GMOs (Control of Release) Expert Group

Confirmed Minutes of the 1st Meeting

Date : 5 July 2011 (Tuesday)

Time : 2:30 p.m.

Venue : Room 701, Agriculture, Fisheries and Conservation Department, 7/F, Cheung Sha Wan Government Offices, 303 Cheung Sha Wan Road, Kowloon

ATTENDANCE

Chairman

Professor WONG Woon-chung Jonathan

Members

Professor CHU Ka-hou

Professor HO Kwok-keung Walter

Dr. LAU Lok-ting Terence

Ms. LAU Yuen-yee Vicky

Dr. LEUNG Mei-yee Kenneth

Dr. LEUNG Sze-lun Alan

Mr. SO Kwok-yin Ken

Professor SUN Sai-ming Samuel

Dr. TSE Tin-yau Anthony

Mr. WONG Hing-keung

Ms. WONG Lai-yin Idy

Mr. LAY Chik-chuen	Assistant Director (Conservation), Agriculture, Fisheries and Conservation Department (AFCD)
Ms. LI Chim-wing Vivien	Senior Administrative Officer (Nature Conservation), Environmental Protection Department
Dr. TO May-kei Liza	Principal Medical and Health Officer, Department of Health

Secretary

Ms. TSANG Yu-man	Conservation Officer (Biodiversity) 3,AFCD

IN ATTENDANCE

AFCD

Mr. CHAN Kin-fung Simon	Senior Conservation Officer (Biodiversity), AFCD
Dr. SHIH Chun-hat Rex	Conservation Officer (Biodiversity) 4, AFCD

Department of Health

Ms. WONG Wai-wai Grace	Senior Pharmacist (Acting), Department of Health

ABSENT WITH APOLOGIES

Dr. MAN Chi-sum

OPENING REMARKS BY THE CHAIRMAN

1. The Chairman welcomed all to the first meeting of the Genetically Modified Organisms (Control of Release) Expert Group (the Expert Group).

2. The Chairman introduced the Terms of Reference of the Expert Group.

3. The Chairman informed members that, as an established practice, to facilitate the taking of meeting minutes, sound recording would be made during the meeting. The audio records would be destroyed after the meeting minutes had been confirmed.

AGENDA ITEMS

I. Declaration of Interests and Transparency Measures

4. The Chairman invited Mr. Simon CHAN to brief members on the arrangement of declaration of interests and transparency measures to be adopted by the Expert Group.

II. Overview on the Genetically Modified Organisms (Control of Release) Ordinance, Cap. 607

5. The Chairman invited Mr. Simon CHAN to brief members on the Genetically Modified Organisms (Control of Release) Ordinance, Cap.607 (the Ordinance) including the objectives of the legislation, control regime of the Ordinance and guidelines for genetically modified organisms (GMOs) approval application and documentation requirements.

6. In response to a member's enquiry on whether the risk assessment should be carried out by authorized institutions, Mr. Simon CHAN said that the Ordinance did not specify that risk assessment shall be conducted by any particular institution. On the other hand, the Ordinance had laid down some general principles for the risk assessment of GMOs. The applicant should follow those principles when undertaking the risk assessment. The Chairman asked whether the risk assessment should be carried out by a third party. Mr. C.C. LAY said that the applicant could carry out the risk assessment by himself or employ a third party to undertake such assessment. AFCD would vet the approval application together with the risk assessment report in accordance with the relevant requirements and principles laid down under the Ordinance, and would seek advice from the Expert Group when necessary.

7. Upon a member's enquiry, Mr. C.C. LAY said that a field trial in an open field was regarded as a release of GMO into the environment and would require prior approval. The applicant should provide in the risk assessment report that effective measures would be taken so that the potential biosafety impact to the environment was acceptable or manageable. Currently, there were GMOs approved for release into environment in other overseas countries. Hence the applicant could make reference to the overseas risk assessment reports in the approval application.

