LIVING MODIFIED ORGANISMS AND THE ENVIRONMENT

AN INTERNATIONAL CONFERENCE

Final Rapporteurs' Report

INTRODUCTION

1. This report has been produced by the co-rapporteurs—Calestous Juma, Audia Barnett, and Iain Gillespie. It represents their personal interpretation of the key issues brought out in the conference. This final version has benefited from comments made by participants to the Conference over the following six weeks. The decision to incorporate specific comments in the text has been the sole responsibility of the three rapporteurs.

2. The objective of the Conference was to bring together a diverse group of participants for a constructive dialogue on the underlying science for assessing living modified organisms (LMOs) in the environment. The emphasis was on transgenic crops because these are the most common applications at the current time. However, other applications were also considered, such as the use of transgenic trees in forestry and fish in aquaculture. The conference promoted a dialogue between developed and developing countries in order to identify unique assessment needs and experiences of different countries and regions. The Conference was attended by around 250 participants from some 20 OECD countries and around 25 non-OECD countries drawn from government, industry, academia and civil society.

3. The conference was chaired initially by Rita Colwell and in the later stages by Calestous Juma and sought answers to four general questions:

- What are the current trends and future prospects for applications of LMOs and what are the potential benefits and risks.
- What are the current scientific data, information and hypotheses underlying the assessment of LMOs in the environment.
- What are the particular issues with respect to the environmental assessment of transgenic crops and what are the similarities or differences between environmental assessments conducted on transgenic crops and other types of LMOs.
- What future work on scientific environmental assessment is necessary.

4. In opening the conference, Dr Colwell emphasised the value of a broad inclusive dialogue between countries. Science needs to refocus from enabling remediation and amelioration and do more to support prediction and prevention.

5. Accurate, accessible and high quality data and information could help create knowledge and development. Notwithstanding recent concerns about misuse of biological data, the clock must not be turned back on exchanging knowledge and information. On the contrary, science can elucidate our times and contribute to the further development of our world, but the scientific community clearly needs to do more to bring this message of promise to a wider public audience.

6. In his opening remarks, the OECD Secretary General, Donald Johnston, also emphasized the need for public dialogue, not least to help engender more confidence and less insecurity about biotechnology especially in view of its rapid pace of development. There is a need to communicate knowledge convincingly to the public and to continue the debate on issues raised by biotechnology with all stakeholders. The environmental impacts of the technology continue to need to be considered. The key challenges are to achieve balance between scientific opportunity and safety and to identify gaps in knowledge and what more needs to be done to address these gaps.

STRUCTURE OF THIS REPORT

7. This report is divided into four parts. The first section provides a status review of trends in the development of LMOs, the practice of risk assessment, the scientific framework for assessment and challenges and opportunities for environmental assessment. It is, in effect, a précis of the proceedings of the conference. The second section summarises the key areas of general agreement among participants while the third section covers areas where there is as yet no general agreement. The final section charts the way forward focusing on measures which might help to improve ways of assessing the impact of LMOs on the environment, areas requiring further investigation and opportunities for international harmonisation as well as co-operation.

1. STATUS REVIEW

1.1 Trends in the commercialisation of transgenic crops

8. Agriculture has always been based on selecting and modifying plants to develop useful crops. Agricultural science is utilising biotechnology.

9. Advances in genomics and informatics are helping push back the limits to agricultural production. A new generation of potential traits is being addressed – including factors affecting yield, quality, tolerance to environmental stress. While there has been a great deal of research work on transgenic varieties in many important plant species, large scale and commercial experience to date has been predominantly based on a relatively few crops modified in the main for herbicide tolerance or pest resistance. Changes in technology, including plastid transformation and better gene targeting may contribute to improved safety of LMOs.

10. Adequate food availability and food security continue to be considerable challenges for many developing countries. Biotechnology potentially offers "packaged technology in a seed" that could improve quality and quantity without compromising local traditional or established cultural practices.

11. In China, one LMO crop has been commercialised (Bt cotton) and work continues on development of several others. Data that were presented at the conference, suggests that there are benefits to the health of agricultural workers (from reduced pesticide poisoning) and that economic benefits appear to accrue mainly to small farmers.

12. The agricultural priorities in developing countries – including food security and supply, nutritional and post-harvest quality, and appropriate pest resistance - are not always the same as those of developed countries. Most commercialisation of LMOs has focused on the needs of the latter. Local farmers are important actors in uptake of technology and better ways need to be found to improve communication between scientists and society. While biotechnology is not likely to be the whole answer to human and environmental needs, international dialogue is required to ensure developing countries' priorities are not ignored.

