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FAO RESEARCH AND TECHNOLOGY PAPER

11

Results from the FAO Biotechnology Forum

Background and dialogue on selected issues

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by
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ABBREVIATIONS

AFLP = Amplified fragment length polymorphism
ARI = Advanced research institute
Bt = *Bacillus thuringiensis*
CBD = Convention on Biological Diversity
CBO = Conventionally bred organism
CGIAR = Consultative Group on International Agricultural Research
CIMMYT = International Maize and Wheat Improvement Center
DGGE = Denaturing gradient gel electrophoresis
FAO = Food and Agriculture Organization of the United Nations
GAS = Gene assisted selection
GDP= Gross domestic product
GE = Genetically engineered
GEF = Global Environment Facility
GFAR = Global Forum on Agricultural Research
GM = Genetically modified
GMO = Genetically modified organism
IAEA = International Atomic Energy Agency
IARC = International agricultural research centre
ICTs = Information and communication technologies
IFAD = International Fund for Agricultural Development
IFPRI = International Food Policy Research Institute
IPR = Intellectual property rights
ISAAA = International Service for the Acquisition of Agri-biotech Applications
ISNAR = International Service for National Agricultural Research
LD = Linkage disequilibrium
LE = Linkage equilibrium
LMOs = Living modified organisms
MAS = Marker-assisted selection
MNC = Multinational corporation
NARS = National agricultural research systems
NBF = National biosafety framework
NGO = Non-governmental organization
OECD = Organisation for Economic Co-operation and Development
PCR = Polymerase chain reaction
QTLs = Quantitative trait loci
R&D = Research and development
RAPD = Random amplified polymorphic DNA
RFLPs = Restriction fragment length polymorphisms
SCP = Single cell protein
SNPs = Single nucleotide polymorphisms
TRIPS Agreement = World Trade Organization agreement on Trade-Related Aspects of Intellectual Property Rights
UN = United Nations
UNDP = United Nations Development Programme
UNECE = United Nations Economic Commission for Europe
UNEP = United Nations Environment Programme
WHO = World Health Organization
WTO = World Trade Organization

EXECUTIVE SUMMARY

The FAO Biotechnology Forum is an e-mail based forum launched in the year 2000 with the aim of providing quality balanced information on agricultural biotechnology in developing countries and making a neutral platform available for people to exchange views and experiences on this sometimes controversial subject.

The Forum has hosted a series of moderated e-mail conferences, each one dedicated to a particular theme relevant to agricultural biotechnology in developing countries and lasting just a few weeks. For each conference, two key documents are produced. Firstly, before the conference takes place, a document is prepared to give a good background to the conference theme, in a balanced neutral way, and written in easily-understandable language so that people with little knowledge of the area may understand what the theme is about. The document also highlights any particular issues of special relevance to developing countries. Secondly, after the conference, a document is prepared to provide a summary of the main issues that were discussed during the conference, based on the messages posted by the participants. This publication presents these background and summary documents from six moderated e-mail conferences, each lasting just over four weeks, hosted by the Forum from 2002 to 2005.

Agricultural biotechnology is a broad collection of tools and these tools can be applied for a range of different purposes (e.g. genetic improvement to increase yield; genetic characterization and conservation of populations; disease diagnosis and vaccine development) in the crop, animal, fisheries and forestry sectors. One of the tools, genetic modification, can be used to create genetically modified organisms (GMOs) i.e. organisms that have been transformed by the insertion of one or more genes (called transgenes), usually from a different species. Whereas the other biotechnology tools are little discussed outside of academic circles, genetic modification and GMOs have been highly controversial worldwide and received much focus in the media and the issue of GMOs and GMO regulation has engaged policy-makers at the highest international level. For this reason, although the Forum covers the wide range of biotechnology tools that are available, particular attention has been paid to genetic modification.

Three of the six conferences reported here focused on GMOs, dealing with gene flow from GM to non-GM populations; regulation of GMOs; and participation of the rural people in decision-making regarding GMOs (Chapters 2, 4 and 7 respectively). Two conferences covered the entire range of biotechnology tools (including GMOs), dealing with the role and focus of biotechnology in the agricultural research agenda (Chapter 3) and applications of biotechnology in food processing (Chapter 6). The remaining conference dealt with a non-GMO biotechnology, the use of molecular markers for genetic improvement of agricultural populations (Chapter 5). The conferences were multisectorial, covering the use of biotechnology in the animal, crop, fishery and forestry sectors, and each one was moderated, where the Moderator's main tasks were to ensure that the participants' messages focused on the conference theme and to provide additional technical information (references to scientific articles, explanations of technical terms, etc.), when appropriate.

For each conference, there were 350 to 630 participants and between 8 to 19 percent of them posted messages. Very few people posted messages in more than one conference. Over half of all messages came from people living in developing countries. About one-quarter of messages came from people living in Asia, roughly 20 percent each from Europe, North America and

Africa and just under 10 percent each from Latin America and the Caribbean region and Oceania. The messages came from a total of 61 different countries, with the United States and India topping the list. The greatest proportion of messages (33 percent) came from people working in universities, followed by 30 percent from research institutes/organizations, including governmental research institutes and CGIAR centres. Just over 10 percent each came from people working as independent consultants or in NGOs and 5 percent or less each came from people working in government ministries/bodies, farmers' organizations, private industry or UN organizations.

From a global consideration of the conferences, it was concluded that there is a large demand for good quality science-based unbiased information regarding agricultural biotechnology in developing countries, and secondly, that people in developing countries have a great interest and willingness to participate in dialogues on this subject. Regarding GMOs, there was no evidence of the intensity and polarization of the debate declining while regarding non-GMO biotechnologies, on the other hand, there was general agreement about the positive role that they can play in developing countries and that they should complement more conventional technologies. For both GMOs and non-GMO biotechnologies, intellectual property rights were perceived as an important issue and their consequences were generally seen as negative. Finally, the conferences indicated that many developing countries currently lack the resources and capacity to minimize the risks and maximize the benefits of agricultural biotechnology and that capacity building should be prioritized.

CHAPTER 1.
INTRODUCTION TO THE FAO BIOTECHNOLOGY FORUM AND THE E-MAIL CONFERENCES

In this chapter some background information on the FAO Biotechnology Forum is provided, together with a description of the operation of the six e-mail conferences. An overview of participation in the different conferences is also provided.

1.1 BACKGROUND TO THE FORUM

Biotechnology is a broad collection of tools and these tools can be applied for a range of different purposes (e.g. genetic improvement of plant varieties and animal populations to increase their yields or efficiency; genetic characterization and conservation of genetic resources; disease diagnosis and vaccine development; improvement of feeds). Some of the technologies may be applied to all the food and agriculture sectors, such as the use of molecular DNA markers or genetic modification, while others are more sector-specific, such as vegetative reproduction (crops and forest trees), embryo transfer and freezing (livestock) or triploidization and sex-reversal (fish). FAO considers that biotechnology provides powerful tools for the sustainable development of agriculture, fisheries and forestry, as well as the food industry and that when appropriately integrated with other technologies for the production of food, agricultural products and services, it can be of significant assistance in meeting the needs of an expanding and increasingly urbanized population (www.fao.org/biotech/stat.asp).

One of the tools in the biotechnology toolbox, genetic modification, has been at the centre of a major debate worldwide for several years now (see e.g. Stone, 2002) and there are still no signs of the controversy abating. The debate about genetically modified organisms (GMOs) includes a lot of potentially contentious issues, involving science (e.g. whether food from GMOs is as safe as from conventionally bred organisms; what the impacts of GMOs are on the environment; whether GMOs increase food production), geopolitics (e.g. the majority of commercial GM crops are developed in North America; food from GM crops has been offered as aid to developing countries), ethics (e.g. some parties consider development of GMOs to be inappropriate interventions in nature), trade (the GM crops currently released include some commodities that are extensively traded internationally) and socio-economics (e.g. GMO development has been driven primarily by the private sector; GM products have largely been developed for richer farmers; the products/techniques involved are often covered by intellectual property rights). As a consequence of this heated debate, attention has focused on GMOs and tended to neglect other applications of biotechnology, which may be highly relevant for addressing development problems (see e.g. FAO, 2004, 2005).

The FAO Biotechnology Forum is an e-mail based forum, launched in 2000 with the aim of providing quality balanced information on agricultural biotechnology in developing countries and to make a neutral platform available for people to exchange views and experiences on this subject. The Forum has hosted a series of moderated e-mail conferences, each dedicated to one particular subject, focusing on developing countries, and lasting only a few weeks. Conferences take place in the English language. Although it is an e-mail forum, all documents and e-mail messages are also made available on the web (at www.fao.org/biotech/forum.asp). The first six conferences, held in 2000-2001, covered the themes of the appropriateness of biotechnology in the crop, forestry, livestock and fishery sectors, its implications for hunger and food security and

the impact of intellectual property rights and were reported in FAO (2001). This second book reports on the next six e-mail conferences, conferences 7 to 12, hosted by the Forum in 2002-2005.

1.2 HOW EACH E-MAIL CONFERENCE TOOK PLACE

A standard procedure was generally followed for each of the e-mail conferences i.e.

1.2.1 Before the conference

The theme of the individual conferences was decided by the FAO Working Group on Biotechnology. Once the topic was defined, a Background Document was prepared to provide easily-understandable background information on the conference theme, so that those with little knowledge of the area could understand what the theme was about. This was sent to all of the Forum members by e-mail (currently about 2 800 people), on average two weeks before the conference began, together with instructions on how to subscribe to the conference (i.e. by sending an e-mail message to an automatic FAO mail server). The document was subsequently put on the Forum web site. The Background Documents for the six conferences are provided here in the first part of Chapters 2 to 7. Members of the Forum were not automatically registered for any e-mail conference, but had to do this themselves. The conference was also announced a couple of months before the starting date through a variety of e-mail and web-based information services, such as the electronic bulletin FAO-BiotechNews. The conference was open to everybody. As part of the build up to one of the conferences (nr. 10, on marker-assisted selection [MAS]), an international workshop on the same theme was held in Turin, Italy, one month before the conference began. The papers presented in Turin were used extensively in preparing the Background Document.

Each conference was moderated by John Ruane. Just before each conference began, the Moderator posted an opening message welcoming the subscribers to the conference and briefly reminding them of some of the main guidelines about the running of the conference i.e.

- participants should introduce themselves briefly in their first posting to the conference;
- messages should not exceed 600 words;
- people posting messages are assumed to be speaking on their own behalf and not on behalf of their employers;
- the Background Document sets the scene for the conference and therefore, participants are strongly encouraged to read it.

1.2.2 During the conference

Any subscriber to the conference could submit a message. The Moderator's main task was to read these messages before they were posted to all the conference participants to ensure that they followed the main guidelines of the Forum and were relevant to the theme of the conference. In addition, the Moderator played an active role in the conference by ensuring that each message was understandable and, often, providing additional information of benefit to participants (such as web links to additional information sources, references to scientific articles or explanations of technical terms used in the messages). After this initial filtering/moderating process (usually lasting no more than an hour), the message was posted to all of the conference participants (normally several hundred) simultaneously. Each message posted was numbered in chronological order, so that the Moderator and participants could easily refer to previously posted

messages and that participants could be sure that they had received all messages. The message number was put on the subject line together with the title of the message. The messages posted were later (usually within a day or two) also made available on the Forum web site. In the six conferences, only a handful of messages were refused for posting and the motive was that the content was not directly relevant to the theme of the specific conference. When necessary, members of the FAO Working Group on Biotechnology provided technical support to the Moderator.

1.2.3 After the conference

After each conference, a Summary Document was prepared, aiming to provide a summary of the main issues that were discussed during the e-mail conference, based on the messages posted by the participants. The document was sent to all of the Forum members by e-mail and was also made available on the Forum web site. Any comments received from Forum members on the Summary Documents have been positive and no-one indicated that the contents of their messages had been misrepresented in a Summary Document. The Summary Documents from the six conferences are provided in the second part of Chapters 2 to 7.

1.3 THE SIX CONFERENCES

Three of the conferences were devoted exclusively to GMOs, two to biotechnology in general (including GMOs) and one to the use of molecular markers. Two conferences were held each year in 2002 and 2003 and one each in 2004 and 2005. All six conferences were multisectorial, covering the use of biotechnology in animals, crops, fish and forest trees.

