in November 2008.

AUSTRIA

Legislation and developments concerning Austrian Safeguard measures on GM maize lines:

Two amendments of the Austrian Regulatory Framework on Biosafety have been introduced since the last meeting concerning the Austrian safeguard measures on GM maize lines MON810 and T25.

The Environment Council on October 30, 2007 discussed proposals delivered by the European Commission to partially lift the safeguard measures adopted by Austria with regard to the import of GM maize MON810 and GM maize T25. The Environmental Council however failed to take a decision, since no qualified majority in favour of the Commission proposals or rejecting the proposals were reached. According to the EU regulatory system the European Commission was thereupon entitled to take a decision in the matter and decided on May 7, 2008 to lift the safeguard measures with regard to import and further processing for food and feed of both GM products.

Accordingly Austria repealed its ordinances to prohibit the importation of GM maize lines T25 and MON 810, but maintained its safeguard clauses for cultivation of GM maize MON810 and T25 in Austria.

4th Report from the Austrian Gene Technology Commission

According to Austrian legislation the national Gene Technology Commission has to submit every three years a report to the Parliament about the experiences with contained uses, deliberate releases and marketing of GMOs, as well as human gene analysis and gene therapy. The 4th Report has been finalized and will be submitted to Parliament and made publicly available later this year.

Publications and activities concerning the Risk Assessment of GMOs:

A number of publications concerning Risk Assessment of GMOs have been published by Austrian institutions:

Concerning the decision by the WTO panel in the dispute case "EC: Biotech" that the justifications for the Austrian safeguard measures concerning several GM maize lines were not in line with WTO requirements (specifically the SPS Agreement), the Austrian Federal Ministry of Health, Family and Youth published a document, which contains a competing risk assessment of GM maize lines subject to safeguard measures. The delivered risk assessment focused on the issues of concern raised by Austria and was prepared according to international guidance in line with WTO requirements. Taking into regard the specific environmental conditions in Austria the submitted risk assessment supports the introduction of safeguard measures.

The report is accessible at the website of the Ministry of Health, Family and Youth:

http://www.bmgfj.gv.at/cms/site/attachments/0/8/6/CH0810/CMS1196158149332/cms1201531756840_forschungsbericht_band_4-2007.pdf

Other studies published by the Ministry of Health, Family and Youth included documents on:

- Risk Assessment of Antibiotic Resistance Marker Genes in Genetically Modified Organisms: http://www.bmgfj.gv.at/cms/site/attachments/7/4/2/CH0810/CMS1198058130229/woegerbauer_2007.pdf

- Assessment of Toxic and Ecotoxic Properties of Novel Proteins in GMOs: http://www.bmgfj.gv.at/cms/site/standard.html?channel=CH0810&doc=CMS1206433032207

- Transgenic Animals - Status-quo in Relation to Risk Assessment and the State of Research http://www.bmgfj.gv.at/cms/site/attachments/1/3/8/CH0808/CMS1209380857705/forschungsbericht_2-08.pdf

Umweltbundesamt has published a study (in German language) concerning Nature conservation issues with regard to the cultivation of GMOs.

Information in English is available at:

http://www.umweltbundesamt.at/en/umweltschutz/gentechnik/koexistenz/koexistenznaturschutzfragen/

BELGIUM

Notifications for commercialisation

There are no new dossiers as lead CA under the Directive 2001/18/EC. Relevant documents can be consulted on http://www.bio-council.be and (http://www.biosafety.be/gmcropff/EN/TP/SBB_NotificationC_BE_96_01.html).

Belgium is actively involved in the EFSA consultation for placing on the market of GM crops. Input in the risk assessment is provided through the Biosafety Advisory Council, which besides food and feed aspects also evaluates environmental impacts of GM crops. Belgium is currently carrying out the environmental risk assessment of a GM maize (triple stack: 59122x1507xNK603) submitted under the GM Food and Feed Regulation.

Notifications for field trials in Belgium

A new notification for a field trial with transgenic poplar (modified lignin content) has been submitted. The Belgian Authorities declined the execution of the field trial. General information about genetically modified plants that have been modified/approved in Belgium for deliberate release into the environment is available from the Belgian Biosafety Server (http://www.biosafety.be).

Coexistence

Coexistence is treated on a regional level in Belgium (Flanders and Wallonia). A decree on coexistence of the Walloon region has been approved recently (11 June 2008). In Flanders, there is a decree proposal, which has been notified to the European Commission (EC) early 2008. The text has been changed based on the reply of the EC and will be put forward to the Government and Parliament for final approval (expected late 2008). The decrees contain basic arrangements on coexistence, liability and compensation schemes; management measures to be taken to avoid gene flow will be put down in orders laying down detailed rules for the application of the decrees.

GMO detection in Belgium

There is no significant information since the officialisation of the **'National Reference Laboratory'** for Genetically Modified Organisms on 15 June 2006. The NRL-GMO is fully operational and has been involved in all the enforcement actions implemented by the Belgian Federal Agency for the Safety of the Food Chain.

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CANADA

Confined plant field trial update

The Canadian Food Inspection Agency (CFIA) authorized confined field trials of 131 plants with novel traits (PNTs) for the 2008 growing season. These trials involved a number of different plant species / trait combinations, for example industrial enzyme production in safflower, nutritional changes in soybean, insect resistant spruce trees, or herbicide tolerant wheat (which was a product of mutagenesis). These trials were conducted at 131 trial locations across Canada.

Unconfined release authorizations update of plants

A transgenic cotton line (GHB614), which is herbicide tolerant, and a transgenic corn line (MON 89788), that is resistant to herbicides, have been authorized for food use, feed use and environmental release. A sunflower line (ExpressSun Sunflower SU7), which is tolerant to herbicides, was also authorized for food use, feed use and environmental release. This sunflower line was modified through chemical mutagenesis. Also, one line of soybean, with reduced glycinin content to approve palatability, was authorized for feed use. This soybean line resulted from conventional breeding methods.