1.2 Future trends and applications

13. The exponential growth in genetic data has enormous potential to deliver improvements for crops. The key challenges are, in an era of agribusiness consolidation, to move to a more precise discovery model for new agrochemicals, develop better ways to process the flood of available genetic data, and deliver useful new traits and genes to meet the expectations of those investing in research.

14. A number of current trends were identified. Functional genomics and the ability to sequence whole plant genomes provide a powerful model system for discovery. "Industrialisation" of phenotype analysis is increasing the rate of trait assessment. There is greater integration of information scientists with biologists in discovery teams, and combining genomics, proteomics, "transcriptionomics" and "metabolomics" heralds the age of "system biology". The key drivers for these developments are the increasing trends towards narrower, more targeted markets and increasing "democratisation" of discovery and information sharing.

1.3 The practice of environmental assessment

15. Many countries have systems of risk/safety assessment in place to evaluate release of LMOs into the environment. The Cartagena Protocol on Biosafety, as well as many national systems, lays down a methodology for risk/safety analysis including a number of systematic steps and a list of points to consider. Different regulatory systems base their assessments on very similar sets of data requirements concerning the organism, insert, trait and environment. Though there is variability between the detail of risk assessments, the issues that they address are common across OECD countries and beyond. Several initiatives are in place to offer capacity building on the practical application of risk assessment to LMOs. Even in relatively developed non-OECD economies human capacity remains a challenge.

16. There is over ten years of field release data on LMOs. The available information includes data on agronomic and environmental effects. The current regulatory systems have dealt with these releases. Some participants were of the view that the systems need to be looked at to ensure that they are able to cope with future introductions of increasingly complex genetic constructs in LMOs. For example, crops containing stacked genes for herbicide tolerance and unexpected secondary functions of introduced sequences. A number of participants were of the view that the regulatory frameworks in their countries allow for these broader and more complex issues to be taken into account.

17. Much debate continues to focus on gene flow between LMOs and other plant species in the environment and on the extent to which increased weediness might occur. To assess gene flow, when plants with which genes might be exchanged in the environment are present, more knowledge is often required on the biology and spatial location both of the LMOs and such plants. . To assess the potential impacts of gene flow, the characteristics of the introduced genes and related altered traits have to be taken into account. Uncertainty about the implications of gene flow is more of a concern when there are wild relatives in the environment and most particularly when such wild relatives are within centres of diversity.

18. The availability of robust data on the potential for gene flow – and particularly on the location of wild relatives – is sometimes patchy. However, it is feasible to construct databases of the biology and location of wild relatives, landraces and LMOs. Such databases can be used to identify areas where there is a high or a low probability of introgression following the release of LMOs, though the predictive ability of such systems for environments that have not been rigorously mapped needs to be further tested.

19. Many countries have regulatory systems in place addressing the issue of gene flow. Different countries place different relative emphasis on various factors affecting gene flow.

20. Many experts emphasised that a distinction needs to be drawn between information necessary to reach a conclusion on safety/ risk assessment and information that would simply be scientifically interesting. Lessons can be learned from chemical risk assessment experience, but there are important differences.

21. Many if not most experts consider that gene flow *per se* is not harmful. However, relatively few empirical data are available on the long-term consequences of gene flow. Uncertainty about possible consequences of gene flow may be higher for these potential long term effects than for short term effects. Assessment of whether flow of particular genes affects fitness, for example, could be done step-wise, including prospective assessment of wild populations to determine likely selection pressures and head-to-head fitness comparisons of transgenic with non-transgenic populations. Assessment might also address whether mitigation measures could be appropriate and available.

22. Some evidence suggests that there are environmental benefits associated with the introduction of some LMOs. For example, in South Africa there are indications that insect, bird and frog biodiversity may benefit from the use of Bt cotton rather than traditional varieties subject to normal insecticide regimes. Speakers also referred to work in Columbia and China that suggests some environmental benefit. However, more research is needed to validate this.

23. Risk assessments of genetically modified crops have in the main focused on agronomic characteristics in temperate regions. Comparative risks and benefits of the introduction of LMOs with alternative cultivation methods need to be assessed on a case by case basis, taking into account regional agricultural practices and, where appropriate, socio-economic considerations. Baseline data required for environmental impact assessment, including information on endogenous species and existence of sexually compatible wild relatives of agricultural crop plants are scant.