8. The member further asked whether only risk assessment done by overseas institutions would be accepted in the application. Mr. C.C. LAY replied that AFCD would vet the approval application together with the risk assessment report to ensure that they fulfil the requirements and principles laid down under the Ordinance. Thus, the evaluation of the application would be focused mainly on the contents of the report rather than requiring the risk assessment to be conducted by overseas institutions.

9. A member asked about the applicability of overseas risk assessment in Hong

Kong in view of the differences in environmental conditions. The member also asked whether the Expert Group would be given sufficient information in considering the risk assessment reports. Mr. C.C. LAY said that there were currently over 190 and 160 Parties to the Convention on Biological Diversity (the Convention) and the Cartagena Protocol on Biosafety (the Protocol) respectively. Therefore, AFCD and the Expert Group could make reference to the experience from other countries when considering the GMO approval application. In evaluating the risk assessment report, local conditions (e.g. local biodiversity, presence of close relatives and potential of gene contamination in Hong Kong) would be taken into account.

10. The Chairman recapitulated that the role of the Expert Group was to give recommendations to the Director of Agriculture, Fisheries and Conservation (the Director) on the potential biosafety impacts of individual GMO approval applications. In case the Expert Group found that the information provided by the applicant was insufficient to draw a conclusion for the approval application, the Expert Group might ask for additional information to better evaluate the risk assessment.

11. Dr. Liza TO enquired whether the Ordinance covered the risks of GMOs to human health. Dr. Liza TO reminded that the Cartagena Protocol and the risk assessment requirements mentioned about the adverse effects on biological diversity, taking also into account risks to human health. However, the information provided in the risk assessment papers did not include assessment to risks on human health. Mr. Simon CHAN clarified that under the Cartagena Protocol, the risks to human health were considered as indirect impact from the adverse effects of the GMOs on biological diversity. In addition, the direct risks of GMOs to human health were regulated by other international organizations such as the World Health Organization and the Codex Alimentarius Commission. The objectives of the Ordinance were to control the handling and use of GMOs that may have adverse effects on the conservation of biological diversity in Hong Kong but not direct risks of GMOs to human health.

12. In response to a member's enquiry on whether the safety of GM food was regulated by the Ordinance, Mr. C.C. LAY clarified that it had been clearly pointed out in the Bills Committee during the drafting of the Ordinance and consultation with the relevant advisory bodies including the Advisory Council on Food and Environmental Hygiene that the Ordinance was not related to food safety or labelling of GM food.

13. With regard to the risks of GMOs to human health, a member asked whether the Ordinance controlled GM pharmaceutical products which could cause allergy to human. Mr. C.C. LAY said that the Protocol did not apply to GMOs which are pharmaceuticals for humans. Besides, all GM pharmaceutical products for use by human beings in Hong Kong should be registered with the Department of Health. As they were for human use, these products were excluded from control under the Ordinance.

14. A member said that some GM pharmaceutical products for use by human beings (e.g. asthma sprays) might spread into the environment through air transmission. This might impose adverse impacts on the local wildlife. Mr. C.C. LAY emphasized again that all GM pharmaceutical products for use by human beings were excluded from control under the Ordinance. Nevertheless, he pointed out that AFCD would liaise with the Department of Health on the registration of GM pharmaceutical products for use by human beings in case they were found to impose adverse biosafety impact to local environment.

15. A member asked if there were any new development on the human health issues of GMOs in the recent Meeting of the Parties (MOP) to the Protocol. Mr. Simon CHAN said that the drafting of the current legislation followed the Protocol and the decisions of MOPs as well as the guidelines issued by IUCN ("An Explanatory Guide to the Cartagena Protocol on Biosafety"). The Parties to the Protocol reached a consensus in 2003 that the direct risks of GMOs to human health were outside the scope of the Protocol.

16. The Chairman clarified that the objectives of the Ordinance were to conserve the local biodiversity from the potential adverse impacts of GMOs. Direct human health impacts from GMOs were therefore not regulated under the current legislation. The Chairman also requested AFCD to provide members with the soft copies of "An Explanatory Guide to the Cartagena Protocol on Biosafety" after the meeting.