To date, 58 PNTs have been authorized for unconfined release in Canada and 68 PNTs have been authorized for feed and food uses.

Regulatory Research

Canada continues to support regulatory science by sponsoring risk assessment research including an analysis of global changes in gene expression associated with transgene insertion, potential hybridization between *Camelina sativa* and *Brassica* sp., updating the Canadian soybean biology document and a review paper on Commercial Energy Grass Production and Implications for Invasive Species in Canada. Results from some of these research projects will be published in peer reviewed scientific journals. Scientists who receive funding from the CFIA for risk assessment research are from academia or other federal government departments.

The CFIA is working in close collaboration with the research community to create a research network to examine the use of species new to Canada that could be modified for the production of industrial or pharmaceutical compounds.

The CFIA hosted a science symposium entitled "Plant Risk Assessment Challenges for the 21st Century: New Crops and New Uses." The Symposium was held with the aim to help identify current gaps in risk assessment approaches relating to biofuel and bioindustrial platforms, as well as to further refine the risk assessment approaches to these challenging products. The symposium took place over two-and-a-half days from March 12 to 14, 2008 in Ottawa. Participants of the science symposium included 55 high calibre members of academia, industry and government from Canada, the United States, Mexico, Brazil, the UK, Italy and New Zealand. A report of the proceedings is being drafted and will be available on the website before the end of summer.

Canada will be co-hosting a workshop with New Zealand and the United Kingdom on modelling invasive characteristics that will be held as a side event of the 10th ISBGMO in Wellington, New Zealand.

Regulatory Policy Development for Plants

The CFIA continually updates its science-based regulatory system for biotechnology as new and more complex products are developed, and as the regulatory science evolves, in order to provide an effective and

scientifically defensible regulatory program. The CFIA has undertaken the following initiatives in support of keeping Canada's regulatory system up to date with current knowledge:

Plant Molecular Farming (PMF)

To date, no PNT intended for PMF has been granted authorization for its commercial cultivation in the Canadian environment, only limited field trials have taken place. The Canadian Food Inspection Agency (CFIA) is currently developing a regulatory framework for the environmental release of plants which would require closed-loop confinement for commercial production due to potential food, feed, or environmental safety issues, a release termed commercial confined environmental release (CCER). The environmental release of plants intended for plant molecular farming is expected to be regulated under this new framework.

Regulatory Efficiency

Towards further regulatory modernization and increased efficiency, the CFIA, in cooperation with Health Canada, have formed a joint working group (WG) to create a venue for continued opportunities in increasing regulatory transparency and efficiency. The group's focus is on novel foods and novel feeds derived from biotechnology and including plants with novel traits.

The group hosted a second workshop on optimizing submission data package quality for these types of novel products in March 2008. The purpose of this workshop was to impart a better understanding of the assessment criteria and the assessment process to applicants, with the goal of improving the quality of submitted data packages and, consequently enhancing the overall efficiency of the regulatory process. Participants worked through hypothetical case studies and scenarios containing common problem areas in order to view the assessment process from a regulator's perspective.

The working group is also developing guidance for applicants to use as part of the optional pre-submission consultation process for their products. This guidance will not only help applicants to prepare for this process, it will also be used as a communication tool to increase awareness of this optional tool in the regulatory process.

Second consultation on proposed amendments to the New Substances Notification Regulations (Organisms)

Environment Canada (EC) and Health Canada (HC) conducted a second multi-stakeholder consultation on proposed amendments to the New Substances Notification Regulations (NSNR) for Organisms of the Canadian Environmental Protection Act, 1999 on December 5-6, 2007 (the previous one was held in June, 2006). The consultation addressed notification and exemption requirements for organisms other than micro-organisms (i.e. higher organisms including insects, fish, laboratory rodents, and livestock) (see http://www.ec.gc.ca/substances/nsb/bio_disc_07/eng/toc_e.htm for the consultation document). The workshop was attended by 52 participants representing key interested parties including, other government departments and agencies, provincial governments, animal care and other ENGOs, academia, industry and research funding organizations. Proceedings are being developed and will be available on our website (www.ec.gc.ca/substances)

Assessment of 'existing' microorganisms on Canada's 'Domestic Substances List' (DSL)

EC and HC have now hosted four meetings with a Technical Experts Group (TEG) on the subject of the assessment of microorganisms on the DSL – the work is progressing well as these experts provide us with advice on the risk assessment framework ('how' we do risk assessment of microorganisms), as we draft our risk assessment report (*Pseudomonas aeruginosa*), as we consider implementing a mandatory

information gathering survey, and as we consider how to implement an information sharing regime with other jurisdictions. We are using the OECD Pseudomonas consensus document as a reference in the draft report.

Assessment of import of industrial crop seed for processing

EC and HC have completed the first ever assessment of a commercial seed import for processing into an industrial compound.

CZECH REPUBLIC

Legislative Framework

The legislative framework of the Czech Republic has been harmonised with the EU legislation. The basic national legal instrument concerning biosafety issues (use of GMOs) is the Act No. 78/2004 Coll., on the Use of Genetically Modified Organisms and Genetic Products, as amended by the Act No. 346/2005 Coll., with an implementing Decree No. 209/2004. The Act transposes EU Directives 2001/18/EC and 98/81/EC, therefore it covers the contained use, deliberate release of GMOs into the environment and placing on the market of GMOs as or in products. It has been in force since February 2004.