24. While the likelihood of harm is a function of both hazard and exposure, the public debate is dominated by hazard identification, often neglecting issues such as exposure and the likelihood of harm, an evaluation of the final consequence and a comparison with the existing situation. The press coverage of potential harm to the Monarch butterfly is a prime example of this focus on hazard identification.

25. In ecological impact assessments, it is problematic to extrapolate from small scale field trials to the commercial scale cultivation. Countries have taken a number of approaches to dealing with this problem. In the UK, the approach has been to hold farm scale field trials that address scale, and integrate regional cultivation practices and farmer behavioural issues. The research process takes into account factors affecting credibility. It is entirely government funded, foresees peer review and public review of results. The driving issue of this study is the assessment of the impact of herbicide tolerant crops on farmland biodiversity. An ecological model is being developed using specific species as indicators for this purpose.

26. The cost of these issue-targeted farm scale field trials may be prohibitive for routine assessments of impacts of individual LMOs in every case. More generally, regulatory requirements may impose a cost barrier for development of minor crops (eg many vegetables and fruits).

27. Risk assessments are based on the best available sound science. However, there remains debate about the extent to which subsequent regulatory approvals currently or in the future ought to draw on other factors such as public attitudes and socio-economic factors. One view is that the assessment of risk from LMOs is currently performed on too narrow basis and that a more interdisciplinary approach is required

that draws on more ecological data, considers long term effects, and considers risks alongside benefits in a more transparent and participatory manner.

28. There is a clear need for better communication on scientific and risk issues between scientists and the public. Public participation is essential in risk assessment and management. However, the debate continues as to how this can best be achieved.

29. There also remains a difference of view in how to cope with uncertainty in risk assessments. Some participants thought that lessons might be drawn from the introduction of chemical entities where harmful effects took some time to manifest themselves. According to this view, risk management might be applied in advance of assessment, so that risks that, based on current scientific knowledge, could not be assessed rationally were simply avoided. A number of countries apply such a "precautionary" approach. However, others thought that it is not possible to manage risks that cannot be assessed rationally and that governments should focus on assessing and managing identifiable risk.

30. Further issues that remain under debate are whether assessment of risk and uncertainty should be applied primarily to new technologies or might also be applied to conventional practices and the extent to which the use of concepts like life cycle assessment might contribute to sustainable agricultural development.

1.4 Scientific framework for assessment

31. There was a discussion about the science underpinning effective risk assessment.

32. Assessing ecological impacts of LMOs is not without problems, particularly long term or "secondary" impacts. One approach could be to compare LMOs with organisms produced using more traditional breeding techniques. However problems remain such as lack of reliable base line data, the relevance of extrapolation from small to large scale, ability to detect rare events within a relatively short experimental time scale, lags between introduction and manifestation of impacts and general ignorance about the complexity of ecosystems. Furthermore, there remain problems, concerns and/or disagreements around how to place any observed change in the context of changes occurring through traditional agricultural practices. There is a need for international consensus on how these difficulties might best be addressed..

33. Measuring ecological impact within soil systems is perhaps most challenging of all. Relevant indicators need to be selected that reflect changes in the rhizosphere and that affect crop performance or food quality. Accurate measurement of rhizosphere populations is difficult. Changes in soils have to be measured by changes in gene products and/or marker genes rather than as change in microbe populations.

34. Assessment of non-target impacts of LMOs needs to reflect the complexity of real environments. For example, exposure experiments need to consider how an organism accesses its food chain within a given environment as well as considering potential impacts on non-target species that play a significant role in ecosystem functioning when such impacts might plausibly introduce risks.

35. A more systematic approach is possible and necessary to assess non-target effects.

36. Constancy of yield is important for developing countries. An inclusive approach to use of technology may be required that integrates pest control, farming and social practices. LMOs that could impact on pest or weed control are best introduced within this integrated framework, cognizant of regional conditions and practices, so that there are adequate levels of control of the target.

37. Introducing into an LMO several genes that assist the LMO to resist a pest ("stacking" or "pyramiding" of these genes) rather than a single gene is one strategy for reducing the probability that the target pest population will develop a means of countering these genes. Adequate information exchange between public and private sector researchers is necessary to develop a battery of resistance genes for stacking. Risk assessment systems need to evolve to deal with such stacking or pyramiding strategies and international discussion may facilitate this.

38. For the most part, transgenic plants expressing pharmaceuticals are being developed to reduce production costs and may improve product safety. The gene products expressed by such LMOs may pose different challenges for the assessment methodology. Close monitoring will be required of such LMOs which are likely to be grown in sites dedicated to maintaining product quality through a variety of enhanced isolation procedures.