[Post-meeting note: The soft copies of "An Explanatory Guide to the Cartagena Protocol on Biosafety" were distributed to members on 5 September 2011.]

III. Vetting Criteria for Approval of Genetically Modified Organisms

(Discussion Paper: GMO/01/2011)

17. The Chairman invited Mr. Simon CHAN to brief members on the paper.

18. In response to the enquiry of the Chairman, Mr. Simon CHAN explained that the proposed vetting criteria were drawn up based on the requirements of the risk assessment laid down under the Protocol and with reference to the existing vetting criteria adopted in overseas countries such as the European Union and Japan.

19. With regard to the vetting criterion point (e) the acceptability of the risk to the local environment, a member pointed out that "Risk-Benefit Analysis" was carried out in Europe and US to assess the acceptability of GMOs intended for release into the environment to the general public and key stakeholders. Generally, public consultation would be conducted and feedback and comments from the key stakeholders would be collected. The risk-benefit analysis played a key role in the risk assessment of GMOs. He wondered whether the risk-benefit analysis should also be one of the vetting criteria. The member added that the objectives of the risk assessment report were firstly to provide objective and scientific data to help AFCD and the Expert Group to make the decision, and secondly to build up public trust. Hence, the risk assessment should be transparent and involve public participation. Mr. Simon CHAN said that public consultation and focus group meetings with key stakeholders had been conducted throughout the whole legislative process of the Ordinance. A member further enquired whether there would be public consultation for each approval application under the Ordinance as there was public inspection period during the process of GMO approval application in overseas countries. The member also remarked that public comments could be discussed in the Expert Group meeting. A member said that the Environmental Impact Assessment (EIA) Ordinance had a 60-day public inspection period for the EIA report of a designated project and opined that AFCD might also consider collecting public views on the GMO approval application in a similar way. Mr. C.C. LAY replied that AFCD would collect the views of the public through different channels especially for cases involving public interest.

20. A member suggested that AFCD should provide the Expert Group with the definition of "acceptability of the risk to the local environment" when vetting the approval applications. The member also added that once AFCD and the Expert Group made up the decision on the risk assessment of a particular GMO, all relevant information on the decision should be uploaded onto the GMOs Register for public access. Mr. Simon CHAN responded that the relevant papers and notes of meeting of the Expert Group would be made available to the public in the online GMOs Register.

21. A member said that the qualifications and the impartiality of the organization carrying out the risk assessment should be included in the proposed vetting criteria. Mr. C.C. LAY explained that AFCD would evaluate the risk assessment report against the proposed vetting criteria. The qualifications of the organization would also be considered during the evaluation. AFCD would provide recommendation on the risk assessment report to the Expert Group for their consideration.

22. Upon a member's enquiry on if the manageability of risks would be one of the requirements in the risk assessment report, Mr. C.C. LAY pointed out that the risk assessment report should provide scientifically sound and practical strategies to manage the potential risks of GMOs intended for the release into the environment. AFCD also noticed that, with the enactment of Ordinance, the local tertiary institutions had better managed the risks associated with GMOs for contained uses in terms of improvement in containment measures in greenhouses and laboratories to avoid accidental release of GMOs into the environment. Mr. Simon CHAN added that AFCD could attach appropriate conditions to the approval of GMOs for release into the environment. If the applicant contravenes any of these conditions, AFCD could revoke the approval. The Chairman added that the manageability of risks was one of the proposed vetting criteria.

23. A member asked whether the practicability and the difficulty of enforcement would be considered when vetting the application of GMO approval. Mr. C.C. LAY said that the practicability and the difficulty of enforcement would not affect the decision on the approval application. The application would be vetted in an objective and scientific manner. The Chairman said that the GMO approval application would be vetted according to the proposed criteria which were objective and scientific. He also added that the role of the Expert Group was to provide comments under the Ordinance on a scientific basis.