The EC Regulations 1829/2003, 1830/2003 concerning authorisation of GM food and feed, traceability and labelling of GMOs and GM food and feed and Regulation 1946/2003 implementing the Cartagena Protocol have been directly applicable in the Czech Republic since its accession to the EU in May 2004.

General rules on the co-existence of genetically modified crops with conventional and organic farming are set by the amendment to the Act on Agriculture and are complemented by case-specific measures for each GM crop by the implementing Decree (so far for maize and potatoes).

State Administration

The Competent Authority handling the notifications and regulating the use of GMOs in the Czech Republic is the Ministry of the Environment of the Czech Republic (Competent Authority under EU Directive 2001/18/EC). It co-operates with the Ministry of Health as regards risks for human health and with the Ministry of Agriculture as the agricultural risk, animal health, crops and feeds are concerned. An expert advisory body to the Ministry of the Environment is the Czech Commission for the Use of GMOs and Genetic Products that consists of scientists, representatives of administrative authorities and NGOs. The Ministry of the Environment is the Competent Authority and the focal point for the Cartagena Protocol on Biosafety and for the EC Regulation No 1946/2003 as well.

The Competent Authority on state supervision of the use of GMOs is the Czech Environmental Inspectorate. It co-operates with other state supervision bodies in fulfilling this task.

The Ministry of the Agriculture of the Czech Republic is the Competent Authority under the EC Regulation 1829/2003 on genetically modified food and feed. It also sets down the rules of coexistence.

Approvals

More than 80 institutions are authorised for the contained use of GMOs in the Czech Republic. All contained use notifications so far have concerned class 1 and 2, there are no cases of class 3 nor 4 contained use.

In the growing season 2008 following field trials with GM crops are conducted:

- potatoes with altered starch composition notified by BASF (various modifications, including Amflora potatoes pending in the EU approval process for placing on the market),

- potatoes with modified sugar content notified by the Institute of Experimental Botany, Czech Academy of Science,

- potato with increased resistance to Phytophtora infestans, notified by BASF,

- maize GA21, herbicide tolerant, notified by Syngenta,
- maize NK 603 and hybrid NK603 x MON 810 notified by Monsanto,
- maize 98140, herbicide tolerant, notified by Pioneer,
- flax with various modifications notified by the Czech company Agritec (a small trial for research purposes),
- plum tree with a modification conferring virus-resistance notified by the Crop Research Institute (a small trial for research purposes).

Following the registration of MON 810 varieties into the European seed catalogue this maize was commercially cultivated for the first time on 270 ha in 2005 season. In 2006, the area of GM maize increased up to 1,290 ha, in 2007 it reached 5,000 ha. This year about 8,000 ha is expected. The competent authorities keep lists of the locations where GM maize is grown.

The list of the authorised users and the issued approvals together with the relevant legislation and other information are made available to the public and updated on the website of the Ministry of the Environment, Czech Republic, at the address: www.env.cz.

GERMANY

In Germany the Act amending the Genetic Engineering Act came into effect in April 2008. The act includes a number of changes to the Genetic Engineering Act and to some ordinances based on this act. In addition to these changes, rules of good farming practice have been specified by ordinance, which also came into force in April. Furthermore it is now possible to label food with a label stating "ohne Gentechnik", which can be translated as "not genetically engineered".

The most important changes are:

- some regulatory processes are now made easier through enabling simplified registration and notification conditions for genetic engineering plants and laboratories and the legally binding safeguarding of what are known as "simplified processes" for field trials involving genetically modified organisms.

- In the future safe organisms can be excluded by way of ordinance from the regulations regarding the contained use of GMOs.

- Harvest products that contain small traces of GMOs being tested in the field will be allowed to be used commercially, but not as or in food or feed, but for instance for production of energy.

- The GMO location register, which is open for the public, will contain data about where, when and which genetically modified plants are cultivated in Germany. The Federal Office of Consumer Protection and Food Safety (BVL) collects information about all areas on which genetically modified plants are or will be cultivated. This affects both commercial application and research.

- Rules of good farming practice have been specified by ordinance, which have to be obeyed by farmers using genetically modified organisms. This ordinance provides general rules for all plants and plant products during harvest, transport and storage and specific instructions for specific plant species, starting with gm maize. Here the draft ordinance envisages specific separation distances between fields with GM maize/corn and fields with conventional maize or organic maize as well as the duty to inform neighbours about the planned cultivation of GMOs. The distances are 150m for conventional and 300m for organic maize/corn. Neighbouring farmers may be able to agree on lesser distances between fields with genetically modified and conventional maize than the prescribed 150 or 300 metres. The agreement must be recorded in the public location register.

- If the authorization of a certain GMO contains provisions regarding the protection of specific ecosystems or protected areas, the farmer is obliged to contact the competent authority to ascertain whether these provisions apply for the cultivation area.

Regarding the labelling of food, a new label has been created.

The label "not genetically engineered" can be used if the producer can prove that food made from plants does not contain GMOs and in case of animal products, that the animals have not been fed on genetically engineered feedstuffs.

However, the label allows the use of additives such as enzymes, vitamins, amino acids or vaccines produced by GMOs in exceptional cases. If such additives are used for the production of food or feed, they must be approved by the EU Regulation on Organic Production and Labelling of Organic Products, and it must be ensured that there is no alternative product made without the use of GMOs available.