The dates and titles were:

- Conference 7 (31 May to 6 July 2002): Gene flow from GM to non-GM populations in the crop, forestry, animal and fishery sectors.
- Conference 8 (13 November to 16 December 2002): What should be the role and focus of biotechnology in the agricultural research agendas of developing countries?
- Conference 9 (28 April to 1 June 2003): Regulating GMOs in developing and transition countries.
- Conference 10 (17 November to 14 December 2003): Molecular marker-assisted selection as a potential tool for genetic improvement of crops, forest trees, livestock and fish in developing countries.
- Conference 11 (14 June to 15 July 2004): Biotechnology applications in food processing: Can developing countries benefit?
- Conference 12 (17 January to 13 February 2005): Public participation in decision-making regarding GMOs in developing countries: How to effectively involve rural people.

1.4 PARTICIPATION IN THE CONFERENCES

As seen in Table 1.1, an average e-mail conference lasted just over four weeks and had roughly 450 participants. Of these, 55 people, living in 26 different countries, posted at least one message (on average two). Looking at the individual conferences, the number of participants per conference ranged from 350 to 630. It is worth noting that although three conferences were dedicated solely to GMOs the highest participation was recorded for the conference with no discussion of GMOs, dedicated to MAS. Participation in this MAS conference was no doubt boosted by the prior organization of an international workshop on the same theme as part of the

build up to the e-mail conference. The beneficial effects of organizing a workshop on participation in a subsequent e-mail conference was also seen for Conference 13 of the Forum (on "the role of biotechnology for the characterization and conservation of crop, forest, animal and fishery genetic resources in developing countries"), the results of which are included in a separate publication together with papers from the workshop (FAO, 2006).

The conferences were usually announced for the first time about two months before they began, which explains the finding that the vast majority of participants were already subscribed before the conference began and the first e-mail message was posted. They thus received all e-mail messages posted in the conference. Analysis also showed that after subscribing, very few people unsubscribed once the conference began.

1.4.1 Active participation

Table 1.1 shows that the proportion of participants that posted messages (i.e. active participants) varied from 8 to 19 percent in the different conferences. The conference (on MAS) with the highest number of total participants had the lowest active participation rate while the conference (on research) with the lowest number of total participants had the highest active participation rate. Research on online communities has shown that the proportion of subscribers that do not post messages (i.e. passive participants) is normally quite high, with figures of over 90 percent reported in some studies, as well as others indicating an average of 46 and 82 percent for a range of health and software-support e-mail discussion lists respectively (Preece et al., 2004). These figures vary widely between individual communities. People participate passively rather than actively in online communities for a number of reasons. A frequent one is that they just wish to learn and to have updated information about the given subject. As the discussion in these e-mail conferences was often quite technical, it is likely that this was a key reason. Indeed, this is supported by the finding that the highest proportion of passive participation (92 percent) was in Conference 10 (on MAS), where almost 90 percent of messages came from people working in universities or research centres and where the topics discussed were often highly technical. The fact that large numbers of people chose to subscribe themselves to the conferences and that they rarely unsubscribed themselves after they began suggests they found the information useful and that the conferences have been playing a useful role in capacity building.

Were the active participants the same in each conference? Analysis shows this was clearly not the case. Summing the number of active participants in the six conferences gives a total of 331 (Table 1.1). Analysis showed that these 331 participants were in fact 266 different individuals, comprising 225 (85 percent) individuals who posted messages in just one conference; 23 (9 percent) who participated actively in two conferences; 13 (5 percent) in three conferences; 4 (2 percent) in four conferences; and one individual (<1 percent) who posted messages to five conferences. No-one posted messages in all six conferences. As the themes of the different conferences were distinct and had little overlap, it is therefore not surprising that the people wishing to share their ideas and experiences on the themes were also different.

1.4.2 Where the messages came from

People were asked to introduce themselves in their first message to each conference and they typically provided their full work/home address and a description of their professional background and current occupation. Based on the address, an analysis was carried out of participation by country, geographical area and by developing versus developed country. Note, the analysis is based on where people were living when they posted the message and does not indicate where they come from originally.

As described in Chapter 7.1, there are tremendous global inequalities in the use of information and communication technologies (ICTs), where e.g. nearly 40 percent of people in the Organisation for Economic Co-operation and Development (OECD) countries have access to the Internet compared with just 4 percent for developing countries. In this situation, participation from developing countries in the conferences has therefore been very active, as over half of all messages came from people living in developing countries (Table 1.2). The highest proportion (71 percent) was in Conference 11 (on food processing) and the lowest (32 percent) in Conference 7 (on gene flow). It is noteworthy that the proportion was lowest for the three GMO-specific conferences (numbers 7, 9 and 12; i.e. 32, 49 and 50 percent respectively), possibly reflecting the fact that the majority of GM products are currently cultivated in industrialized, and not developing, countries. Note, in practice, the relative contribution of developing world participants to the six conferences was higher than this as a substantial proportion of messages posted from developed countries came from people born in developing countries but living in developed countries for the purposes of work/study.

For each conference, messages came from people living in 19 to 35 different countries (Table 1.1) and from all of the world's major geographical areas (Table 1.3). About one-quarter of messages came from people living in Asia, a figure that ranged from 14 percent (on public participation and GMOs) to 33 percent (on MAS) in individual conferences. India and the Philippines were by far the major contributors from Asia (Table 1.4) while the absence of contributions from China was noteworthy. As the conferences took place in English, language was presumably a factor here. It did not, however, prevent people living in Latin America and the Caribbean from posting about 10 percent of messages, with more than half of them coming from Peru, Brazil, Venezuela, Chile and Mexico. Roughly 20 percent of messages came from people living in Europe, with the highest number (34) from the United Kingdom, followed by Spain, Italy, Netherlands, Belgium and France. A further 20 percent of messages came from North America, mostly from the United States. Whereas the proportion of messages from Europe was relatively stable in the different conferences, it varied considerably for North America, being highest for the GMO-specific conferences (41, 29 and 17 percent) and lowest for the other three (7, 8 and 14 percent). Just under 20 percent of messages came from people living in Africa, ranging from 9 percent (on MAS) to 40 percent (on food processing, where traditional fermented African foods were much discussed). Most African messages came from South Africa, Nigeria, Egypt and Kenya. People living in Oceania, mainly Australia, were responsible for the remainder (8 percent) of messages posted.

Table 1.4 shows that during the six conferences, messages were posted from people living in a total of 61 different countries, with two in particular (United States and India, with 96 and 87 messages each) dominating. Messages from ten countries (United States, India, Australia, United Kingdom, Canada, the Philippines, South Africa, Nigeria, Spain and Egypt) accounted for 65 percent of the total.

1.4.3 Work place of the participants

Table 1.5 presents the results of the analysis of the work place of the people who posted messages, based on the work address they provided when sending their messages. Note, these are only an approximation – people may have several roles at any one time (e.g. a participant with a university work address could also be on a governmental advisory board and/or a member of an NGO). The largest proportion of messages (33 percent) came from people working in universities, ranging from 25 to 46 percent per conference. A total of 26 percent of messages came from people in national research institutes or organizations, including governmental

research institutes. Including the CGIAR, people working in universities and research institutes posted 63 percent of all messages, ranging from 53 to 88 percent in individual conferences. Just over 10 percent each came from people working as independent consultants or in NGOs. About 5 percent of messages came from people working in government ministries or bodies, 4 percent in farmers' organizations and, finally, 3 percent each from private industry or UN organizations.

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Table 1.1 Number of people that registered for each conference, number of messages posted, number of countries and people providing the messages (including percent of people registered for each conference that posted messages) and duration of the conferences

Conference theme	No. participants	No. (and %) of participants who sent messages	No. of messages	No. of countries	Duration (weeks)
Gene Flow	382	61 (16)	118	25	5
Research	347	67 (19)	128	29	5
Regulation	401	44 (11)	93	20	5
MAS	627	52 (8)	85	26	4
Food processing	411	37 (9)	68	19	4.5
Public participation	508	70 (14)	116	35	4
Average	**446**	**55 (13)**	**101**	**26**	**4.6**

Table 1.2 Number (and percentage) of messages posted from individuals in developing[1] or developed countries for each of the six conferences

Conference	No. (%) of messages from developing countries	No. (%) of messages from developed countries
Gene Flow	38 (32)	80 (68)
Research	74 (58)	54 (42)
Regulation	46 (49)	47 (51)
MAS	50 (59)	35 (41)
Food processing	48 (71)	20 (29)
Public participation	58 (50)	58 (50)
Total	**314 (52)**	**294 (48)**

[1]Defined as countries in Part I and the 'more advanced developing countries' in Part II of the Development Assistance Committee (DAC) list of aid recipients (www.oecd.org/dataoecd/35/9/2488552.pdf).

Table 1.3 Number (and percentage) of messages coming from individuals in different geographical areas for each of the six conferences. Percentages add up to 100 in each row

Conference theme	Africa	Asia	Europe	Latin America and the Caribbean	North America	Oceania	Total
Gene Flow	14 (12%)	21 (18)	25 (21)	5 (4)	48 (41)	5 (4)	118
Research	20 (16)	40 (31)	30 (23)	11 (9)	18 (14)	9 (7)	128
Regulation	18 (19)	21 (23)	12 (13)	7 (8)	27 (29)	8 (9)	93
MAS	8 (9)	28 (33)	22 (26)	12 (14)	7 (8)	8 (9)	85
Food processing	27 (40)	20 (29)	14 (21)	2 (3)	5 (7)	-	68
Public participation	23 (20)	16 (14)	24 (21)	17 (15)	20 (17)	16 (14)	116
Total	**110 (18)**	**146 (24)**	**127 (21)**	**54 (9)**	**125 (21)**	**46 (8)**	**608**

Table 1.5 Number (and percentage) of messages coming from participants in different occupations for each of the six conferences. Percentages add up to 100 in each column

WORK PLACE	C O N F E R E N C E T H E M E						
	Gene Flow	Research	Regulation	MAS	Food processing	Public participation	Total
University	38 (32%)	32 (25)	24 (26)	31 (37)	31 (46)	43 (37)	199 (33)
Research organization or institute[1]	24 (20)	42 (33)	24 (26)	38 (45)	12 (18)	21 (18)	161 (26)
CGIAR[2]	4 (3)	7 (5)	1 (1)	6 (7)	2 (3)	2 (2)	22 (4)
Independent consultant	6 (5)	13 (10)	15 (16)	4 (5)	11 (16)	26 (22)	75 (12)
NGO	20 (17)	13 (10)	14 (15)	1 (1)	3 (4)	13 (11)	64 (11)
Government[1]	8 (7)	7 (5)	7 (8)	1 (1)	3 (4)	3 (3)	29 (5)
Farmers Org	-------	9 (7)	4 (4)	3 (4)	2 (3)	7 (6)	25 (4)
Private company	14 (12)	---------	-------	------	3 (4)	-------	17 (3)
UN Organization	4 (3)	5 (4)	4 (4)	1 (1)	1 (1)	1 (1)	16 (3)
Total	**118**	**128**	**93**	**85**	**68**	**116**	**608**

[1] "Research organization or institute" includes governmental research institutes

[2] Includes individuals from the CGIAR research centres and its Science Council

Table 1.4 Number of messages coming from individuals in different countries for each of the six conferences

COUNTRY	CONFERENCE THEME						
	Gene Flow	Research	Regulation	MAS	Food Processing	Public participation	Total
United States	35	18	17	7	5	14	96
India	3	21	17	21	17	8	87
Australia	4	9	8	8	-	12	41
United Kingdom	9	8	4	6	3	4	34
Canada	13	-	10	-	-	6	29
Philippines	10	12	-	3	-	4	29
South Africa	9	6	11	-	-	1	27
Nigeria	-	1	4	2	14	3	24
Spain	-	6	-	4	-	5	15
Egypt	4	7	1	1	-	1	14
Italy	3	5	2	-	1	1	12
Netherlands	5	6	-	1	-	-	12
Kenya	1	-	1	2	3	4	11
Belgium	1	-	-	-	9	-	10
France	-	-	-	3	-	7	10
Germany	-	1	3	1	1	3	9
Peru	2	-	1	5	1	-	9
Sri Lanka	5	3	-	-	1	-	9
Brazil	1	2	-	3	-	2	8
Venezuela	-	4	-	-	-	3	7
Austria	3	-	-	1	-	2	6
Chile	-	1	4	1	-	-	6
Mexico	1	1	1	2	1	-	6
Jamaica	-	-	-	-	-	5	5
Switzerland	1	-	2	-	-	2	5
Thailand	-	-	3	-	-	2	5
Turkey	-	3	1	1	-	-	5
Zimbabwe	-	1	-	-	2	2	5
Benin	-	-	-	2	2	-	4
Ghana	-	1	-	-	3	-	4
Ireland	-	1	-	3	-	-	4
Israel	1	-	-	3	-	-	4
Japan	2	-	1	-	1	-	4