23. A member cited the relevant legislation in China which required the applicant to provide all the past approval documents, such as the approved test results of pilot-scale and full-scale production tests of the application of a GMO before it was approved for release into the environment. The member asked whether the applicant was required to submit these documents. Mr. Simon CHAN explained that the mentioned mechanism in China was applicable to the application of new GMOs for release into the environment. Under the Ordinance, the applicant could provide all relevant documents such as previous field trial studies, in the risk assessment report to support the approval application.

25. The Chairman concluded that the Expert Group would adopt the proposed criteria in vetting GMO approval application. Further amendments to the vetting criteria could be made in the future when need arose.

IV. Risk Assessment and Disposal of Live Recombinant Veterinary Vaccines
(Discussion Paper: GMO/02/2011)

26. The Chairman invited Dr. Rex SHIH to take members through the paper.

27. A member asked whether the assessments of some vaccines were omitted in the part of "donor organism" in the discussion paper (GMO/02/2011). Dr. Rex SHIH explained that the paper had listed out all donor organisms associated with the named vaccines but some vaccines might not have donor organisms.

28. A member commented that there were a wide variety of recombinant vaccines available in the market. The hosts of these vaccines also occurred naturally in the environment. The member said that the potential biosafety risk from shedding when large doses of new recombinant veterinary vaccines were used in poultry and pig farms should have already been thoroughly considered when the vaccines were developed in overseas countries. Therefore, the use of such vaccines should be pretty safe in general. On the other hand, if new vaccines could be imported by any veterinary surgeons without registration, there might be a risk if the vaccines were used in large amount. Ms. Grace WONG said that large quantities of unregistered veterinary vaccines could not be available for use by local veterinary surgeons because all pharmaceutical products including vaccines must be registered with the Pharmacy and Poisons Board before they could be legally sold. For unregistered veterinary vaccine, it could be imported for the purpose of treatment by a registered veterinary surgeon of a particular animal only.

29. Dr. Liza TO said that according to EPD's regulations, unused live recombinant veterinary vaccines should be handled as clinical wastes and should be disposed of by incineration Mr. C.C. LAY pointed out that any dead vaccines were not considered as GMOs and incineration would destroy any live recombinant veterinary vaccines, and therefore there would not be any biosafety concern.

30. In response to the enquiry of a member on the risk management of potential veterinary vaccines which had adverse biosafety impacts but were exempted, Mr.

Simon CHAN replied that the use of live recombinant veterinary vaccines was regulated by relevant authorities in overseas countries. They were confirmed to be safe for use before commercialization. A member commented that Hong Kong should not surrender the protection of our biosafety to other countries' regulatory mechanisms for commercialization of GM vaccines. Another member said that application of live recombinant veterinary vaccines was subject to various international guidelines, and the risk to the use of such vaccines was very low. Nevertheless, there might be development of live recombinant veterinary vaccines using new vectors which might have potential effect on biodiversity. Mr. Simon CHAN responded that while Hong Kong had its own regulatory mechanism on GM vaccines, AFCD would make reference to risk assessment of GM vaccines available from overseas countries. Besides, AFCD would keep in view the development of live recombinant veterinary vaccines.

31. Upon the Chairman's enquiry on the reasons for the exemptions of all live recombinant veterinary vaccines, Mr. Simon CHAN responded that the discussion paper (GMO/02/2011) provided an overview of the potential biosafety risks of 16 strains of commercially available live recombinant veterinary vaccines to be used on pets and poultry. The risk assessment concluded that the potential risk of the live recombinant veterinary vaccines to local biodiversity was very low. Live recombinant veterinary vaccines were modified by modern biotechnology by largely identical methods and of similar properties, and various similar strains of live recombinant veterinary vaccines had been developed and approved for use in China and other countries. Also, it was necessary to cater for the need of application of veterinary vaccines in emergency situations. Taking into account the similar structures, modification methods and biosafety risks posed by live recombinant veterinary vaccines, it was recommended to grant exemption to all live recombinant veterinary vaccines from the application of section 5 (restriction on release into the environment and maintenance of lives of GMOs) and 7 (restriction on import of GMOs intended for release into environment) of the Ordinance, provided that the live recombinant veterinary vaccines were registered with the Pharmacy and Poisons Board, or imported/administrated for the purpose of treatment by a registered veterinary surgeon of a particular animal. Mr. Simon CHAN added that currently no live recombinant veterinary vaccines were registered in Hong Kong. AFCD would be consulted if there was any application for registration of live recombinant veterinary vaccine under the Pharmacy and Poisons Ordinance Cap. 138.