JAPAN

In accordance with the ratification of the Cartagena Protocol in November 2003, Japan had completed in February 2004, through successful collaboration of six Ministries, to develop three major components of regulatory frameworks. First, the new Act "Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms" came into force. Secondly, "Regulations related to the Enforcement of the Act" and "Guidance for Implementation of Assessment of Adverse Effect on Biological Diversity of Type 1 Use (unconfined use) of LMOs" came into force. Thirdly, national Biosafety Clearing House has been established and functioning in the Ministry of Environment (MoE). The documents of the Act and Regulations are available in the national BCH both in Japanese and English. (http://www.bch.biodic.go.jp/english/e_index.html)

The frameworks also include a system for risk/safety assessment, "Committee of Impact Assessment on Biological Diversity" composed by four sub-Committees (Crops, Forest trees, Aquatic organisms and Microorganisms) and one Integrated Committee. Each Committee is composed by several scientists designated by Ministers of Ministry of Agriculture, Forestry and Fisheries (MAFF) and MoE. Those LMOs of which environmental risk/safety were previously confirmed under the old MAFF Guidelines are also needed to be approved for safety according to the new Act, after the certain interim period during which maximum use of scientific data obtained under the old Guidelines is applicable.

Under the new Act, 97 GM crops and 2 GM trees were approved as of May 2008. They include 30 events for pre-commercialization field trials (rice 17; corn 4; carnation 1; cotton 3; soybean 2; bentgrass 1 and poplar tree 2) and 69 events for commercialization which allow cultivation and/or use as FFPs (alfalfa 3; carnation 5; soybean 5; sugarbeet 1; corn 31; rose 2; oilseed rape 9 and cotton 13). Some dossiers on risk assessment of the approved GM crops are available in the national BCH. As for LMOs under interim measures, there are other 3 GM crops (corn 1; oilseed rape 1 and papaya 1). All of the above applications, from either new or interim framework, have cleared or been receiving sequential reviews of the Biodiversity Impact Assessment.

In May 2007, MAFF initiated to organize a very comprehensive conference on the advancement of R&D for GM crops. In January 2008, this conference completed to compile a list of areas that should be emphasized for advancing R&D and goals for each area, as well as a strategy for promoting such R&D most efficiently and effectively based on analysis of the current situation and issues surrounding R&D of GM crops. In accordance with the report of the conference, we are promoting in strategic and efficient manners the R&D of various GM crops, including multiple disease resistant crops, the resistant crops to unfavorable environment, nutritionally-improved crops and bioremediating plants. We also conduct proactive communication activities in the aim to increase public understanding.

As it was expected that the approved GM crops will actually be cultivated in Japan in not remote future, MAFF started a 5-year research project “Assurance of Safe Use of Genetically Modified Organisms” from 2006. This project intends to develop several technical methods for co-existence, such as “Techniques preventing the dispersals of genes derived from LMO”. In 2007, this project has achieved some outcomes including the selection of a cleistogamous mutant rice line and identification of mutated genes which causes cleistogamy in this line, and the isolation of a gene which could lead to male sterility in brassica species.

The public in Japan still has concerns about LMOs and their products for their potential adverse effects on human health and/or on the environment, even if the GM crops have been officially approved by the national safety framework through science-based assessments. We recognize the importance of activities on the communication with the public on the basis of our experiences on risk analysis procedures.

Therefore, a series of meetings on communication issues and of the opinion surveys for the public have also been conducted in various ways.

Since September 2007, two types of communication meetings have been organized with the participation of more than a dozen or a few hundred participants from public sectors, including farmers and consumers, along with scientific experts. The communication meetings are carried out for increasing public understandings about GM crops through dissemination of easily understandable information and promotion of dialogue among the public. MAFF plans to continuously organize some meetings of a similar framework.

Unintended contamination of transgenes of approved GM crops in conventional crops could occur through cross pollination in the field or accidental mixing during agronomic practices. Further, mass media sometimes reported widely the cases of unintended contamination of unapproved GM crops or materials. We should manage these situations carefully because it could lead to undermine confidence of the public in the safety framework on LMO.

In case where national institutes administered by MAFF conduct the field trials of approved GM crops, "the Guideline for field trials of unconfined (type 1) use" is strictly applied for them in order to promote smooth implementation of the field trials. This Guideline provides measures to prevent unintended crossing between the approved GM crops under test and conventional crops, including the isolation distance between them. Meetings of the Commission governing this Guideline are held regularly to update the contents, on the basis of the latest scientific knowledge on crossing. These involve issues related to co-existence.

Usefulness of the "Consensus Documents" and "BioTrack" has been affirmed in various ways in Japan, especially in improving procedures and dossiers needed for risk/safety assessment and decision making, and in deliberating at related scientific meetings. The Consensus Documents of virus resistance and rice developed by Working Group, and Task Force documents of rice, maize and animal feedstuffs are translated into Japanese and distributed to the related parties in Japan.

KOREA

Implementation of the Cartagena Protocol on Biosafety and Preparation of National Biosafety Frameworks

The Cartagena Biosafety Protocol has taken effects on the transboundary movement of LMO in Korea since January 1, 2008. In order to implement the protocol, there are the law on the transboundary movement of LMO and its enforcement ordinance and regulations, which were prepared before. Last year, an integrated guideline was recorded on the Korean government official gazette.

Following the integrated guideline, umbrella government organizations of the Ministry of Agriculture and Fisheries prepared a few practical guidelines for LMO – FFP and seeds and LMO quarantine.

1) Practical guideline for animal-feed LMO was announced on December 31, 2007, especially, to ensure the approval process of imported-feed LMOs and management after their import by the National Agricultural Products Quality Management Service.

2) Practical guideline for LMO quarantine at the site of national boundary was also prepared by the National Plant Quarantine Service, on December 31, 2007.

3) The National Seed and Variety Service, Ministry of Food, Agriculture, Forestry and Fisheries, prepared also a guideline for LMO intended to be used for seeds on January 7, 2008.

The risk management plan of LMO is currently being prepared, expecting completing by the end of this year. As a part of the preparation, public hearings for the plan will be held about this coming August, 2008. NGOs and environmental activists requested the establishment of LMO management system. The LMO management plan has to be established every five years and its detailed actions plans are supposed to be prepared each year. The National Institute of Environmental Research (NIER), Ministry of Environment, is consulting the potential influence of LMOs on natural eco-system, including imported LMOs-FFP as well as LMO for environmental release. NIER formulated the national framework of LMO environmental risk assessment and management early this year.