COUNTRY	C O N F E R E N C E T H E M E						
Senegal	-	2	-	-	1	1	4
Zambia	-	1	1	-	-	2	4
Bahamas	-	-	-	-	-	3	3
Malawi	-	-	-	-	-	3	3
Malaysia	-	3	-	-	-	-	3
New Zealand	1	-	-	-	-	2	3
United Republic of Tanzania	-	-	-	-	1	2	3
Argentina	-	1	-	1	-	-	2
Colombia	1	1	-	-	-	-	2
Cuba	-	-	-	-	-	2	2
Ecuador	-	-	-	-	-	2	2
Eritrea	-	-	-	-	-	2	2
Fiji	-	-	-	-	-	2	2
Madagascar	-	-	-	1	-	1	2
Syria	-	-	-	1	1	-	2
Bangladesh	-	-	-	-	-	1	1
Bolivia	-	1	-	-	-	-	1
Burkina Faso	-	-	-	-	1	-	1
Cameroon	-	-	-	-	-	1	1
Cyprus	-	-	-	1	-	-	1
Finland	-	-	-	1	-	-	1
Guyana	-	-	1	-	-	-	1
Iran	-	-	-	-	-	1	1
Mali	-	1	-	-	-	-	1
Norway	1	-	-	-	-	-	1
Poland	1	-	-	-	-	-	1
Saudi Arabia	-	1	-	-	-	-	1
Sweden	1	-	-	-	-	-	1
Total	**118**	**128**	**93**	**85**	**68**	**116**	**608**

CHAPTER 2.
GENE FLOW FROM GM TO NON-GM POPULATIONS IN THE CROP, FORESTRY, ANIMAL AND FISHERY SECTORS

2.1 BACKGROUND DOCUMENT

2.1.1 Introduction

The theme of this conference is the potential importance and impact of gene flow from genetically modified (GM) crops, forest trees, fish or animals to non-GM populations, with particular focus on developing countries. This issue has been raised on numerous occasions by participants in previous e-mail conferences hosted by this Forum (FAO, 2001). The issue of the potential importance and consequence of transgenes moving from GM crops to traditional landraces was also brought sharply to the forefront recently, following reports of transgenic material in maize landraces cultivated in Oaxaca in southern Mexico, part of the centre of origin and diversification of this crop.

The issue of gene flow from GM populations is not only of potential relevance to crop landraces or traditional varieties but also to wild relatives of the domesticated species, organic crops or non-GM crops, cultivated under intensive conditions. Furthermore, the issue does not only concern crop plants. The current media focus on gene flow in crops is determined primarily by the fact that there is no commercial-scale planting of GM trees and no GM animals or fish are currently approved for human consumption. If (or when) this situation changes, there will also be much focus on gene flow issues in these sectors and therefore they are included in this publication.

The aim of this document is to provide background to the subject as well as to mention some of the factors that should be considered in the conference.

2.1.2 Background on genetically modified organisms (GMOs)

A genetically modified organism (GMO) is an organism that has been transformed by the insertion of one or more genes (called transgenes), usually from a different species. For example, two genes from the daffodil *Narcissus pseudonarcissus* and one gene from the bacteria *Erwinia uredovora* were inserted into the genetic material of rice to produce the transgenic rice variety commonly known as “Golden Rice”, which produces provitamin A.

Different types of genetic modification can be distinguished, depending on the source of the genetic material inserted. Tester (1999) suggested that three classes could be considered, namely:

- wide transfer: where genes are transferred from one kingdom to another (e.g. from a bacterium to a plant);
- close transfer: where genes are transferred from one species to another within the same kingdom (e.g. from one plant species to another); and
- tweaking: where a gene already present in a species is modified to alter its level or pattern of expression.

Active research into genetic modification of living organisms has been ongoing since the 1980s. However, large-scale production of GMOs in agriculture has only taken off in the last few

years, with the commercial planting of GM crops. In this publication, the current status of GMOs in the crop, forestry, animal and fishery sectors is considered. Note, GM plants and animals being developed to produce human pharmaceuticals (e.g. potatoes containing cholera vaccines or sheep producing proteins for treatment of cystic fibrosis) are not of primary interest in this conference and therefore, are not mentioned below.

2.1.2.1 GM crops

It has been estimated that the global area cultivated with transgenic crops increased from 1.7 to 52.6 million hectares from 1996 to 2001 respectively (James, 2001). From the 2001 estimates, it can be seen that virtually all transgenic crops were grown in just four countries, the United States, Argentina, Canada and China, responsible for 68, 22, 6 and 3 percent of the cultivated area, respectively. Four crops were responsible for virtually all the area cultivated with transgenic varieties, namely soybean (63 percent), maize (19 percent), cotton (13 percent) and canola (5 percent). Of the 52.6 million hectares, 40.6 million hectares (i.e. 77 percent) were planted with crops modified for herbicide tolerance; 7.8 million hectares (15 percent) were modified to include one of the toxin-producing genes from the soil bacterium, *Bacillus thuringiensis*, to confer insect resistance, while 4.2 million hectares (8 percent) were planted with crops having both herbicide tolerance and insect resistance.

In addition, several thousand field trials of GM crops have been carried out, involving a wide range of species. In the United States, the majority of trials has been on maize, potatoes and soybeans while in the European Union most trials have been on maize, sugar beet and canola.

2.1.2.2 GM forest trees

There is no reported commercial-scale production of GM forest trees. However, as the title of a recent article by Mann and Plummer (2002) in the journal 'Science' confirms ("Forest biotech edges out of lab"), there is much active research in the area of genetic modification of trees and much technical interest in bringing the GM products past the research stage. The first reported trials with GM trees go back to the 1980s. A study by Owusu (1999) indicated that more than 100 reported trials have been carried out since 1988, involving at least 24 tree species, and that the majority of the trials was carried out in the United States and Canada. Mann and Plummer (2002) reported that the United States Department of Agriculture had received applications to field-test 138 types of GM trees, 52 of them in the last two years. The traits of interest for GM forest research include herbicide tolerance and pest resistance (as for crops), but also a range of other features, such as delayed flowering (so that trees can be harvested before they pollinate) or lowered amounts of lignin (to reduce the costs and environmental pollution associated with paper-making). A review of the developments of new biotechnologies, including genetic modification, in forestry was carried out recently for FAO (Yanchuk, 2001) and some additional information can be found at www.fao.org/forestry/site/7247/en. All studies point out the difficult decisions facing the forest industry (and particularly the pulp and paper companies) regarding the adoption of GM tree technologies.

2.1.2.3 GM animals

Although transgenic animals (especially mice) are used routinely for research purposes, no GM animals are commercially produced for food purposes. Regulatory approval for GM food animals (excluding fish, that are covered below), has only been sought in a single case, namely, for a GM pig in Australia containing a growth hormone transgene allowing the animals to

produce meat more efficiently, however, the meat never made it to the market. The kinds of transgenes currently being studied for potential use in commercial populations include the growth hormone gene (to increase growth rates), the phytase gene from bacteria (to reduce phosphorous emissions from pigs) or keratin genes (to improve the properties of wool in sheep).

2.1.2.4 GM fish

Commercial-scale farming of fish is a relatively recent phenomenon compared with crop or livestock production, as is the application of conventional genetic selection programmes to most fish populations. Nevertheless, there is much research and commercial interest in the production of GM fish. The trait of major interest is increased growth rate and transgenic fish from about 20 species, including carp, catfish, salmon and tilapia, have been produced with a growth hormone transgene, for experimental purposes. Two transgenic fish species are awaiting regulatory approval for food purposes, a GM salmon in the United States and a GM tilapia in Cuba; decisions on approval are still pending. The GM salmon is the AquAdvantage Atlantic salmon which contains the Chinook salmon growth hormone gene together with a promoter from the ocean pout's antifreeze gene, allowing the salmon to continue to grow well in winter when, in non-GM salmon, growth would slow down. The GM tilapia is a hybrid containing a modified tilapia growth hormone gene to improve growth and conversion efficiency.

2.1.3 Gene flow from GM to non-GM populations

For plants, gene flow may occur in nature by pollen spreading from one population to another. The pollen may be spread in a variety of ways, e.g. by wind, water or animals. Genes from the resulting offspring can be spread further by pollen or by seeds. The minimum requirements for GM gene flow to occur are thus the presence of a sexually-compatible non-GM population in close proximity to the GM population, the possibility of outcrossing between the two populations and the production of fertile hybrids. The degree of outcrossing varies amongst species e.g. maize and millet are typically cross-pollinated while rice, wheat and barley are primarily self-pollinated. Note that gene flow refers to the exchange of genes among populations and not simply to the dispersal of pollen or seeds. For animals or fish, transgene flow could occur by transgenic individuals mating with non-GM partners and the subsequent production of fertile offspring.

Gene flow may also be facilitated unknowingly by human intervention. For example, for GM crops, this may occur through aid or relief agencies accidentally providing GM seeds in programmes to replenish a ravaged country or region's seed stocks or through farmers using transgenic material, intended as food aid, as seeding stock. In some other situations, GM crop material may be illegally introduced by farmers to non-GM populations because they see an economic advantage in using them.

If gene flow has first occurred, the transgenic material may subsequently spread within the formerly GM-free population or be lost from the population in later generations. A range of factors may influence this outcome, such as the size of the non-GM population, the amount of crossing between the GM and non-GM populations and the number and viability of the resulting seeds or offspring. Another important factor is whether the transgene involved confers a selective advantage. If it does, for example by increasing survival or reproduction, it is likely to spread more rapidly through the population. Conversely, if it has a detrimental impact on the fitness of individuals, the rate of gene flow is likely to be reduced and the transgene may eventually be lost.

In this conference, the issue of gene flow from GM crops, forest trees, animals or fish to non-GM populations, will be considered with special focus on developing countries. What kind of "non-GM populations" are referred to? They might crudely be categorized into three classes of populations:

- wild or feral relatives of domesticated species;
- landraces or "traditional" populations; and
- "modern" or "improved" populations.

Some aspects concerning gene flow to these three populations, will be briefly considered.

2.1.3.1 Wild or feral relatives

About 10 000 years ago, our ancestors began domesticating wild animals and plants, and eating the livestock and crops they produced. The centres of origin for most individual species of domesticated animals and plants are well established. For example, the potato, cassava, llama and guinea pig were all domesticated in the Andes and Amazonia region. Most centres of origin are in developing countries. The cultivation of any GM crop, for example, in its centre of origin has been viewed with concern because of the genetic importance of the wild ancestors of domesticated crops and the wish to protect the biological diversity that these wild relatives represent.

Crossing of domesticated populations with their wild relatives has been well documented in certain crop, forest tree, animal and fish species. For example, in crops, gene flow has been observed between rice and perennial rice, between maize and teosinte and between sugar beet and wild beet, while in animals, there is evidence of crossing of domestic cattle with wild North American bison and of domestic pigs with European wild boars.

Potential gene flow from intensively bred forest trees to wild relatives is considered a serious issue by forestry scientists, because of the extensive gene flow possible from trees (e.g. due to their longevity) and their relatively recent domestication history (apart from fruit trees and other crop trees). This point, however, is not specific to GMOs. Introduction of new forest tree populations, varieties or genotypes in areas where local populations are present, and the undocumented movement of forest tree germplasm, represent a major risk of "genetic pollution" in forestry. These risks have been limited, in many cases, by establishing provenance tests (to assess geographic variability in performance) and trials outside of the natural distribution area of native populations, although there are also examples where native populations or species have been brought to the verge of extinction due to gene flow and hybridization (e.g. the poplar *Popolus nigra*).