32. Mr. C.C. LAY supplemented that without the exemption, it might take as long as

270 days to make a decision on the approval application for import of the vaccines under the Ordinance. It was thus impossible to cater for the need of use of such vaccines under emergency circumstances.

33. Upon a member's enquiry, Mr. Simon CHAN said that other overseas countries such as the European Union had granted exemption to all live recombinant veterinary vaccines from approval application considering their low risk posed to the biodiversity and the necessity to cater for application in emergency situations.

34. A member asked if the proposed exemption would only be applied to those vaccines approved by the Parties to the Protocol. Mr. C.C. LAY responded that non-Parties to the Protocol should also comply with the legal or regulatory requirements on the import and export of GMOs to/from Parties. Therefore, the vaccines produced by these non-Parties such as US and Canada would also be covered.

35. Dr. Liza TO considered the two conditions for the proposed exemption, i.e. (1) the live recombinant veterinary vaccines were registered with the Pharmacy and Poisons Board, or (2) imported/administrated for the purpose of treatment by a registered veterinary surgeon of a particular animal, were not relevant to the proposed exemption. Dr. Liza TO clarified that Department of Health regulated pharmaceutical products under Cap. 138 for the purpose of human safety, but Department of Health did not have the legal power or the expertise to regulate the impact on biosafety or the environment. The pharmaceutical product's effect on biodiversity or the environment was under the control of Cap. 607. A pharmaceutical product should fulfil the requirements of both Cap. 138 and Cap. 607. Dr. Liza TO added that AFCD should consider establishing an emergency vetting mechanism under the Ordinance or formulating contingency plans on the use of unapproved veterinary vaccines in emergency situations. Mr. C.C. LAY responded that the two Ordinances would operate within their respective jurisdictions in an independent manner, but that the proposed exemption conditions would avoid a potential dilemma when AFCD approved the import of certain live recombinant veterinary vaccines and the Department of Health disapproved the registration or uses of those vaccines. He added that the risk assessment on the live recombinant veterinary vaccines had indicated that the possible adverse effect of the vaccines on the conservation of biodiversity in the local environment was very low. Hence, AFCD considered the proposed exemption would be a proper strategy on risk management of the use of live recombinant veterinary vaccines under emergency situations.

36. Dr. Liza TO pointed out that paragraph 12 of the discussion paper (GMO/02/2011) stated that "*Considering the above, it is recommended to grant exemption to live recombinant veterinary vaccines from the application of section 5 and 7 of the Ordinance, provided that the live recombinant veterinary vaccines are registered with the Pharmacy and Poisons Board, or imported/ administered for the purpose of treatment by a registered veterinary surgeon of a particular animal.*" Dr. Liza TO requested that the paragraph be revised to clearly to state that the Pharmacy and Poisons Ordinance (Cap. 138) did not regulate the biosafety effects of the live recombinant veterinary vaccines. Mr. C.C. LAY pointed out that it was clear from the paper that the two ordinances (i.e. Cap. 138 and Cap.607) had different scopes and biosafety was within the ambit of Cap. 607, and would not cause confusion. Nevertheless, Dr. Liza TO's comments would be duly recorded in the minutes of meeting.