Some national contacts of Korean government changed their name due to the recent reshuffling of government structure. We can have the changed names of national contacts on the Korean Biosafety Clearing-House (http://www.biosafety.or.kr) soon after updating relevant information. National competent authority is the Bionano Division, Ministry of Knowledge Economy (telephone+8222110-4766, facsimile+8225039492), which was reformed from Ministry of Commerce, Industries and Energy in the past. Agricultural GMO-related regulations are under the new Ministry of Food, Agriculture, Forestry and Fisheries, which renamed from last Ministry of Agriculture and Forestry, and its umbrella government bodies.

Approval of GMOs for food, feed and processing purpose

So far, a total of 43 LMOs (1 soybean, 24 maizes, 11 cotton, 6 canola, 1 alfalfa) have been approved for agricultural environment safety by RDA. A total of 60 LMOs have been approved for food safety by KFDA including 1 soybean, 28 maizes, 13 cotton, 6 canola, 3 alfalfa, 3 potato and 1 sugar beet.

MEXICO

The Inter-secretarial Commission of Biosafety of Genetically Modified Organisms (CIBIOGEM) has formally established the Social Consultative Council, which is an advisory council for the CIBIOGEM, comprising private, social and productive sectors.

The Mexican Government has published in the Official Federal Gazette two new regulations. On December 2007, the organizational procedures of CIBIOGEM and the rules of organization for its technical and advising committees and councils, and on March 19th 2008, the bylaw for the biosafety law of GMO (http://www.cibiogem.gob.mx/). For this last one there have been 5 lawsuits against its publication, as well as a Constitutional controversy.

Last April the national competent authority has registered several procedures derived from the Biosafety Law of Genetic Modified Organism at the Federal Commission of Regulatory Improvement (COFEMER). From those, nine have been registered and other five are in the amendment process according to the conclusion by COFEMER.

According to the bylaw a first part of an Agreement between the ministries of Environment and Agriculture, called Special Regime for the Protection of Maize**,** was submitted for public consultation at the COFEMER. It received more than 7000 comments and now is under evaluation (http://www.apps.cofemer.gob.mx/cofemerapps/scd_expediente_3.asp?id=12/0846/040408).

These past months**,** Mexico has received 31 applications for environmental release of transgenic crops (http://148.243.71.63/default.asp?id=699). These are 16 for GM cotton events (10 of them are approved, three are in the process of permit emission; and three are under evaluation). Three applications were for soybean events (two are approved, and one is still under evaluation). Seven applications are for alfalfa, all of these are under evaluation. The reports on monitoring insect-pest resistance received from past releases of Bt cotton, have shown no evidence of pest resistance.

There are no new applications yet for permits of experimental release of transgenic maize, even though the bylaw is published.

We have also received ten applications for approval to importation as commodity and use for human consumption as direct food, feed and processing. Three of them for transgenic maize and seven for cotton. They are all under evaluation.

Mexico is also participating in a trilateral technical group along with Canada and the United States, to explore ways to synchronize submission of GM crops, and to share information and experiences in risk analyses.

The National Institute of Ecology GMO detection Lab, has organized a Second national workshop on detection, identification and quantification methods for testing GM material or material suspected to contain GM (http://www.ine.gob.mx/bioseguridad/).

The National Institute of Ecology and SENASICA have organized two national workshops on monitoring of GMOs, aimed to establish a Mexican Network for Monitoring GMOs, which will be coordinated by the Executive Secretariat of the CIBIOGEM (http://www.ine.gob.mx/bioseguridad/).

THE NETHERLANDS

Since the last meeting one of our main concerns has been the preparation of the COPMOP of the Cartagena Protocol, and the COPMOP itself. One of the main issues was liability and redress, which was co-chaired by Mr. Lefeber from the Netherlands, and risk assessment and risk management, where we have also been actively involved.

The COPMOP was very successful from our point of view, reaching good results on all important points, and we are very grateful to Germany for very efficiently organizing this meeting, and for Slovenia, who did an excellent job as President of the EU.

The following scientific reports on risk assessment of GMOs are available through the BIRC of the Cartagena Protocol:

- 'Botanical Files 2003; An exploration of the scientific literature on two aspects of GM crop biosafety: 1) The application of molecular markers to detect gene flow between crops and wild relatives 2) The possibilities of the use of gene function knowledge from *Arabidopsis* to assessing environmental safety of transgenes in GM crops' by Clemens van de Wiel. URL to follow

- 'Novel aspects of the environmental risk assessment of drought-tolerant genetically modified maize and omega-3 fatty acid genetically modified soybean' by P. Schenkelaars. URL of the BIRC record: http://bch.cbd.int/database/record.shtml?id=45858

Reprints of a peer reviewed paper: 'Identification of potentially hazardous human gene products in GMO risk assessment' by Bergmans, H., Logie, C., Van Maanen, K., Hermsen, H, Meredyth, M., Van der Vlugt, C., Environ. Biosafety Res. 7 (2008), 1 – 9, are available through hans.bergmans@rivm.nl.

NORWAY

Revised legislation

Revised regulations on GM food and feed are foreseen to be adopted in 2008/2009. The revision will incorporate EC regulations 1829/2003 and 1830/2003 into Norwegian legislation.

EU Directive on release of GMO's in the environment, 2001/18/EC, was incorporated into the Agreement on the European Economic Area in September 2007. Norwegian legislation was revised in 2005 in order to implement the Directive and the Cartagena Protocol. Norway follows EU procedures regarding health and environmental risk assessment, but in addition Norwegian national GMO legislation includes consideration of ethical issues, benefit to society and sustainable development and these criteria still stand after incorporation and implementation of the directive.