For fish, crossing of escaped farmed Atlantic salmon with wild Atlantic salmon is a much-discussed problem and it is also noteworthy that the potential ecological risk of releasing GM fish was the dominant theme raised by participants in the Forum conference devoted to the fishery sector held in the Summer of 2000 (see FAO, 2001). Gene flow involving alien (introduced) species is a real issue in the fishery sector, where their hybridization with wild relatives or with farmed fish is well documented.

In this first class of non-GM populations, feral populations i.e. those that were formerly domesticated but are now growing or living independently of humans, could also be included.

2.1.3.2 Landraces

Landraces, or traditional varieties and breeds, are populations that are the product of breeding or selection carried out by farmers, either deliberately or not, continuously over many generations. They tend to contain high levels of genetic diversity and to be adapted to specific environments, being especially important in environmentally marginal areas. Developing countries typically rely on landraces for much of their production. They are important genetic resources, representing an insurance policy against uncertain markets and environmental conditions for food and agriculture in the future. There are concerns that gene flow from GM populations might negatively affect these valuable genetic resources.

Landraces, like the wild relatives of domesticated species, are not static or genetically frozen in time. They evolve and genetically change from one generation to the next as a result of environmental pressures and selection by the farmers. In addition, gene flow amongst different landraces, between landraces and improved populations and, particularly in centres of origin, between landraces and wild relatives are documented phenomena for crop and livestock species.

2.1.3.3 "Modern" or "improved" populations

Modern populations, or improved varieties and breeds, may be defined as the products of breeding in the formal system (sometimes called "scientific breeding") by professional breeders working in publicly-funded research institutes or private companies. Compared with traditional agriculture, modern agriculture tends to rely on higher inputs (of water, fertilizers and pesticides for crops and of feeds and veterinary services for animals) and to focus on fewer species and on a smaller number of high-yielding varieties that have less genetic diversity.

Although modern farmers and foresters might be able to afford the use of GM technologies, they might decide not to do so for a variety of reasons, e.g. trade (if exporting to a country not accepting GM products), economics (if they consider that the extra cost of GM material outweighs the potential economic advantage) or personal choice. These considerations are also relevant at the industry level. What are the consequences for farmers of gene flow from GM stocks to these non-GM populations?

In this context, populations within organic agriculture, a system that relies on ecosystem management rather than external agricultural inputs and where the use of GMOs is not permitted during any stage of food production, processing or handling may be considered. Gene flow from GM populations to organic populations might jeopardize the GM-free status of organic products and potentially impact on the organic certification of individual farmers.

2.1.4 Certain factors to be considered in the discussion:

This conference considers one particular aspect of the whole agricultural biotechnology debate i.e. gene flow from GM to non-GM populations, focusing on developing countries. Throughout the conference, there are certain items that should be discussed. These are:

- how frequently and at what rate may gene flow occur from GM to non-GM populations. For the crop sector (where an estimated 53 million hectares of GM crops were cultivated in 2001), how frequently is gene flow from GM to non-GM populations currently taking place?
- the possibilities for detecting gene flow from GM to non-GM populations;

- the potential socio-economical or environmental impacts of gene flow from GM to non-GM populations in developing countries;
- whether the potential consequences differ in the crop, forestry, animal or fishery sectors;
- whether the potential consequences differ amongst particular regions of the developing world;
- whether the potential consequences are greater for wild relatives, landraces or improved populations;
- who should be liable for any negative consequences of undesired gene flow?
- whether gene flow from GM populations is different, or has a greater potential impact, than gene flow from certain kinds of non-GM populations, such as alien (introduced) species or modern populations selected for similar characteristics as GM populations (such as increased growth rates or disease resistance);
- whether the potential impacts of gene flow from GM populations producing human pharmaceuticals (such as human vaccines from bananas or human interferons from hens) are different than from GM populations modified for agricultural traits;
- whether the nature of the genetic modification (i.e. wide transfer, close transfer or tweaking, see Section 2.1.2) should be considered when evaluating the potential impacts of gene flow from GM populations.

2.1.5 References

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2.2 SUMMARY DOCUMENT

Executive summary

Discussions focused primarily on issues concerning gene flow (from GM to non-GM populations) in the crop sector with only a few messages dedicated solely to forest trees, fish or animals. From the discussions it was clear that widely differing opinions are held regarding GMOs and the current or potential impacts of gene flow. The main topic of discussion was the real or potential ecological impacts of gene flow and in addition, how a science-based ecological risk assessment framework might be applied to gene flow. Regarding the ecological impacts, discussions focused on two main areas. The first was the ecological impacts of specific transgenes, either those currently in use, affecting herbicide tolerance or insect resistance traits, where it was argued that spread of these transgenes to non-target plants could have or already had negative ecological impacts (the case of herbicide tolerant GM canola in Canada was mentioned in particular), or transgenes that might be used in the future. As specific transgenes may raise different ecological issues in different environments, it was proposed that the ecological impacts of gene flow should be considered on a case by case basis rather than as a whole. The second area discussed was the impacts of gene flow on biodiversity, where it was emphasized that they should also be compared with the impacts that other factors, such as introduction of invasive alien species, had on biodiversity.

Assessing the ecological risk of gene flow was considered by participants to be very important prior to GMO release. The problems of identifying the hazards and testing for them were raised, as well as the complexities involved in predicting exposure. There was no consensus on the important question of whether GMOs are fundamentally different from conventionally bred organisms (CBOs), thus raising new hazards regarding gene flow. The question was highly contentious, resulting from a clear split in the way that different people view GMOs in relation to CBOs. Participants were generally positive about using population genetics mathematical models to predict the spread of transgenes in the wild. For ecological risk assessment in developing countries, the lack of key information on the ecology of native plant species was a common theme and the need to generate this information to enable risk assessment to be carried out using local ecological information was emphasized. It was also argued that the assessment needs to be based on the realities of local farming systems in developing countries, where farm sizes may be small and mixing of varieties and seed saving may be common practices. Following the ecological risk assessment, several participants emphasized the importance of weighing up the risks in a larger context i.e. against the gene flow risks associated with CBOs; considering the environment in which the GMOs might be used (e.g. whether suffering environmental degradation); and against the potential benefits of the GMOs. There seemed to be general support for the use of strategies to simply prevent or limit gene flow and the merits of different strategies, such as the use of sterile GMOs or temporal/spatial separation of GM and non-GM populations, were discussed. Gene flow was seen to have an economic, as well as an ecological, dimension due to potential impacts on trade and exports to non-GMO markets; and on individual farmers due to liability arising from intellectual property issues.

Apart from the ecological and economic impacts, there is also a philosophical/ethical dimension to the gene flow question and its potential importance for indigenous peoples was raised. Regarding gene flow in centres of origin and diversification, participants emphasized that the topic requires special attention because of the complex mixture of scientific, social and cultural issues that it raises. Finally, discussions showed that gene flow to organic agriculture also requires special attention.

2.2.1 Introduction

From 31 May to 6 July 2002, a total of 118 messages were posted and they were numbered in the order of posting. In this document, specific references to messages posted, giving the participant's surname and the message number are included. All individual messages can be viewed at www.fao.org/biotech/logs/c7logs.htm. Before summarizing the main arguments and concerns raised in the 118 messages, some general observations can be made about the conference.

Firstly, the topic of gene flow involving GMOs was clearly of great interest. Although running for a shorter time period (five weeks) than any of the previous conferences of the FAO Biotechnology Forum (which lasted, on average, nine weeks), more people joined (382) and sent messages (61) than in any other conference. Only Conference 1, which lasted ten weeks, had more messages (138). The large interest in the topic may be explained by the importance given to it by people like Choudhary (message 20), saying that "cross pollination between GM and non-GM compatible species is a vital issue as far as the future of GM crops are concerned" and/or by the urgency expressed by Stamp (42) i.e. "we believe that the advent of GMOs cannot be turned back, therefore any potential risks linked to the release of pollen from GMOs should be reduced or prevented NOW". The recent controversy about GM gene flow in the centre of origin and diversity of maize may also be a factor.

Secondly, widely differing opinions are held regarding GMOs and the potential impacts of gene flow from GM to non-GM populations. In the past, the debate on GMOs has tended to be highly controversial and polarized. From this conference, there is no evidence of any change. The divergent views exchanged on the term "genetic pollution" and on gene flow terminology (e.g. Cummins, 31; Ghislain, 37; Redenbaugh, 39; Ashton, 47) illustrate this clearly. However, it can be hoped that, by providing a neutral, moderated platform for the airing of the wide range of views on this subject, the conference may have at least increased the understanding of the other arguments. Comments of two participants on the last day are positive in this regard i.e. "participants of this debate in my opinion have mainly focused on geneflow in what I consider a valuable and rather respectful exchange of thoughts" (De Lange, 111) and "many of the contributions I read gave me cause to reflect on my own fundamental beliefs" (Nickson, 115).

Thirdly, discussions focused overwhelmingly on the issues concerning gene flow in the crop sector with only a small minority of messages dedicated solely to these issues in forest trees (Lindgren, 100; Heinze, 103; Cummins 104, 106, 107), fish (Cummins, 97) or animals (Blair, 81). This tendency was also noted in previous Forum conferences and seems to be a consequence of the fact that GM crops are already a reality, having been cultivated now for a number of years, and the complex of issues that they raise are already been dealt with by policy-makers, consumers and researchers, etc. In contrast, there is still no commercial-scale planting of GM trees and no GM animals or fish are currently produced for human consumption.

Finally, Muir's comment (110) that "the primary impact of gene flow (from GM to non-GM organisms) is ecological, secondary impacts may be political, economic, social, and pathological" was reflected in the conference, where participants gave far greater emphasis to the ecological impacts (and to ecological risk assessment) of gene flow than to the other potential impacts.

In Section 2.2.2 of this document, the main elements of the discussions are summarized under eight main themes. Section 2.2.3 provides some information about participation in the conference and Section 2.2.4 gives the name and country of the people that sent referenced

messages. Note, unless otherwise stated, the term gene flow used here refers to gene flow from GM to non-GM populations.

2.2.2 Main themes discussed in the conference

2.2.2.1 The ecological impacts of gene flow from GM to non-GM populations

Participants focused on two main areas. The first was the impacts of GM gene flow on biodiversity (and the relative importance of these impacts compared with those caused by other factors). The second was the specific ecological impacts of known transgenes, either those affecting herbicide tolerance and insect resistance traits (present in the majority of GM crops currently cultivated) or those that might be inserted in future commercialized GMOs.

a) Impacts on biodiversity

As Muhunthan (2) dramatically put it: “the million dollar question is whether gene flow from GM to non-GM populations will affect genetic diversity and pollute its purity?”. As a precaution, he proposed carrying out studies prior to GMO release and setting up buffer zones to prevent gene flow. Menne (84) argued that gene flow could lead to loss of traditional plant varieties and agricultural diversity.

Muir (34) tried to answer Muhunthan's (2) question by analytically considering the potential implications of a GM plant or animal escaping into an ecosystem on genetic diversity at three levels, within a species, amongst species within a community, and thirdly, amongst communities. For the first level, he argued that if the species is wild and its population size is large, spread of the transgene should not reduce genetic diversity of other genes. If the population size however, is small and the transgene spread due to selection and was eventually fixed, then genes linked to the transgene may also become fixed, leading to some reduction in genetic variability. If, on the other hand, the species is domesticated then farmers might choose to preferentially use and breed from the GM plant or animal and neglect other plant varieties or animal breeds, resulting in a large loss of genetic variation. He pointed out that this could also happen with conventional breeding, if farmers had a strong preference for one kind of genetic material (as had already happened with Holstein dairy cattle, an example also used by Blair [81]). At the next two levels, Muir (34) argued that if the transgene allowed a species to expand its niche it could result in loss of species within a community and that, at the third level, if this happened in several communities they would become more homogenous.

Both Knibb (51) and Mettler (53) argued that if considering the risk of transgenes to biodiversity, then it should be compared with risk to biodiversity from natural mutations in non-GM populations, as they lead to genes being altered and rearranged each generation.