37. Ms. Grace WONG said that the registration criteria of pharmaceutical products and vaccines included consideration of their safety, quality and efficacy. Therefore, a pharmaceutical product applying for registration would not be refused purely on the ground of its potential adverse impacts to the local biological diversity. Mr. C.C. LAY pointed out that it was very clear that vaccines were regulated by the Department of Health from the aspect of human health while the potential biosafety impacts of live recombinant veterinary vaccines were overseen by AFCD. The two Ordinances (i.e. Cap.138 and Cap.607) had different scopes and would be administered independently under their respective ambits. He reiterated that the biosafety impacts from shredding of live recombinant veterinary vaccines would be low and manageable because the registered vaccines could only be applied to a particular animal or be used in poultry farms under the monitoring of AFCD. The exemption had strived a balance between the potential biosafety effect to the local biodiversity and the necessity to cater for the need of application of veterinary vaccines in emergency situations. Having considered the above, it was considered that the proposed conditions for the exemption, that is, the live recombinant veterinary vaccines were registered with the Pharmacy and Poisons Board, or imported/administered for the purpose of treatment by a registered veterinary surgeon of a particular animal, might not necessarily be included in the proposed exemption.

38. A member enquired about the notification to the Director in case of release of exempted GMOs into the environment under section 6 (Notification to Director of certain release of GMOs) of the Ordinance. Mr. Simon CHAN confirmed that, under

section 6, the person who had control of a GMO had to inform the Director by a written notice of the release if a GMO had been released into the environment and the GMO was not exempted/approved, or was exempted but any condition for the exemption of the GMO had not been complied with.

39. In response to the enquiry of a member, Mr. Simon CHAN said that the Director might refer any question in connection with the administration of the Ordinance including the granting of exemption to the Expert Group for advice. The Expert Group would be consulted for any proposed exemption.

40. A member recommended that AFCD could keep an inventory of imported live recombinant veterinary vaccines for reviewing the exemption. The member suggested that the exempted vaccines should be reviewed from time to time and the exemption be revoked if it was found to have adverse biosafety impacts to the local biodiversity. Mr. C.C. LAY said that AFCD would keep in view of the legislative development and management of GM vaccines in other countries as well as their biosafety effects on the local environment. He added that the review of the exemption of recombinant vaccines could be done every three years and the Expert Group would be informed of the progress of the review regularly.

41. A member suggested that AFCD could establish a monitoring mechanism and keep record of imports of new vaccines once exemption was granted. Mr. C.C. LAY pointed out that it would be difficult to trace small-scale use of vaccines. On the other hand, when the vaccines were used in large scale, AFCD would be able to monitor the use. Mr. Simon Chan added that, for treatment on a particular animal by a registered veterinary surgeon, import licence issued under the Import and Export Ordinance was required. Ms. Grace WONG said that the Department of Health has records of import and export of registered or unregistered pharmaceutical products imported for the purposes of treatment of named patients. The Chairman suggested that a notification mechanism for sharing information on imported veterinary vaccines could be considered.

42. Having considered the deliberations above, the Chairman asked for views of the non-official members on the proposed exemption of live recombinant veterinary vaccines. Two members expressed reservation on the proposed exemption while other members supported the proposed exemption. The Chairman concluded that the Expert Group supported the recommendation of the paper to exempt live recombinant veterinary vaccines from the application of section 5 and section 7 of the Ordinance.

However, the proposed exemption conditions would not be included in view of the comments given by the Department of Health. On the other hand, AFCD should continue to monitor the latest progress and development of live recombinant veterinary vaccines and carry out a review of the exemption of live recombinant veterinary vaccines in a three years' time for reporting to the Expert Group

(Dr. Walter HO left the meeting at 4:30 p.m. and Mr. H.K. Wong left the meeting at 4:45 p.m.)

V. Risk Assessment and Disposal of Genetically Modified Papayas

(Discussion Paper: GMO/03/2011)

43. The Chairman invited Dr. Rex SHIH to take members through the paper.

44. Mr. C.C. LAY pointed out that papaya was exotic to Hong Kong and was a monotypic species. Members agreed that the potential of gene flow from GM papaya to its wild relatives did not exist in Hong Kong given no native species of the Family Caricaceae were known to occur in Hong Kong.