The Norwegian preparations of the national legislation on co-existence issues are at the final stage. The draft regulation will, when completed, be sent on a public hearing. The regulation will include amongst others agronomic measures (e.g. isolation distances, sanitary measures), best practice courses and liability and compensation.

Field trials

We have not received any notifications for field trials in 2008.

CP and BCH

Norway has ratified the Cartagena Protocol on Biosafety and has established a national Biosafety Clearing House Portal.

Key websites

The Norwegian Biosafety Clearing House Portal

http://bch.dirnat.no/hoved.aspx?kontroll=velkommen&spraak=engelsk.

Use of consensus documents

We have used the consensus documents in capacity building to developing countries and as information in national risk assessment of GMOs.

SLOVAK REPUBLIC

Planting Area of GM maize in Slovakia is 1930 hectares in this growing season. It is more than 100% increase comparing to last year. Only varieties derived from MON810 type have been used.

Approved and established were 9 field trials with GM maize, which are modified for tolerance to glyphosate, resistance to *Lepidoptera* and *Diabrotica* pests (corn borer and rootworm) and their combinations. (List of unique identifiers is: MON-88Ø17-3, MON-89Ø34-3, MON-89Ø34-3 x MON-88Ø17-3, DAS-59122-7, MON-ØØ6Ø3-6, DP-Ø9814Ø-6, DP-Ø9814Ø-6 x DAS-Ø15Ø7-1 and DP-Ø9814Ø-6 x DAS-Ø15Ø7-1 x DAS-59122-7).

Amendment of the Act on GMOs was adopted by Slovak Parliament. It comes into force on July 1st. Unfortunately amending the Decree to the mentioned act is in approval process in the present time and it comes into force not earlier as in September.

Biosafety team together with the team of national and foreign experts starts to work on preparing the proposal for the Slovak Biosafety Strategy. The results will be known by the end of this year. It is expected that Strategy will be based on case-by-case principle, without strict expressions.

SWITZERLAND

On 28th of November 2005, a referendum concerning a moratorium of green biotechnology was accepted in Switzerland. Since, the agricultural cultivation of GMO is banned for a period of 5 years, i.e. until 27th of November 2010. This moratorium does not affect, however, field trials nor importation of GM food and feed. They only need authorization by federal agencies.

The Swiss Federal Government, being concerned about potential negative effects of the moratorium on research in biotechnology and biosafety, decided to launch a national research program on use and risks of GM Plants in Switzerland, including hotly debated questions on coexistence. This program is currently under way and will last till the end of 2011.

The research program contains 30 projects on biological, social and legal topics. It includes 2 field trials with GM wheat to study different genes for fungal resistance and one trial with a hybrid of GM wheat and an endemic wild grass to study introgression of transgenes into the wild grass genome. These trials were approved by the Swiss competent authority, which is the federal agency for the environment, in autumn 2007 for a period of three years. Yet they must be conducted in a very hostile environment. At one site near Lake Geneva, work has not yet begun because of plaints from the neighbourhood. At the other site near Zurich, work has well started until in mid June 08 vandals have intruded into the site and damaged some of the experiments. Nevertheless, the applicants have decided to continue the studies.

Even though in 2005 the Federal Government had recommended to voters to reject the moratorium, it recently (May 08) changed its mind and decided to submit to the parliament a proposal for a prolongation of the moratorium by three years until 2013. It hopes by this measure to take some political pressure from the scientists involved in the research program and eventually to dispose of final results from the research program and of a good base for the political discussion.

THE UNITED STATES

Regulatory update for the United States Department of Agriculture

Currently, the USDA-Animal and Plant Health Inspection Service has twelve pending petitions that include glyphosate-tolerant creeping bentgrass, multiple herbicide resistant soybean, altered flower color carnation, high oleic acid soybean, thermostable alpha-amylase corn, papaya ringspot resistant papaya, glyphosate tolerant alfalfa, glyphosate and imidazolinon tolerant corn, glyphosate tolerant cotton, European Corn Borer resistant corn and MIR 601.

Since the October 2007 meeting of the Working Group, 22 permits for environmental release have been granted. Also since October, a total of 786 permits and notifications were received for importation, interstate movement, or release (generally field trials). Of these, 59 are pending, 35 were withdrawn, and two were denied.

(http://www.aphis.usda.gov/help/biotechnology_sitemap.shtml)

Regulatory update for the United States Environmental Protection Agency

Since the October 2007 meeting, EPA registered no new products (http://www.epa.gov/pesticides/biopesticides/pips).

At the last Working Group meeting in October 2007, the availability for comment of an EPA Draft White Paper was announced. In April, 2008, EPA finalized its White Paper recommending withdrawal of the Food and Drug Administration's guidance to test for StarLink corn (73 FR 22715). The final White Paper includes EPA's responses to public comment. EPA concludes that the Cry9C protein has been sufficiently removed from the human food supply to render the level of risk low enough that continued testing for the protein in yellow corn at dry mills and masa production facilities provides no added public health protection. Testing of yellow corn started in 2000 following the detection of illegal residues of StarLink corn in the food supply. The U.S. Food and Drug Administration (FDA) published a Federal Register notice announcing its withdrawal of guidance: "Guidance for Industry on the FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues" in the same April Federal Register issue that EPA's final White Paper was published and also made this known on the FDA website (http://www.cfsan.fda.gov/~lrd/fr080425.html).