Some participants argued that, compared with transgene flow, other factors had greater impacts on biodiversity. Livermore (18) suggested that farmers selecting seed for the next generation was “the only potential threat to genetic diversity” of landraces, while Mettler (53), similar to Dusi (9), suggested that “by far, the real threat to biodiversity is the extent of land that is devoted to agriculture and the simple displacement of existing ecosystems by farms”. Uijtewaal (4), supported by Muhunthan (8) and Dusi (9), pointed out that introduction of a species to a new area where it could mate with wild relatives could be a “disaster”. Claparols (54) also highlighted the negative impacts that invasive alien species had on biodiversity, but argued that this example should encourage more prudence with GMOs, as scientific consideration of the risks of gene transfer are still unclear. This point was echoed by Ashton (55) who wondered,

given that it had taken a long time to recognize the risks and costs of intercontinental transfer of invasive alien species, "how long must it take us to realise the dangers" of genetic modification.

In contrast to these discussions about the potential detrimental impacts of gene flow on biodiversity, Halos (14) suggested it could have a positive impact in developing countries with limited resources. She argued that in situations where local domesticated plant varieties are sensitive to a disease, then gene flow from nearby disease resistant GM plants would be a cost-effective way of transferring disease resistance to the local varieties and ensuring their survival.

b) Spread of herbicide tolerance and insect resistance genes to non-target plants

As explained in the Background Document, the majority of commercially available GMOs is crops modified for just two traits, herbicide tolerance or insect resistance. In 2001, it was estimated that 77 percent of GM crops was modified for herbicide tolerance; that 15 percent included one of the toxin-producing genes from the soil bacterium, *Bacillus thuringiensis (Bt)*, to confer insect resistance, while 8 percent had both herbicide tolerance and insect resistance characteristics. It was argued that spread of these transgenes to non-target plants already had or could have negative ecological impacts.

i) Herbicide tolerance genes

Regarding the spread of herbicide tolerant genes, participants focused on crosses of herbicide tolerant canola in Canada with canola that was not herbicide tolerant or that was modified for tolerance to different herbicides. A range of herbicide tolerant GM canola varieties is commercially available in western Canada, including tolerance to glyphosate, glufosinate or imazethapyr (Cummins, 12). Although mainly self pollinating, canola may cross with plants of the same species and with weedy relatives. In a paper published in the journal "Weed Science" (2000, volume 48, pages 688-694), Hall and co-authors presented results from a farm in Alberta, western Canada, where canola plants with resistance to two and three herbicides had been found. They concluded that gene flow amongst different GM varieties was the most likely explanation for development of multiple resistance. Both Cummins (12) and Jenkins (27) emphasized the gravity of this situation, as herbicide tolerant volunteer plants can become a major weed problem (Jenkins, 27) and weedy relatives exist with which the multiple resistant plants could form hybrids (Cummins, 12). Nickson (62), responding to their concerns, emphasized instead that "this study constituted one grower in Alberta"; that practices on the farm were atypical; and that "this example does not constitute a measurable ecological risk". He concluded, instead, that "it is a good example of how agricultural systems have to adapt to new technology".

Due to the extensive gene flow, Cummins (12) and Jenkins (93) also stated that conventionally bred canola in Canada could no longer be guaranteed GM-free, a situation with detrimental consequences for organic farming (Cummins, 12; Di-Giovanni, 23). This is discussed further in Section 2.2.2.8.

ii) Insect resistance genes

Regarding the so-called Bt-crops (containing Bt genes), Menne (84) warned that gene flow from Bt cotton and maize represented an ecological threat to their closely related wild species (such as *Gossypium herbaceum* in cotton) because of "contamination". For Bt-cotton, Wozniak (87) stated that the United States Environmental Protection Agency had taken a cautious approach to the question of gene flow "since it is not possible to say with any certainty what the impacts on these wild populations might be if this novel Bt insect resistance trait were to

introgress". He pointed out that recent preliminary research results on Bt sunflowers in the United States indicated that there were potential weediness impacts, as gene flow to weedy relatives could increase their fecundity and fitness under natural conditions. Nickson (71) also raised this issue, indicating that in canola as well as sunflower, field trials were showing that Bt genes could confer a fitness advantage to wild relatives and that "a thorough risk assessment would have to carefully evaluate the potential for this altered property of the transgenic plant to confer a hazard". Knibb (76) was sceptical about claims that GMOs had increased fitness in a natural setting, although Muir (69, 79) argued that it had been clearly demonstrated in natural environments for both canola (Muir, 69) and papaya (Muir, 79).

Verzola (78) also suggested that spread of Bt genes to non-target varieties, and hence the increased levels of expression of the Bt genes in the field, would hasten the development of Bt resistance among pests, resulting in the eventual loss of an important tool for pest control.

c) Ecological impacts may depend on the transgene

Different transgenes may raise different ecological issues in different environments. For example, Halos (14) hypothesized that, in the Philippines where coconuts are threatened by a viroid disease, gene flow from disease resistant GM varieties would be beneficial. Nishio (10) asked rhetorically whether flow of a transgene conferring high phosphorous uptake efficiency, which could enable plants to out compete others, from crops to native populations, should be considered "good" or "bad". Cummins (106) considered the potential impacts of developing transgenic trees to convert highly toxic ionic or organic mercury to less toxic elemental mercury. He argued that such phytoremediation of mercury pollution would merely relocate soil mercury from contaminated soil sites in the South and redistribute the mercury to the North and that if gene flow occurred, resulting in large expanses of transgenic trees, it "could lead to a global catastrophe". He also signalled potential ecological risks from growing GM forest trees modified for growth (Cummins, 107) or low lignin traits (Cummins, 104).

Due to the wide range of potential ecological issues that can be raised, it was proposed that the ecological impacts of gene flow from GMOs should be considered on a case by case basis rather than as a whole (e.g. Muhunthan, 2; Valdivia-Granda, 40; Aniol, 58).

2.2.2.2 The economic impacts of gene flow from GM to non-GM populations

Discussions on the economic impacts of gene flow dealt with two main aspects: the impacts on trade and exports if gene flow occurred and secondly, the impacts on individual farmers due to liability arising from intellectual property issues.

a) Trade

In the words of Louwaars (50), "where farmers intend to sell their product at premium prices in certified non-GMO markets, unintended introgression of transgenes may pose a threat to the commercial position of these farmers". Menne (84) argued that gene flow could result both in loss of markets and in additional costs associated with labelling and separation of GM-free produce. Verzola (82) emphasized that "because developing countries are usually dependent on a few agricultural products for export", they could not afford market loss through GM gene flow and given that there was also a current preference for GM-free products, he advocated that developing countries, like the Philippines, should aim "to keep their entire territory GE-free, by avoiding field releases including field-testing" (Verzola, 105). Gallego-Beltran (108) supported this strategy, saying it would offer a potential advantage for reaching selective markets.

b) Liability

As mentioned in the Background Document to Conference 6 of the Forum (www.fao.org/biotech/C6doc.htm), which dealt with the issue of intellectual property rights, patents have been granted in the field of agriculture "on a wide range of biotechnology processes and products, involving genes, viruses, bacteria and even living higher organisms". Ownership of genes or seeds thus introduces additional potential impacts of gene flow.

For example, if gene flow has negative consequences, then someone may have to pay. According to Nishio (11) "if one owns the gene, and it escapes and causes economic and social damage, then the owner should be held responsible. It is the risk of ownership". However, Di-Giovanni (23) felt that this was not the reality with gene flow i.e. "in the environmental field, the concept of 'polluter pays' is well established. However, in agriculture, the onus has generally been on the producer of the crop (products) to sufficiently isolate their fields so as to produce a 'pure' product". Ashton (98) argued that in cases of gene flow in Canada, Mexico and the United States, involving conventional and organic farms, "supporters of transgenics have shown remarkable reluctance to accept responsibility".

Another impact is that patent owners may enforce intellectual property legislation if gene flow has taken place i.e. that "introgression of patented genes may sooner or later lead to claims by the holder of the patent, even where the genes were introduced unintentionally" (Louwaars, 50). Muhunthan (15) argued that in developing countries, because of small farm sizes, it would not be possible to prevent gene flow from GM to non-GM crops and that if farmers were sued by seed companies for breach of patents following gene flow, they would suffer serious economic consequences. Verzola (78) pointed out that in developing countries, such claims would be especially contentious as the majority of patents are owned by companies in the developed world.

Wozniak (33) and Namai (114) provided a reminder that, although not the subject of this conference, gene flow can also take place from non-GM to GM populations and that for farmers willing to pay extra for GM seed there might be economic losses due to "contamination" with non-GM pollen.

2.2.2.3 Assessing the ecological risk of gene flow from GM to non-GM populations

As seen in Section 2.2.2.1 (and elsewhere), there is much concern about the current and/or potential ecological impacts of gene flow from GM to non-GM populations. Assessment of these risks, prior to GM release, was therefore considered highly important (e.g. Muhunthan, 2; Wuerthele, 80). In addition, Wuerthele (80) suggested that risk assessment of GMOs was especially important for developing countries, as they "are least able to afford additional environmental problems". There was much discussion in the conference about how a science-based risk assessment framework might be applied to gene flow and how the results might eventually be used.

Nickson (24) began the discussion by briefly describing the fundamental principles of the ecological risk assessment framework used for GM plants produced by his company and by explaining that to conduct an appropriate risk assessment for gene flow it was critical to have "clearly defined and operational terms" and that the two most important terms in risk assessment are hazard and exposure, where risk = hazard x exposure. Stated simply, this key formula relates

risk (i.e. in this case, the ecological risk resulting from gene flow from GM to non-GM populations) to hazard (undesired/injurious events or harm caused by gene flow to the environment) and exposure (the frequency of gene flow or the probability of the transgene spreading in the environment) (Nickson, 24; Muir, 69). The assessment of ecological risk is carried out by a consideration of these two key components.

a) Hazard

According to Nickson (24), "the challenge that faces scientific risk assessors studying gene flow is having an accurate and testable definition for hazard. Given that hazard is a property that has undesired or injurious consequences, the challenge for scientists is to develop risk assessment experiments that can quantitatively or qualitatively assess the nature and magnitude of an injurious event associated with gene flow". He argued that there were "broad characterizations of the hazards associated with gene flow from GM crops such as: impacts on biodiversity, impacts on population dynamics, genetic swamping, and alterations of gene pools; all of which are inoperative in terms of science based hypothesis testing". The hazard that his company focused on was "the potential for the transgene to confer increased weediness to the crop or its sexually compatible wild relative", which could be scientifically assessed.

Jenkins (27) wrote that, on the contrary, the broad potential hazards mentioned by Nickson (24) were amenable to scientific testing but that the difficulty in testing for them lay in trying to draw conclusions about the real world in which GM crops would be applied from small-scale field tests. Raybould (61) disagreed with this point, arguing that several of the phenomena described by Nickson (24) were not operational "because we are not agreed on the variables that specify them. Unless we can agree on the changes in measurable variables that constitute 'genetic swamping', 'impacts on biodiversity', 'alterations of gene pools', etc., even very large experiments will fail to advance scientific risk assessment" and that ecologists needed to be able to predict "how agreed variables would change after the release of a GM plant".

Wuerthele (80) emphasized that in risk assessment it was first necessary to identify what potential adverse outcomes should be considered. She argued that since GMOs are fundamentally different from conventionally bred organisms, they might present new hazards (discussed in more detail in Section 2.2.2.5). Muir (69) said it was very difficult (perhaps impossible) to address the issue of potential environmental harms resulting from gene flow as "all potential harms may not be known *a priori*". He preferred instead to focus on the second term, exposure, which could be more easily addressed, arguing that if there was a low probability of the transgene spreading, then the issue of potential harms became irrelevant.

b) Exposure

In real life, a large number of factors can influence the frequency of gene flow and spread of a transgene in the environment and these should be included in the risk assessment analysis. They include "fitness in a specific environment; gene flow based on characteristics of the inserted gene elements; distance of pollen movement; presence of pollinators; crop rotation; intercropping systems, as well as volunteer plants and their removal" (Valdivia-Granda, 40). Transgenes may also be spread through human intervention e.g. by road transport of GM seeds (De Lange, 91), by whole-grain GM food provided as aid (Ashton, 98) or, simply, through "brown bag" seed being passed from one farmer to another (Morris, 74).