39. LMO trees may increase quality and yields and promote sustainability by concentrating planting areas. The technology for the production of transgenic trees is developing faster than the technology for conducting sound environmental risk assessment. OECD first considered genetically modified trees in 1999. The case by case and step by step approach was considered important. Monitoring is difficult because of tree longevity.

40. Though transgenic insect technology is promising as a possible method of controlling parasite vectors, we know very little about hazards and risks. There is a need for scientific peer review as well as government funds to support research on risk analysis.

41. Some argue that transgenic fish may pose negligible ecological risks as they are unlikely to be selected for in the presence of wild populations. However, large numbers of LMO fish interbreeding with natural populations may present an issue. Recovery after release is unlikely. Studies based on one individual environment, for example in contained facilities, are inadequate to predict behaviour and performance in natural environments.

42. Advances in genomics raise questions about how we approach risk assessment, as novel genes identified by genomics and available for biotechnological applications will be characterised by novel standards.. The general principles underlying risk/safety assessment remain similar however.

1.5 Maize at the centre of origin and diversity

43. There was a presentation about maize production in Mexico. Local farmers routinely incorporate genetic material in land races to maintain vigour. Preliminary data presented suggest that Mexican land races might contain introgressed transgenic sequences. These data, however, need to be confirmed through other methods of detailed molecular analysis.

44. The question was posed whether there are any unique risks posed by the introgression of transgenic traits into land races. Discussions centred around whether an adverse effect would be associated with introgression of the Bt trait into land races. Questions raised in this context included: (i) will such introgression affect future levels of diversity in maize? (ii) will such introgression affect other organisms; (iii) will such introgression require adaptation of crop management practices to control the pests. This discussion included questions about whether there had been any adverse effect demonstrated with the use of the Bt gene in any instance. In Mexico socio-economic considerations were said to be important since cultural practices of farmers greatly influence their farm management.

45. A number of questions were posed about the implications of these events for regulation. Stakeholder and public consultation on the appropriate course of action was considered paramount, as

fundamental national values are attached to maize in Mexico. The appropriateness of a moratorium was debated, and the ability to enforce quarantine measures was discussed.

46. Mention was made of the need to continue to promote cooperation regarding implementation of the objectives of the Cartagena Protocol on Biosafety.

1.6 Challenges and opportunities for environmental assessment

47. Public wariness of new and novel food products is not a new phenomenon, but rather has occurred many times over the centuries. The story of the adoption of coffee is an eloquent illustration of earlier debate on the consequences for society of introduction of new types of product.

48. Monitoring can be a key element of risk management. Insect resistance management in Bt crops has been the topic of much debate during the meeting. Programme designs, and the reasons for them, need to be well communicated to and understood by farmers as well as scientists. Farmers are likely to be one of the best early warning mechanisms for any adverse events and cooperation between neighbouring farmers is invaluable. Different approaches will be appropriate for different crops and environments, and for different countries and regions. In the US, no field resistance to Bt in LMOs has been reported to date and farmer compliance with insect resistance management strategies has been very high.

49. Common elements of all pre-commercial and commercial monitoring programmes include stakeholder consultation on parameters and implementation, scientific consultation, peer review of monitoring plan, close collaborate implementation of public sector, private sector and farmers to take account of the regional diversity in ecological agronomic environments and cultivation practices, public workshops and communication of results. The processes described were all iterative, to provide for continuous review of what is monitored and how monitoring proceeds according to the latest scientific developments and feedback from scientific and public consultation.

50. Challenges include sampling methodologies and cost effectiveness of methods in particular if they are to be carried out on a case by case basis. Common international methodologies could be developed for monitoring and sharing of data. Particularly in the tropics there is a real need for more baseline data. Integration of information derived by molecular techniques, global information system technology and ecological studies may help to map areas where gene flow could occur.

51. An interdisciplinary approach to use of the technology might take into account costs of labour, time, management skills, as well as income to farmers and public acceptability. .

52. There is a need for a common understanding of what constitutes an adverse effect, as well as a common understanding of indicators, risk assessment criteria, and end points.

53. A key set of questions remain around the extent to which biotechnology will successfully deliver benefits to developing countries and represent a true public good. Delivering research and products that address local needs, but with an eye on international markets, creates great challenges to the leadership and available capacity in developing countries. Public research in Africa, South America and Asia is addressing a number of crops and traits. Progress is being made but few are yet commercialised. In countries carrying out such LMO research, biosafety systems are in place though capacity, management and administration and the wider legal system needs development.