ARGENTINA

Commercial release

The latest event approved for commercial release is a stacked Maize: lepidopteran resistant, tolerant to glyphosate and ammonium glufosinate (TC1507 x NK603). With this one, we have already approved 12 GM crops so far (as well as several recombinant veterinary vaccines). These crops are 1 soybean, 9 maize and 2 cotton. Two of the commercial approved maize crops are not longer available. The recombinant vaccines were attenuated Canarypox viral vectors carrying genes coding for immunogenic antigens of several animal viruses.

Other releases (field trials and production of regulated maize seed)

Requiring only first phase approval

In the last trimester of 2007 we have authorized *66 applications including field tests* (GM crops and microorganisms), *counter-season productions of regulated Maize seed* and *GM animals* (bovines producing an insulin precursor in their milk, the later granted at the beginning of 2008).

So far in 2008, we have received *154 applications* (a projection will give that we can expect about 300 applications in 2008). These include *field trials* (113), *counter-season production of regulated maize* (35), *GM microorganisms* (5, animal vaccines based on recombinant antigens) and *GM animal* (1). These applications are already approved or in the process of being approved.

The Pipeline

Twelve GM crops are in the process of review at the second phase of our regulatory system. These are 2 soybean, 7 maize, 1 cotton, 1 rice and 1 potato. The soybean events are tolerant to the herbicide ammonium glufosinate. Interestingly, there are two difficulties which are directly related with the question of the LLP, which is one of the main subjects of this meeting: the first difficulty is that these events are not yet approved in the EU (the main importer of our soybean meal), and the second difficulty, directly related to the question of LLP, will be the unavoidable LLP during a transition period of an eventual asynchrony approval. It is important to realize how the LLP issue has impact on the trade of GM products and therefore on the economy of exporting countries.

Detail of GM materials in second phase

GM materials which have concluded satisfactorily the environmental review process:

- Stacked Cotton (lepidopteran resistant and glyphosate tolerant (MON 1445 x MON 531)
- Stacked Maize (same traits, Bt 11 x GA 21)
- Maize, high Lysine content, food safety approved
- Soybean (2, tolerant to ammonium glufosinate herbicides), food safety approved.

GM materials under review:

- Potato with resistance to PVY (SY230 y SY233)
- Maize resistant to Lepidopteran (MON89034)
- Stacked Maíze: resistant to Lepidopteran, Coleopters and tolerant to glyphosate (MON88017xMON89034).
- Stacked Maize: high Lysine content and lepidopteran resistant
- Stacked Maize: tolerant to glyphosate and to ALS inhibitors herbicides (DP-Ø9814Ø-6 (GAT/HRA).
- Rice tolerant to ammonium glufosinate (LLRice)
- Potato, resistant to PVY.

Prospective pipeline (at first phase stage)

We have observed a variety of very interesting traits at this preliminary stage:

Rice and soybean:

Stress tolerance (several strategies)

Yield improvement (by enhancing nutrient use, photosynthetic rate, modification in the expression of chaperons, with stability effects on certain mRNAs)

Maize:

Yield improvement by the above mechanisms

Insect resistance by mechanisms different from Bt toxins

Wheat:

Drought tolerance

Celebration of Anniversary of our Regulatory Framework

Last year in October we have celebrated the 15th Anniversary of the implementation of the first regulatory framework on GMOs and the 10th Anniversary of the first approval for commercial release of a GM crop. Since 1992, the guidelines have been modified twice, and they are currently in a review process in order to adopt latest advances in the methodology of environmental risk assessment. We expect to achieve this by the end of this year to be in force next year.

Informatics at the Biotechnology Office

We have continued with the incorporation of electronic tools in the administrative work at the regulatory tasks of the Biotechnology Office. The developments so far are:

- a standardized Model of the data
- a module for the electronic submission of application forms
- a workflow routine for the automatic processing of applications
- the database for the registration of applications
- a system for automatic submission of reports
- a register and traceability of information attached to applications
- a system for the automatic submission of approvals, communications with the applicants, email notifications to applicants
- control board for the measurements of processing time and reporting developped an automatic backup for the information

Participation at COP- MOP 4

Argentina has participated as observer (Argentina has signed the Cartagena Protocol but has not ratified it).

FAO Regional Project

FAO has granted funds for a Technical Cooperation Project (TCP 3109, *Desarrollo de Herramientas Técnicas de Referencia para la Gestión de la Bioseguridad en los Países Integrantes del Mercosur Ampliado*) aimed at the development of a Common Biosafety Regulatory Platform for the Mercosur plus Bolivia and Chile. The first organizational meeting was held on January, 2008. The Biotechnology Office is the National Coordinator for Argentina, acting with the other five similar coordinators in a Regional Commission. The Project will have a duration of 18 months. The first documents are currently being discussed: one on Information requirements for Environmental Risk Analysis and other on Molecular Genetics Characterization. A regional meeting will be held shortly in Asuncion, Paraguay.

Biosafety Course (I)

In September 2007, we have held a one week Course on Biosafety, with emphasis in the challenges of the regulation of the new complex phenotypes. The Course received support from the ICGEB and was organized by the ICGEB, the Brazilian Biosafety Association, the Secretariat of Agriculture of Argentina and several other institutions from Brazil and Argentina. Scientists from Italy, Switzerland, the United States, as well as Argentina and Brazil were the Faculty of the Course. As regards to the opinion of the member of the ICGEB attending as speaker and representing the funding party, it was one of the best of its kind organized by them in the last years.

Biosafety Course (II)

During March and April 2008 we have held a three weeks course on Biosafety of Genetically Modified Crops. This is the second year of this activity and we plan to make it every year.

The Course was for professionals (28 participants) from both the public (some in regulatory institutions) and private sector. Participants were local and regional (3 from Brazil, 1 from Cuba, 4 from Paraguay and 1 from Uruguay). Almost all the foreign participants were from regulatory agencies and therefore it was a contribution to the development of regulatory frameworks in the region. The Faculty were local experts in the areas of Agronomy and Molecular Biology related with biosafety of genetically modified crops.