In the conference there was much discussion about the potential value of population genetics mathematical models (described by Muir [69, 73, 77]), which, given that gene flow has

first taken place, try to predict whether the transgene will be eliminated or increase in frequency in a natural setting. The models assume that the ultimate fate of the transgene can be predicted based on estimates of fitness components (e.g. adult viability, mating success) of the GM individuals and they can be applied regardless of whether the initial release of the transgene occurs by pollen spreading, animals escaping or intentional release by humans (Muir, 73).

Knibb (72) was not convinced by the value of such models, arguing that "because of simplifying assumptions required to operate population genetic models,....these mathematical models inherently are of little or no predictive use in real world situations". Muir (73) replied that two potential weaknesses of the models, raised by Knibb (72) in his message, could be dealt with and that the models had already been applied successfully in real situations. Trus (75) maintained that these kind of models were "essential", although it was important that their assumptions be stated clearly. Nielsen (95) argued that they "are the best tools available today to evaluate the consequences of such (GM) gene flow into wild relatives".

However, as Muir (77) wrote, "a model is only as good as the estimates of fitness components put into it" and to obtain accurate estimates, appropriate testing facilities would be required which "could be exceedingly expensive to build, depending on the type of GM organism examined". For forest trees this might be an important issue as Lindgren (100) pointed out that, compared with crops, forest trees are more expensive to field test and the test results may be less reliable. Morris (74) questioned whether such models would be helpful in developing countries because the environmental information is often poorly documented and the spread of GMOs will often occur through human intervention, which is hard to document or model.

c) Risk assessment in developing countries

As the conference had special focus on developing countries, a number of messages dealt with some specific aspects of ecological risk assessment in these countries.

A common theme raised was the dearth of key information on the ecology of native plant species. Morris (6) noted that there was insufficient information available on the potential for crops to cross-pollinate with African wild relatives and secondly, on insect pollinators in Africa and their habits. She emphasized the huge potential for research projects in these areas, while Bothma (48) confirmed that little research has been carried out in Africa regarding gene flow in GM crops. Di-Giovanni (23) agreed with Morris (6), adding that for assessing the probabilities of pollen dispersal and gene flow from wind pollinated outcrossing plants "scientific information on pollination mechanisms of many tropical plants is not as well developed as we would like, and for certain plant-types pre-requisite pollination ecology studies may be required". Badr (21) suggested that a lot of relevant research material is available in libraries, but not electronically.

Louwaars (19), agreeing with Morris (6), stated that "information on possibilities for cross fertilisation is basic to analysis of environmental safety" and continued "whereas food safety research from the North can be used for risk analysis in any other country, cross fertilisation needs to be researched taking the local plant populations into account". He proposed that "botanical files" be built up on local species, whereby "cultivated, weedy, feral and wild populations, can be plotted. Combined with the knowledge on reproductive biology of the species and its relatives in the country/region, this provides exactly the information that Ms. Morris is looking for". The need for local ecological information was also emphasized by Valdivia-Granda (40) who concluded that "gene movement between transgenic crops to other crops and wild species should be examined on a case-by-case basis considering ecogeographical characteristics". The reproductive biology of the species involved may be quite complex, as

shown by Badr's (29) description of the flowering system of the papaya and by Namai's (94, 114) conclusion that breeding systems are highly variable amongst and within plant varieties, where even species normally considered to be self-pollinating can cross-pollinate.

Risk assessment in developing countries should also be based on the realities of their farming systems. Verzola (105) argued that even if the initial levels of gene flow were low, the probability of a transgene spreading was higher in developing than in developed countries as farms tend to be smaller and closer together and farmers commonly save seed for subsequent planting. In addition, in developing countries "it is common to cultivate either several varieties and/or mix them with secondary crops" (Valdivia-Granda, 40).

Muir (110) emphasized that if one is to determine which GM species (plant or animal) might present a gene flow risk in developing countries, then it has to be first considered that gene flow can only occur with species already found in developing countries. For the different agricultural sectors, he summarized that: "many of the domesticated plants came from developing countries, including, but not limited to: rice, papaya, cassava, eucalypti trees, maize, and tomato. Many domesticated animals have their origin in developing countries but the species of perhaps greatest concern is tilapia, which come to us from Africa. The world market for tilapia is growing at record pace and GM tilapia have been developed. The concern is what happens if these GM species find their way back to their global centers of origin?". For forest trees, Lindgren (100) suggested that in order to avoid gene flow to native species, GM forests with exotic species may be proposed for developing countries.

d) Comparative risk assessment and risk/benefit analysis

Having assessed the ecological risk of gene flow from a certain GM variety, what then? Nickson (24) underlined the importance of "comparative risk assessment" i.e. "where the risks associated with the GM plant are characterized and compared with those associated with the conventional system in which the GM crop will be introduced". Wozniak (87) agreed, writing that the ecological risk of GM gene flow to wild relatives needed to be compared "to the impacts already occurring from non-engineered cultivated varieties that hybridize with related species or wild populations". In this comparative context, Muir (110) pointed out that it is easier to determine the ecological risks from GM gene flow than from invasive alien species because the non-GM species already exists in the ecosystem and can act as a control, whereas for an introduced species there is no real control.

Ghislain (35) suggested that any ecological risks from gene flow needed to be put in the context of the environment in which they might be used. He argued that if risk assessment showed that there was a reasonable probability of a certain GM variety posing a threat to biodiversity, then the country would have to develop policies "considering the relevance of these threats for each region. By relevance, I mean in an area of intensive mining, deforestation or urban pollution, it is irrelevant to care about a remote event of gene flow in balance with all the other threats...".

It was also argued that potential ecological risks from gene flow should be weighed up against potential benefits of applying GM crops. Nickson's (115) viewpoint was that "the two basic elements required to conduct a risk/benefit assessment are scientific capacity to interpret experimental science and some form of public policy to assess criteria for acceptability (i.e. define benefit and risk). It is inconceivable to me that a country in this world does not have people with the scientific and public policy capabilities. As such, I firmly believe that a scientifically based, risk assessment that integrates social aspects is the appropriate tool for

decision making anywhere in the world". Morris (102), in the context of developing countries, similarly argued for a risk/benefit approach to the question and suggested that "if the potential benefits for developing countries can be clearly defined, then we should not deny the consumer those benefits in an environment when the risks are low or negligible". For developing countries, Lingareddy (99) also weighed up the potential increases in production from applying GMOs against the potential negative ecological consequences, but felt that for their long-term interests it was better to be cautious and not use them.

Jeggo (86) pointed out that many countries have committees and procedures in place to carry out evaluations involving the development, release or use of GMOs in terms of safety and benefits and proposed that, since the risks cannot be limited by national boundaries, an international committee be formed to carry out such evaluations.

2.2.2.4 Mechanisms to limit or prevent gene flow from GM to non-GM populations

As seen in the previous section, concerns about the current or potential ecological impact of gene flow from GM to non-GM populations, meant that there was much discussion about how the potential risks might be assessed prior to release. Potential ecological hazards need first to be identified. This may not be straightforward, as it depends on whether GMOs are considered to be fundamentally different from conventionally bred organisms (Wuerthele, 1) or whether potential hazards may be identified prior to release (Muir, 69). The probability of gene flow (exposure) needs then to be calculated and as seen earlier, this can be quite complex and if population genetics models are to be used, may require expensive testing facilities (Muir, 77). In addition, in developing countries, gathering ecological information can be difficult, as funding (Morris, 6) and capacity (Ashton, 47) may be limited.

An alternative approach is to simply prevent or limit gene flow from GM populations (Muir, 110). Gressel (43) pointed out that there are a variety of strategies that would "render gene introgression to other varieties, landraces and wild species nigh impossible" and suggested that "the use of such strategies should be a requirement prior to release when there is a crop at risk". The large number of different strategies available was highlighted by Choudhary (20) and by coincidence, the journal "Nature Biotechnology" (June 2002, Number 6), containing a special section on the environmental impacts of GM crops and describing the current status of these strategies, was released while the conference was underway (Burke, 17; Smyth, 26). As Muir (110) suggested, these strategies could be combined to ensure that gene flow will not take place. A range of different strategies was discussed in the conference.

a) Temporal separation of GM and non-GM populations

According to Nishio (11), timing reproduction of GM crops to occur at different times from native varieties "does not seem feasible". However, Lindgren (100) suggested that growing GM forest trees with short rotation times so that they can be harvested in their juvenile stage (when they typically would have spread little pollen or seeds) might be useful for limiting gene flow.

b) Spatial separation of GM and non-GM populations

Cummins (97) proposed that cultivation of GM fish could be considered as long as it takes place in inland facilities rather than fish pens, where they could escape and mate with wild relatives. For crops, Muhunthan (2) proposed establishing "GM-free zones around the GM

populations to prevent gene flow between GM and non-GM populations", although participants mentioned the problems of defining appropriate isolation distances. Cummins (12) reported that pollen from GM canola had been observed to spread far greater distances in Canada than previously considered. Di-Giovanni (23) highlighted the difficulties of setting standard isolation distances for GM populations as "pollen- and gene-flow are inherently variable phenomena" (potentially influenced by factors such as wind speed, atmospheric stability and turbulence, pollen viability and other biological factors) meaning that "it would be unwise to base decisions on a few field trials". He advocated the use of computer simulation models to assess the probabilities of pollen dispersal for wind pollinated outcrossing plants. Muhunthan (15) argued that because farm sizes are small in developing countries, "there will not be any space left to set up a refuge".

c) Sterility strategies

A number of different strategies to ensure the GMOs (or their pollen) are sterile was discussed. One of them is development of GM plants whose seeds are sterile, using so-called "terminator" technologies (e.g. Nishio, 11; Stuart, 26). Valdivia-Granda (40) warned, however, that the strategy represented a risk to subsistence farmers who might be unable to segregate the sterile seed.

Gressel (43) proposed that for vegetatively propagated GM crops, a gene causing infertility (no pollen) could be inserted in a tandem construct with the transgene, so that gene flow would not be an issue. He pointed out that many genes are already known that render pollen infertile.

For plant species that produce a lot of pollen (e.g. maize, canola), Stamp (42) proposed that dispersal of GM pollen could be eliminated or limited by "growing male sterile GM plants in a mixture with male fertile non-GM plants, which act as pollen donors for the GM plants". He proposed that the male sterile varieties could be based on systems of cytoplasmic male sterility.

For fish, Cummins (97) considered the proposal to use triploidization (i.e. production of individuals with three chromosome sets instead of the normal two) to ensure that GM fish released in the environment are sterile. He argued, however, that triploidization might be problematic as the technique could have physiological side effects and secondly, triploids might be "leaky", allowing some fertile gametes to be produced. Given the potential risk that release of GM fish might have on the environment, he proposed that spatial separation of GM fish rather than triploidization should be used and concluded that "extensive studies on sterile triploid leakiness to produce gametes should be done before any transgenic fish are exposed to the environment".

For forest trees, Lindgren (100) maintained that use of sterile trees could eliminate or reduce gene flow. He pointed out, however, that to "prove absolute sterility, long field-testing under variable conditions is often needed, and this is expensive, complicated and time consuming". He suggested that if tree sterility was a requirement then it "is likely to lead to increased use of vegetative propagation with a few well-tested sterile clones".

d) Chloroplast genetic engineering

Another strategy mentioned was to insert the transgene(s) into the chloroplast genome rather than the nuclear genome (Valdivia-Granda, 40; Murphy, 89). As chloroplast genomes are maternally inherited in most crops, dispersal of transgenes through pollen would thus be prevented, although Valdivia-Granda (40) indicated that it would not be effective in all crops.

Cummins (52) emphasized that some species might not show clear maternal transmission (i.e. it could also be paternal or both) and suggested that pollination of a chloroplast GM plant by other crops or weedy relatives might lead to altered chloroplast transmission. He concluded that "individual crop plants and weeds need full analysis of the mode of chloroplast transmission before it could be concluded that the transgenic chloroplast modifications eliminate transgene transmission through pollen".

2.2.2.5 Are GMOs fundamentally different from conventionally bred organisms (CBOs), thus raising new hazards regarding gene flow from GM to non-GM populations?