2. AREAS OF BROAD CONVERGENCE[1]

54. Provided that the health and environmental impacts of the technology are responsibly addressed, LMOs can offer the opportunity to address global food security and supply challenges.

55. Recent advances in molecular and evolutionary biology have opened a wide range of opportunities related to biotechnology. Advances in genomics, informatics and proteonomics are being integrated into systems biology. These advances open possibilities for the development of products more suited to specific human and environmental needs. At the same time, advances in science offer possibilities to improve safety assessment.

56. Future trends in the economic application of LMOs will depend largely on the extent to which concerns about their environmental implications are addressed. The promise of biotechnology in addressing economic and environmental problems (as reflected in Agenda 21) has been superseded by public scepticism and caution in many countries.

57. There is common agreement that regulatory practices should be built on scientific knowledge.

58. Environmental concerns regarding the commercialisation of LMOs are renewing interest in ecological research. As the range of products expands so will the need to better understand the functioning of ecosystems. This should be matched by adequate funding.

59. There is general agreement that case-by-case, step-by-step approaches are the best available tools for managing risks associated with LMOs. A great deal of experience of field trials has generated much information, but risk assessment needs to continue to make use of best available science as new, less familiar trait/organism combinations are developed. There is agreement that gene flow to wild relatives or other LMOs needs to be considered carefully as part of risk assessment. The view of many participants is that gene flow *per se* is not a particular concern. However, the impact of individual traits in individual circumstances does need to be considered. Centres of origin or diversity offer more potential targets for gene flow that require study and evaluation and so may be particularly vulnerable to gene flow from LMOs.

60. Risk assessment practices need to evolve continually to take account of new developments. There is agreement that better communication with the public is needed to improve the understanding of scientific developments. The European Commission, for example, has launched a public consultation on life sciences and biotechnology that aims to include social and policy considerations in research and make such research activities as inclusive as possible.

61. Continued international co-operation amongst OECD countries and between OECD and non-OECD countries remains essential to harness the potential benefits of this technology in a safe and sustainable way. While assessments need to take into account country or region-specific environments, common approaches and methodologies can nevertheless be developed.

62. As the scientific basis for decision-making becomes increasingly evident, so does the global nature of the policy aspects of the economic use of LMOs. This is partly because of increasing globalisation of the world economy and the associated interdependence among countries through

1. The rapporteurs attempted to draw together what they saw as broad areas of convergence of thinking amongst conference participants. There was no mechanism within the conference by means of which these could be validated. The rapporteurs acknowledge that not all participants would necessarily align themselves with the views summarised in this section.

international trade. Resolving many of the considerations associated with LMOs will require international action and cooperation. But the global nature of these concerns are also accompanied by the need to take into account diversity among nations, ecological systems as well as local or regional needs and priorities.

63. The role of LMOs in solving specific problems of the developing world is emerging as a major policy challenge for the international community. While most of the major crops in commercial use were developed for temperate climates, future technological developments must involve identifying traits of relevance to the needs of developing countries. Indeed, several developing countries are already engaged in research that reflects their own priorities. Nevertheless there is a need to strengthen scientific and technological capabilities in developing countries and foster appropriate partnerships between these countries and industrialised nations.

3. OUTSTANDING ISSUES

64. While there is general agreement that scientific knowledge is essential for risk assessment and management, discussions continue on how to identify appropriate baselines and what constitute appropriate data sets for identifying risks and estimating the likelihood of the identified risk occurring. There was discussion of the distinction between “what it is necessary to know” versus “what it is nice to know” in order to make a determination of risk, and what differentiates the two. Discussion also continues about whether a generic approach to risk assessment might be explored for certain applications.

65. One of the unresolved issues is whether concerns about uncertainty should be applied primarily to crops developed using new technologies and LMOs or should also be applied to crops developed using conventional methods such as wide crosses in breeding.

66. Some conference participants thought that uncertainty over issues such as labelling and traceability might be resolved by using international standards. They considered that such standards could help to avoid disrupting international trade or undercutting the capacity of developing countries to use emerging technologies, while allowing all countries and regions to meet their needs. Many believed strengthened efforts in international co-operation are essential to improve harmonisation of regulatory oversight. Many participants urged that any such international cooperation keep in mind the international framework that will be set up as a result of the Cartagena Protocol on Biosafety.