45. A member said that an experiment of GM papaya undertaken in China showed an increase of gene expression in soil microorganisms. He said more research could be done to ascertain the nature of such changes. Mr. Simon CHAN responded that according to literature the potential of horizontal gene transfer was very low and it would take place naturally even in the absence of GM papayas. A member added that the transgenes obtained from microorganisms were already widely present in the soil microorganisms.

46. A member asked about the potential gene transfer between different GM varieties of papayas. Another member said that even gene transfer occurred between different GM varieties of papayas and produced new varieties of transgenic papayas, they were produced under the same mechanism and therefore the risk factor would be the same.

47. A member asked if GM papayas would become a weedy plant because papaya plants, probably resulted from dispersal by wild birds, were found in his farm. Another member asked if there was any local information on the dispersal of GM papayas by wild birds. A member also asked if there was potential of GM papayas to become weedy species. Mr. C.C. LAY replied that the potential of GM papayas to

become a weedy plant was very low. The papaya plants were currently found in places with human management, such as backyards of village houses. Besides, GM papayas were domesticated plants confined to farmlands and they were unlikely to compete with other local species for space and nutrients in the natural environment. The potential for GM papayas to become a weedy plant, like *Mikania micrantha*, and invade the local biodiversity was very low. Mr. Simon CHAN added that GM papayas were less competitive than other local plant species. GM papayas had existed in Hong Kong for years, however no evidence of invasion of GM papayas in the countryside areas was found so far.

48. Upon a member's enquiry on the risk of GM papayas to agricultural biodiversity, Mr. C.C. LAY explained as papaya was an introduced species and no native species in the same family of papaya occurred locally, growing GM papayas would not affect the local agricultural biodiversity. The member added that papayas had been cultivated in the southern part of China for several hundred years, and different varieties might have been developed to suit local climatic and environmental conditions. The exemption of GM papayas would jeopardize the local agricultural biodiversity of papayas. The member further proposed to include the risk to the agricultural biodiversity in the risk assessment report. Mr. Simon CHAN said that agricultural biodiversity was part of biodiversity and as such the risk assessment would take it into account as well.

49. A member asked about the potential of vertical gene transfer as mentioned in the consensus document on the biosafety regulation of papaya published by the Organization for Economic Cooperation and Development. Mr. Simon CHAN said that there was potential gene contamination on non-GM papayas from GM papayas. However, the Ordinance was to conserve the local biodiversity but not cross contamination of exotic species. The control regime and requirements as set in the Ordinance were in line with overseas regulations relevant to the implementation of the Protocol.

50. In response to the enquiry of a member on other overseas risk assessments done on GM papayas, Mr. Simon CHAN responded that GM papayas were approved for commercial cultivation in Hawaii while a recent risk assessment report on GM papayas carried out in Australia also showed low biosafety impacts of GM papaya to the environment. A member added that the Japanese government had also approved the import of GM papayas from Hawaii recently.

51. Upon a member's enquiry on the survey results of GM papayas, Mr. Simon CHAN said that about 30% of imported papaya fruits from the local markets and about 50% of the home-grown/locally produced papayas were found to be genetically modified.

52. The member further enquired about the commercialization of GM papayas approved for field trials in China. The member did not agree with the exemption of the varieties for field trials as they had not been approved for commercial production. On the other hand, such varieties might have already been present in the local market. Mr. Simon CHAN said that at present two varieties named ZS1 and ZS2 were known to be approved for field trial in China only. A member explained that the commercial production of GM papayas in China would be approved once the GM papayas complied with the requirements for field trials, environmental safety and food safety. A GM variety that was not approved for commercial production might be out of the consideration of its safety, but due to many other reasons, such as the lack of funding for further trials. On the other hand, it demonstrated that the regulation on GM crops was very stringent in China.