This was one of the most divisive topics raised during the conference, resulting from a dichotomy in the way that GMOs are viewed in relation to CBOs. Nielsen (95), agreeing with Wuerthele (1), felt that the essential issue regarding the consequences of gene flow from GMOs was whether transgenic organisms differ fundamentally in their genetic make-up from other traditionally bred organisms, "if the answer to this question is no, then no particular concerns are to be raised that would separate the assessment of GMOs as compared with traditionally bred organisms. If the answer is yes, then the unique features should be identified and the consequences of their dispersal by gene flow evaluated".

Some participants considered that the answer was no and consequently, gene flow from GM-populations is not more of an issue than gene flow from non-GM populations. Thus, Mettler (53) argued that "the identification of one gene as being a transgene (for example for disease resistance), is no more of a threat (to biodiversity) than the already common use of conventionally developed traits for disease resistance", while Burke (17) questioned why herbicide tolerant canola developed using genetic modification or conventional breeding should be treated differently. A number of participants (e.g. Bradshaw 5; Wozniak, 25; Burke, 64) also emphasized that conventional breeding may use technologies with considerable impact on a plant's genetic material i.e. it "includes embryo rescue techniques, pistil/style modifications, colchicine-mediated chromosome doubling, bridging and wide hybrid crosses, phytohormone treatments to alter post-fertilization events, and chemical or irradiation induced mutations. This includes transfer from species through bridging crosses that bring gene combinations together that would otherwise not occur naturally" (Wozniak, 25), and that GMOs are therefore not fundamentally different from CBOs.

Other participants felt that GMOs are fundamentally different from CBOs in one or a number of ways and consequently, there are "novel concerns about their effects on ecosystems at the genetic level and about their behavior in ecosystems at the agricultural level" (Wuerthele, 1). She argued that some of the world's most serious environmental problems came from the failure to identify new hazards raised by new technologies and therefore, "if GMOs are fundamentally different,..., then it is wise to try to fully understand those differences, and use that understanding to consider what new hazards they might present before making conclusions about risk" (Wuerthele, 80).

The principal differences between GMOs and CBOs that participants mentioned in the context of potential impacts for gene flow may be roughly subdivided into the following two categories that are presented here, together with the resulting new hazards they may entail.

a) GMOs may transfer exotic genes to the ecosystem

As described in the Background Document, GMOs typically contain one or more genes from another species. These exotic genes may then be transferred to individuals of the same population, to wild relatives or to different species.

For Wuerthele (1), "GMOs are unique because they are created by recombinant DNA techniques. These processes intentionally introduce into a host species genes from organisms with which the host could never breed. This makes GMOs conduits for the transfer of exotic DNA to the host's genetic ecosystem (the gene pools of all the organisms with which it can breed). In contrast, organisms created by conventional breeding cannot transfer exotic genes because conventional breeding merely rearranges genes already present among compatible species" and "this ability to transfer exotic genes across species is the essence of what makes GMOs unique: they are gene vectors" (Wuerthele, 13). Similarly, Ashton (55) argued that genetic modification runs independently of the evolutionary process "in that a construct that can never naturally occur, has been introduced to the gene pool". Bradshaw (5, 16) was not convinced about the enormity of this difference between GMOs and CBOs, arguing that conventional breeding also involved induced and spontaneous mutations combined with intense artificial selection i.e. more than simple rearrangement of native genes and secondly, that CBOs could also contain exotic genes mentioning, as an example, that the pathogenic bacterium *Agrobacterium tumefaciens* inserts genes into the genome of host plants.

The resulting ecological hazards from gene flow mentioned by participants were primarily related to the evolutionary implications. Nielsen (95) argued that "unintended gene flow from GMOs has the potential to significantly change the evolutionary trajectories of their wild relatives. Whereas traditional breeding is largely based on artificial selection, modern gene technology introduces novel genetic variation that is naturally unachievable in the organism in question. Mechanisms providing genetic variability in higher eukaryotes do not combine DNA sequences from several organisms into a compact functional unit within the time scale achieved by genetic engineering". He suggested, however, that GMOs developed with simple intrachromosome modifications (unlike those developed with species-foreign or novel genes) are likely to cause few concerns in this respect.

In a similar vein, Muir (57), suggested that in contrast to natural mutations, which could result in formation of new species only over a long period of time and which tended to involve small changes, be entirely random and have negative impacts on fitness of the organism, the "creation of new mutations by man (transgenes)" occurs rapidly, they do not occur at random and the transgene normally confers some advantage to the organism. As an illustration, he suggested that a natural mutation allowing goats to produce spider silk in their milk would be impossible. He concluded that the creation of transgenes "that result in formation of new species and elimination of others is clearly unacceptable, we do not have evolutionary time to adjust to the changes that we can bring upon ourselves through such actions. We can also bring about more changes too rapidly for any ecosystem to adapt to". Knibb (63) disagreed with this analysis, arguing that there was no evidence for species formation by genetic modification, that natural mutations could also have large visible effects and that "there is no empirical evidence that genetically engineered changes are more likely (than natural mutations) to be fit in the wild".

Another potential ecological hazard raised is that there might be more horizontal gene flow (gene flow by non-sexual means) to bacteria. Nielsen (95) argued that as transgenes often have DNA sequence homology to prokaryotes, this significantly increases the likelihood of transgene integration in bacteria. Verzola (82) suggested that there were some reports of

horizontal gene flow occurring with GM crops. Valdivia-Granda (22) also raised the issue of GM crops containing the coat protein genes of specific viruses, arguing that, through horizontal gene flow, the transgene could be taken up by infecting viruses, leading to new viral genomes.

In addition, Valdivia-Granda (22) discussed the potential risk of antibiotic resistance genes being transferred to pathogens, because "a distinguishing characteristic of many transgenic plants is the presence of antibiotic resistance genes" used as markers to select transformed cells. He mentioned in particular the kanamycin resistance gene, as the antibiotic kanamycin is still used for treating human infections. Verzola (96) reported that there had been calls to phase out the use of antibiotic resistance genes, although Valdivia-Granda (22) was concerned that the large investments in time and money made in developing a GM plant might make it difficult to withdraw products already available from the market.

b) The genetic modification process may create organisms that are unstable

Wuerthele (1) argued that when identifying the hazards of GMOs, consideration should also be given to the behaviour of the organism itself because recombinant DNA techniques "create organisms with inherently unstable and unpredictable behavior" and that the instability derives from the way GMOs are made (Wuerthele 1, 13). The potential new hazards this raises regarding gene flow were not discussed in detail.

One feature of the genetic modification process mentioned in this respect is the way transgenes are regulated. Wuerthele (1) argued that "transgenes are multiplied in number or are accompanied by promoters so that the products for which they code are expressed in high concentration. Often, transgenic products are not controlled temporally or anatomically, but are expressed throughout the host's tissues and life cycle. Moreover, the (promoters) used to activate transgenes may produce unintended effects by also activating host or retroviral DNA. In contrast, highly expressed traits in conventionally-bred organisms are under genetic controls characteristic of the organism". To this, Bradshaw (5, 16) replied that no general statement of that nature could be made about transgene stability or regulation, that each transgene and transgenic event must be characterized separately.

Nielsen (95) noted that the way transgenes are regulated could, however, increase the likelihood of transgene expression if gene flow occurs to wild relatives, since a feature of transgenes is that they "are often modified to allow broad expression and often require few interactions with the host cytoplasm for activity".

Another feature mentioned is that insertion of the transgene may cause mutations in the host DNA. Wuerthele (13) proposed that "mutations are an unintentional but necessary by-product of inserting foreign genetic material into the host genome" and that "transgene mutations may unexpectedly interfere with important gene function in the GMO as well as be passed to organisms with which it breeds". Bradshaw (5) agreed that transgene insertion could cause insertional mutations that abolish gene function in the organism, but said there was no evidence that this also leads to instability. Verzola (67) highlighted the high frequency of mutations introduced when transgenic events are made and argued that, through gene flow, the risk of damaging mutations would be passed on to other organisms (Verzola, 78). Stewart (68) emphasized that in genetic modification, large numbers of transgenic events are made but only a small minority of resulting plants are selected, based on expression of the gene of interest and on fertility and other characteristics of the plants. He also argued that similar procedures are followed for conventional breeding techniques such as tissue culture or wide-cross or mutation breeding.

Responding to Wuerthele (13), Wozniak (25) argued that there was no evidence that the genetic modification process produced inherently unstable or unpredictable organisms and secondly, that instability in the plant genome (due to transposons, natural mutations or translocation, etc.) was an everyday reality, a point also made by Bradshaw (5). Wozniak also added that the studies he had reviewed regarding stability of transgene inheritance had not provided any suggestion "that the inserted gene construct was unstable or in anyway altered following insertion". Like Datta (7), Burke (64) and Stewart (68), he argued that as with conventional breeding, plants with undesirable characteristics would be identified and discarded through standard production and selection procedures. Uijtewaal (4) stated that characteristics like "stability of expression" and "unexpected side effects" are studied "for at least 3-5 years during an intensive selection program. The costs related to the development and registration of such a (GM) product are so high that a company can not afford to develop a product that will not last".

2.2.2.6 Philosophical/ethical aspects of gene flow from GM to non-GM populations

Apart from the ecological and economic impacts of gene flow, there is also a philosophical/ethical dimension to the question. Louwaars (50) said that one of the impacts of gene flow might be that "genes from foreign species may be regarded by local communities as a threat to the natural integrity of the local crops". De Lange (91) emphasized the importance of this aspect, arguing that in the conference the spiritual dimension had been overlooked, "which is very real for most, if not all, indigenous peoples. Maize, for example, is considered by Mexican and other meso-american indigenous peoples as sacred. Apart from all other dimensions (food safety, environmental safety, patents etc.) the transgenic contamination of Mexican indigenous varieties is considered as spiritual pollution".

Regarding naturalness and integrity of local populations, Trus (75) suggested that "in biological systems there is rarely such a thing as absolute purity. Similarly, the concept of 'pollution' is a relative one only. Any apparent purity in a breeding population is really a function of the amount of time since the last novel genetic 'migrations' (intentional or otherwise), the nature of the novel genetic contributions and the genetic stability of the resulting population". Heaf (66) addressed the issue of naturalness of genetic modification and any resulting gene flow by quoting from a passage in Shakespeare's play "A Winter's Tale", where Polixenes argues that since man is part of nature, anything he makes or does is also the work of nature (i.e. in our context, as man has developed GM varieties then gene flow from GM varieties is also natural).

2.2.2.7 Centres of origin

Following reports of GM maize in southern Mexico (part of the centre of origin and diversification of maize), there has been considerable focus recently on the specific issue of the impacts of gene flow in centres of origin. For developing countries, the issue is especially important because, as Valdivia-Granda (22) pointed out, "many developing countries are the genetic centers of origin for cultivated plants modified by genetic engineering". Participants emphasized strong concern about this issue.

Ashton (47) and Rosset (83) expressed "alarm" about the "Mexican maize contamination saga", with Rosset calling for a moratorium on GM releases in such centres until more information is available. According to Ghislain (35), the issue of gene flow in centres of origin and diversity needs special attention "due to its complex mixture of scientific, social, and cultural

issues", but warned that the scientific and sociocultural aspects should not be confused. Krell (41) urged that the precautionary principle should be embraced regarding this issue and that in centres of origin, conditions should be promoted that favour conservation of their natural genetic resources. He proposed that farmers in these areas should "receive subsidies or other motivation for not using introduced or genetically modified material, but using local varieties". Muir (110) argued that although all GMOs introduced into their centres of origin will not result in harm, they have the potential to produce effects on the ecosystem that are just as devastating as introducing invasive species.

2.2.2.8 Organic agriculture

The issue of gene flow from GMOs to plants on organic farms is especially sensitive as organic agriculture does not permit the use of GMOs. As Nickson (101) put it, "perhaps the most contentious place of detection (of GM material) would be in organic where transgenes have been designated as unacceptable based on personal preferences".