67. Many of the general safety principles that guide debate over LMOs have been developed in fields such as chemical and nuclear safety. While these areas have provided an initial approach to risk/safety assessment and are a major source of information and experience, it is not clear the extent to which the lessons are really applicable to living organisms like LMOs.

4. THE WAY FORWARD

4.1 Improving assessments

68. After a decade or more of work, much progress has been made in understanding the underpinning science and a great deal of experience has been gained with the application and safety assessment of LMOs, including on the environmental aspects of commercial use, though most is drawn from a relatively small number of crop-trait combinations. The time has come to look back on this work and evaluate the data that have been generated.

69. There is a significant body of knowledge on the environmental impacts of the commercial use of LMOs. Much of this information remains unpublished though some has been quoted widely in public

discussions over the environmental safety of LMOs. Synthesis and communication of this existing information might be helpful to inform future more authoritative biosafety assessment. Research showing no impacts tends to be regarded as unattractive for publication in the scientific literature. To the extent possible, companies and other institutions should publish or synthesise unpublished information on the safety of LMOs and make it readily available.

70. In addition to synthesising the available information, there is a need to improve on existing environmental assessment methodologies in the light of experience gained from commercial and research use of LMOs.

71. Most existing risk assessment and management methodologies do not consider in detail the benefits that LMOs might deliver. As a result, much of the policy debate about LMOs risk creating the impression amongst the public that such products only carry risks and offer no benefits.

4.2 Undertaking further scientific investigation

72. There are a number of areas that require further scientific investigation. These include issues such as gene flow, development of resistance and impact on non-target species. The success of such investigations will depend on the development of agreed baseline data, appropriate databases, assessment methodologies that capture the diversity of ecological systems while at the same time allowing for comparability. Also important is the role of modelling (which is used widely in climate impact studies) as a way of dealing with lack of information and other limiting factors in ecological knowledge.

73. Specific issues might include:

(i) more scientific knowledge to establish the way in which ecosystems will respond to introduction of more complex LMOs.

(ii) better understanding of the mechanics and potential impacts of gene flow from living organisms, including LMOs, (the individual trait being a key determinant in considering potential impact) where there are potential hybridisation targets available.

(iii) refinement of research on non-target organisms to ensure that it is relevant to real ecosystems.

4.3 International harmonisation and co-operation

74. The flow of ideas for new LMOs is not limiting new advances, but transfer from the laboratory to the glasshouse then to the field is slowly drying up. An important factor remains the unresolved societal debate.

75. Early phases of technological development are often characterised by regulatory uncertainty and rapid social learning. This requires flexibility and adaptability in existing regulatory frameworks and institutional arrangements based on harmonization and cooperation in research and assessment methods

76. A number of opportunities for such international cooperation have emerged from discussion. These include:

(i) giving further thought to whether comparative risk assessments might usefully be applied to LMOs

(ii) developing consensus on more specific definition of the environment into which LMOs are released in the context of risk/safety assessment in particular how non-target effects might best be assessed

(iii) discussing the extent to which current risk assessment techniques are sufficient and appropriate to deal with non agricultural LMOs, LMOs with stacked genes and products of "systems" biology

(iv) addressing appropriate baselines for assessment and determination of long term effects

(v) working together towards a more harmonised understanding of what constitutes an adverse effect, as well as towards developing risk assessment criteria, assessment endpoints and biotic and abiotic indicators in the context of risk assessment and monitoring of LMOs.

(vi) developing more predictive tools for environmental impact of LMOs

(vii) considering how and when future monitoring schemes for research or commercialisation of LMOs might best be designed

(viii) developing cooperation on research methodology including, for example, detection methods, monitoring and sharing of data

(ix) seeking agreement on how best to determine risk associated with release of "second-generation" LMOs into environments where other LMOs are already present

(x) encouraging a discussion around whether in light of knowledge derived through genome analysis unexpected secondary functions of inserted genes should further be pursued.

77. International co-operation is also essential in area of *capacity* building for science-based and evidence-based biosafety management. Such capacity building should involve cost-effective methods of institutional development. This could be done through the expansion of the mandate and capabilities of existing institutions to address biosafety concerns. Where such institutions do not exist, there may be a case to establish new institutions. Regulatory capabilities for biosafety need to co-evolve with developments in biotechnology competence.

78. The rapporteurs are grateful for the assistance of OECD staff and consultants in assembling this report: Sally de Marcellus, Ariane König, Michael Ryan and Rebecca Weiner.

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