53. In response to the proposal from a member to grant exemption only to the GM papayas which were approved for commercial production, a member said that currently there were only three established mechanisms to produce transgenic papayas. Hence the biosafety impacts of approved and unapproved GM papayas would be similar.

54. Upon a member's enquiry on the exemption from the application of section 7 of the Ordinance, Mr. Simon CHAN explained that the import of GM seeds intended for cultivation in local environment would require prior approval from the Director. However, the approval application was not applicable to GM seeds imported for contained uses (e.g. greenhouse or laboratories).

55. The member further proposed to set an exemption period (e.g. 2 years) on GM papayas as GM papayas were not for commercial production and there was no emergency reason for the exemption. Mr. C.C. LAY suggested the review of exemption to be done every three years and AFCD would carry out market surveys and analysis on the varieties of transgenic papayas available in the territory. The exemption would be reviewed if other potential adverse impacts on the local biodiversity which were not presented in the current discussion paper were observed.

56. A member suggested that AFCD should carry out a baseline survey of distribution of GM papaya plants in Hong Kong. Another member added that the survey should identify the varieties of GM papayas planted in Hong Kong.

57. A member suggested protecting local organic farming of non-GM papayas in view of the potential of cross contamination to local non-GM papayas. On the other hand, another member suggested raising the public awareness on the Ordinance as one of the conditions for exemption. Mr. C.C. LAY explained that protection of organic farming in relation to papaya cultivation in Hong Kong was not under the ambit of the Ordinance. Nonetheless, AFCD would step up education work on GMOs and the potential misuse of seeds from imported GM fruits for cultivation to prevent planting of unapproved GM crops and contravening the Ordinance. He also explained that any conditions to be imposed on the exemption of GM papayas should be based on the potential biosafety effects to the environment.

58. Having considered the deliberations above, the Chairman asked the non-official members to indicate their stance on the proposed exemption of GM papayas. A member expressed reservation on the proposed exemption while another member did not express his view. Other members supported the proposed exemption. The Chairman then concluded that the Expert Group supported the recommendation of the paper to exempt GM papayas from the application of section 5 and section 7 of the Ordinance. AFCD should continue to monitor the latest progress and development of GM papayas and carry out a review of the exemption of GM papayas in a three years' time for reporting to the Expert Group. Besides, AFCD should carry out a survey on the distribution profile of GM papaya in the territory. The Expert Group also recommended that AFCD and other relevant bodies should step up publicity on GM crops and organic farming to both the general public and the stakeholders.

59. Mr. C.C. LAY said that AFCD had conducted detailed risk assessments on GM papaya and live recombinant veterinary vaccines and duly considered the implications of the proposed exemptions. He pointed out that AFCD would continue to keep in view the latest progress and development of GMOs and the Expert Group would be sought for its advice as needed. As regards the recommendation to step up publicity on organic farming and non-GM papaya, AFCD would explore with the relevant parties on possible ways to raise public awareness on organic farming and planting of non-GM papaya in the territory.

(Mr. Ken SO left the meeting at 6:10 p.m. Dr. Liza TO and Ms. Grace WONG left the meeting at 6:50 p.m.)

VI. Any Other Business

Adventitious Threshold

60. A member asked about the basis for setting a zero tolerance for GMOs intended for release into the environment. Mr. Simon CHAN explained that the adventitious threshold for GMOs intended for local release was set at zero to ensure no adverse biosafety impacts would be imposed on the local biodiversity as a result of accidental release of unapproved GMOs. The detection limit for GMO testing was 0.1% which could be used as reference for the level of zero tolerance. The member added that ISO had a guideline on the sampling size required for testing of GMOs.

GM Aquarium Fish

61. A member asked if GM aquarium fish being kept in tanks would be considered as contained uses. The Chairman said the issue could be discussed in the next meeting.

VII. Date of Next Meeting

62. The Chairman said the members would be informed of the meeting date in due course.

63. The meeting adjourned at 7:40 p.m.

- END -