Other Activities

Last April we held, in collaboration with the Embassy of the Netherlands in Argentina, a one day Seminar on both our regulatory systems and on new advances in the development of GM potato crops. Lecturers were scientists from the Netherlands and Argentina, with the participation of The Vice-Ministry of Agriculture of the Netherlands.

International Society of Biosafety Research, Next Symposium

We have just started (last week) to consider a project to hold the next Symposium of the ISBR in Buenos Aires. The Faculty of Agronomy of the University of Buenos Aires would be the host organizer, with help of our Office of Biotechnology and the Secretariat of Agriculture of Argentina.

THE PHILIPPINES

The Country's Registry for approved GM applications:

1. Approval registry for the importation of regulated article for direct use for 28 transformation events and 18 combined trait products;

2. Approval registry for the importation of regulated article for propagation of 3 transformation events and 1 combined trait products;

3. Approval registry for field testing of regulated article.

The country's regulator is undergoing a process of scientific and technical assessment on the following applications with an independent team of Scientific and Technical Review Panel for feed safety of Soybean A2704-12 and Corn MIR 162.

Similarly, there are three field trial applications as follows which are still undergoing a process of scientific and technical assessment:

1. Corn MON89034 Agronomic Equivalency Trial of MON 89034 hybrids with Regulatory Framework in the Philippines for field testing;

2. Corn MON 89034 Field Verification of the Agronomic Performance of Transgenic Corn (Zea mays L) Line 89034 Expressing the Bacillus thuringiensis Cry 1A.105 and Cry2Ab Proteins for Efficacy Against Lepidopterous pests of Corn for field testing;

3. Combined Trait Product Corn: MON89034 X NK603 Expressing the Bacillus thuringiensis Cry1A.105 and Cry2Ab2 Proteins for Efficacy Against Lepidopterous pests of Corn and CP4EPSPS for Tolerance of Roundup Herbicide for field testing.

Applications and supporting documents of Syngenta's Corn Bt 11 and Monsanto's Soybean 40-3-2 were submitted for the renewal of the biosafety permit for direct use which have been approved for direct use both on July 22, 2003. The said applications are currently in the process of scientific and technical assessment. Pursuant to Administrative Order No. 8, the permit for direct use shall be valid for a period of not more than five (5) years and maybe renewed for successive five year periods upon showing by the applicant that the continued importation of the regulated article does not pose any significant risks to human and animal health.

The Department of Agriculture is currently drafting guidelines on Delisting of Approved GM Products for food, feed and processing and studying options for the drafting of guidelines on adventitious presence (or low level presence).

SLOVENIA

Legislation

Contained use of GMOs

In Slovenia, 21 systems for the contained use of GMOs were registered. In total there are 40 systems registered including research laboratories, green houses and industrial research installations.

Deliberate release of GMOs into the environment

Field Trials

Slovenia has still no field trials or commercial growing of GMOs.

Coexistence

Concerning the issue of coexistence a draft of a Slovenian law which was in the process of notification according to EU Directive 98/34/EC got a green light, and the Ministry of Agriculture, Forestry and Food as the leading authority will work on further adoption in the Parliament. The Act lays down the conditions under which genetically modified plants (GMPs) may be cultivated in Slovenia and according to that:

- producers of GMPs must ensure that heads of agricultural holdings or owners of land located in a specific area around an individual piece of land or area (the buffer zone) in which GMPs are to be cultivated are informed in advance of their intention and they agree to it;

- such a producer must be also familiar with the legislation governing the management of GMOs and the traceability of GMOs in agricultural plants, products and processed products, and be aware of the possible consequences that a certain type of management of GMOs and their products could have for other producers' plants or products;

- producer must carry out at least those measures to prevent the adventitious presence of GM plants in other agricultural plants and products.

The Act also allows heads of agricultural holdings to establish, on a voluntary basis (i.e. by written agreement), an area for GM plants cultivation or area in which GM plants will not be cultivated.

The Act also ensures that information on GM plants cultivation will be public;

A monitoring system is planned for supervision of the coexistence of genetically modified and other crops in Slovenia.

Monitoring of GMO in food, feeds and seeds on the market

Slovenia published the results of the regular GMO monitoring in 2007 on food, feed and seed on the market performed by the Ministry of Health, Ministry of Agriculture and Ministry for the Environment. Comprehensive data and results are available on the web pages of the responsible ministries[1] and also on the Slovenian Biosafety Portal[2].

In this respect, 91 samples of foods on the Slovenian market were taken to determine the frequency of the GMO presence. The food samples origin in 21 % from Slovenia, 44 % from EU and 34 % from the rest of the world. The monitoring showed very low frequency of the GMOs presence in foods with regard to 5.5

% of positive results in a products based on RR authorised soy. In all cases the presence of GMOs was proved as technically unavoidable.

Additionally, 34 samples of feedstuffs were taken to monitor and control the GMO presence on the Slovenian market, and RR approved soy was the most frequently present GMO on the market.

In 2007 the Inspectorate of the Republic of Slovenia for Agriculture, Forestry and Food took 22 samples of seed. The survey of the presence of GMOs in non-GM seed varieties for sowing showed presence of GMOs at the limit of detection (<0.1%) in one sample of maize among 15 samples taken. Operator voluntarily decided to withdraw this lot of maize seed from the Slovenian market. On the other hand, there was no detected presence of GMOs in seed of oilseed rape and soy.

[1] http://www.mz.gov.si/, http://www.mkgp.gov.si/, and http://www.mop.gov.si/

[2] http://www.biotechnology-gmo.gov.si/

ANNEX IV

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