Cummins (12) and Di-Giovanni (23) referred to the specific case of organic farmers in Canada where, because of gene flow, "essentially no canola grown in western Canada can be claimed to be free of gene modification" (Cummins, 12) and where legal proceedings are consequently being taken by organic farmers against biotechnology companies (Di-Giovanni, 23). Wozniak (33), agreeing with Cummins (28) that the process of "double fertilisation" could result in detectable GM products in some fruits or grains pollinated by GM crops, noted that the rules governing organic production in most countries tend to be unforgiving regarding the presence of GM material. Redenbaugh (39) also noted that gene flow from CBOs to organic farms was not considered to render the crops non-organic. According to Burke (17), the rules disqualifying growers from organic certification if GM material is detected were "imposed, in essence, by organic farmers on organic farmers" and that such certification bodies were now trying to assert the rules over non-organic farmers.

2.2.3 Participation in the conference

The conference ran for five weeks, from 31 May to 5 July 2002. A total of 275 people had subscribed to the conference by the opening day and the numbers gradually increased to 382 by the final day of the conference. Of these 382 people, 61 (i.e. 16 percent) submitted at least one message. Forty-eight (48) of the 118 messages posted (i.e. 41 percent) came from participants in North America while the others came from Europe (21 percent), Asia (18 percent), Africa (12 percent), Latin America and the Caribbean (4 percent) and Oceania (4 percent).

People sent messages from 25 different countries, the largest proportion came from the United States (30 percent), Canada (11 percent), the Philippines (8 percent), South Africa (8 percent) and the United Kingdom (8 percent). A total of 32 percent of messages was from participants in developing countries and 68 percent from developed countries. (Note that these figures are only an approximate indicator of the relative contributions of the developing versus developed world and of the different world regions to the conference - people from developing countries may be currently living in developed countries [and vice versa]).

The greatest proportion of messages came from people working in universities (32 percent), followed by those in research centres (24 percent), NGOs (17 percent) and private companies (12 percent). Note, again, that these results are only an approximation, people may have several roles at any one time (e.g. a participant with a university work address could also be on a governmental advisory board and/or a member of an NGO) and they may change over time.

2.2.4 Name and country of participants with referenced messages

Aniol, Andrzej. Poland
Ashton, Glenn. South Africa
Badr, Aisha. Egypt
Blair, Hugh. New Zealand
Bothma, Gurling. South Africa
Bradshaw, Toby. United States
Burke, Derek. United Kingdom
Choudhary, Bhagirath. India
Claparols, Javier. The Philippines
Cummins, Joe. Canada
Datta, Swapan. The Philippines
De Lange, Wytze. The Netherlands
Di-Giovanni, Franco. Canada
Dusi, André. Brazil
Gallego-Beltran, Juan. Colombia
Ghislain, Marc. Peru
Gressel, Jonathan, Israel
Halos, Saturnina, The Philippines
Heaf, David. United Kingdom.
Heinze, Berthold. Austria
Jeggo, Martyn. Austria
Jenkins, Peter. United States
Knibb, Wayne. Australia
Krell, Rainer. Italy
Lindgren, Dag. Sweden
Lingareddy, Tulasi. India
Livermore, Martin. United Kingdom
Louwaars, Niels. The Netherlands
Menne, Wally. South Africa
Mettler, Irvin. United States
Morris, Jane. South Africa
Muhunthan, Rajaratnam. Sri Lanka
Muir, William. United States
Murphy, Denis. United Kingdom
Namai, Hyoji. Japan
Nickson, Thomas. United States
Nielsen, Kaare. Norway
Nishio, John. United States
Raybould, Alan. United Kingdom
Redenbaugh, Keith. United States
Rosset, Peter. Mexico
Smyth, Stuart. Canada
Stamp, Peter. Switzerland
Stewart, Neal. United States
Trus, David. Canada
Uijtewaal, Bert. The Netherlands
Valdivia-Granda. Willy. United States
Verzola, Roberto. The Philippines
Wozniak, Chris. United States
Wuerthele, Suzanne. United States

CHAPTER 3.
WHAT SHOULD BE THE ROLE AND FOCUS OF BIOTECHNOLOGY IN THE AGRICULTURAL RESEARCH AGENDAS OF DEVELOPING COUNTRIES?

3.1 BACKGROUND DOCUMENT

3.1.1 Agricultural Research

At the "World Food Summit:*five years later*", which took place from 10 to 13 June 2002 at FAO headquarters, Rome, Italy and was attended by delegations from more than 180 countries, Heads of State and Government unanimously adopted the "Declaration of the World Food Summit:*five years later*" (www.fao.org/DOCREP/MEETING/005/Y7106E/Y7106E09.htm#TopOfPage). Among other things, the Declaration considered (in paragraph 25) agricultural research and biotechnology, stating "We call on the FAO, in conjunction with the Consultative Group on International Agricultural Research (CGIAR) and other international research institutes, to advance agricultural research and research into new technologies, including biotechnology. The introduction of tried and tested new technologies including biotechnology should be accomplished in a safe manner and adapted to local conditions to help improve agricultural productivity in developing countries. We are committed to study, share and facilitate the responsible use of biotechnology in addressing development needs".

The importance of agricultural research is clear when consideration is given to the very difficult challenges that farmers in developing countries must face in the coming decades. For example, Pardey and Beintema (2001) express this quite clearly: "Little land remains for the expansion of agricultural production (and some of the land, water, and other natural resources needed for agriculture are being degraded and diverted to other uses in other sectors), so crop and livestock yields must continue to increase for the decades ahead. They must then be maintained - at these much higher levels - for the foreseeable future against environmental, biological, and other factors that undermine past gains in production. Continued strong performance in research and innovation is needed to maintain a favorable food balance if, in addition to the 6 billion people we already have, we are to feed 3 billion more over the next half century".

In the same report, Pardey and Beintema (2001) provide an overview of the status and key trends in global agricultural research. They estimate that investments in public agricultural research rose from US$11.8 to US$21.7 billion (in inflation-adjusted terms) from 1976 to 1995, although in some areas (e.g. sub-Saharan Africa) growth in spending halted in the most recent years analysed (1991 to 1995). Considering the latest figures (circa 1995), a total of 47 percent of investments was made in developed countries while 53 percent went to developing countries, specifically to China (10 percent), Asia and the Pacific, excluding China (21 percent), Latin America and the Caribbean (9 percent), the Middle East and North Africa (7 percent) and sub-Saharan Africa (6 percent). The influence of individual countries was quite significant. Four countries (France, Germany, Japan and the United States) accounted for two-thirds of the spending in developed countries while three countries (Brazil, China and India) accounted for 44 percent of spending in developing countries.

These public sector investments were, however, quite small when expressed as percentages of the agricultural Gross Domestic Product (GDP) and the percentages were lower in

the developing than the developed world. Investments represented just 0.6 and 2.6 percent of the agricultural GDP in developing and developed countries, respectively (i.e. for every US$100 of agricultural output, developing countries invested US$0.62 in public agricultural research and development). Investment per capita was also considerably lower in the developing world i.e. US$2.5 versus US$12 in developing and developed countries respectively, or US$8.5 versus US$594 spent per agricultural worker.

In addition to publicly funded agricultural research, Pardey and Beintema (2001) estimate that funding from the private sector accounted for an additional US$11.5 billion in the mid 1990s, representing roughly one-third of the global agriculture research investments. However, unlike public sector resources, these were invested almost exclusively (94 percent) in developed countries. Consequently, just over half of all agricultural research carried out in developed countries was funded by the private sector whereas in developing countries, research was almost totally funded by the public sector.

3.1.2 Agricultural biotechnology research

Biotechnology is a collection of tools that can be applied to many areas of food and agriculture. The range of tools is very broad, as can be seen from the Background Documents to the first four conferences of this Forum, dedicated to the crop, forestry, animal and fishery sectors, respectively (FAO, 2001). Some of the technologies may be applied to all these sectors as well as to agro-industry, such as the use of molecular DNA markers, gene manipulation and gene transfer. Others, instead, are more specific, such as vegetative reproduction (crops and forest trees), embryo transfer and freezing (livestock) or triploidization and sex-reversal (fish).

Some of the biotechnologies, offer tremendous potential to address real problems facing farmers in developing countries. For example, the area of genomics, allowing the identification and characterization of individual genes influencing traits such as disease or stress resistance, growth rate or yield, promises to be of great value. The genetic material (genomes) of several hundred species, including mammals, plants, fish, bacteria and viruses, has already been sequenced or sequencing is in progress and the information generated from genomics studies in other fields, such as human medicine or basic science, may also be useful for the application of genomics to food and agriculture.

There are no clear figures in the literature on the relative resources being invested by the various stakeholders in agricultural biotechnology research. The information that is available focuses primarily on the crop sector where it is clear that the vast majority (maybe 65-80 percent) of agricultural biotechnology research is carried out by the private sector in developed countries. For example, Byerlee and Fischer (2000) compile some rough figures which give a general idea of the relative investments being made by the different players. The figures indicate that, annually, the private sector probably invests more than US$1.5 billion, mostly in developed countries; the public research organizations and universities in developed countries invest up to US$1 billion; the public sector national agricultural research systems (NARS) in developing countries invest US$100-150 million from their own resources (excluding donor funding); the 16 international agricultural research centres (IARCs) of the Consultative Group on International Agricultural Research (CGIAR) together invest roughly US$25 million (about 8 percent of their total budget) and finally, donors, such as the Rockefeller Foundation or non-profit technology transfer organizations, invest US$40-50 million in developing countries. The largest single source of investment is therefore the private sector and the majority (about 90 percent) of biotechnology research is carried out in developed countries.

Although the investments made in the developing world are relatively small in this area, there are also major differences amongst the individual developing countries. In the same report, Byerlee and Fischer classify the NARS into three main groups based on their capacity in plant breeding and biotechnology research. The first group ("very strong") includes the NARS in Brazil, China, India, Mexico and South Africa, which have a strong capacity in molecular biology, including the capacity to develop new tools for their own specific needs. The second group ("medium to strong") has a considerable capacity in applied plant breeding research, as well as capacity to apply molecular tools (markers and transformation protocols), but they depend on tools developed elsewhere. The third group ("fragile or weak") has a weak capacity in plant breeding and virtually no capacity in molecular biology. They estimate that the NARS invest on average 5-10 percent of their research expenditures on biotechnology, which comes primarily from the NARS in the first group and a few in the second group. From the first group, recent trends in China are worth a specific mention. The Government (which funds almost all plant biotechnology research) has increasingly prioritized biotechnology in recent years, to the extent that the resources allocated to plant biotechnology in the crop research budget rose to 9 percent in 1999 and where it is estimated that China accounts for more than half of the developing world's expenditures on plant biotechnology (Huang *et al.*, 2002).

The large differences amongst developing countries with respect to biotechnology capacity and financial/human investments (and to the focus of their biotechnology research) is also clear from the data in FAO-BioDeC, a database developed by FAO containing information on the development, adoption and application of crop biotechnologies in Africa, Asia, Eastern Europe, Latin America and the Near East. Information is organized in two sections, the first covering production of genetically modified (GM) crops and the second covering other technologies, grouped into four classes: plant propagation (e.g. anther culture, micropropagation, embryo rescue, protoplast fusion and culture), microbial (e.g. development of biopesticides or biofertilizers), molecular markers and finally, diagnostics (e.g. enzyme linked immunosorbent assays [ELISA]). The database is available at www.fao.org/biotech/inventory_admin/dep/default.asp.

Results from a preliminary and far from comprehensive analysis show, for example, that the majority of countries in Asia and Latin America are either carrying out research on or field testing GM crops, while few countries in other regions have reached that stage. The analysis indicates that countries like Argentina, Brazil, China, Cuba, Egypt, India, Mexico and South Africa have well-developed biotechnology programmes, with a wide range of initiatives. In addition, countries like Bangladesh, Indonesia, Malaysia, the Philippines and Thailand in Asia; Cameroon, Morocco, Kenya, Nigeria, Tunisia and Zimbabwe in Africa; and Chile, Colombia and Venezuela in Latin America have medium-sized biotechnology programmes, making use of a wide range of technologies, including molecular markers and diagnostics, although the number of initiatives underway is not substantial.

As agricultural biotechnology research is primarily being carried out in developed countries and by the private sector in these countries, the research and the biotechnology products being developed or released are directed primarily to the needs of farmers in developed (and not developing) countries and of richer (and not poor) farmers that can afford the products. For example, in a recent Technology Policy Brief from the Institute for New Technologies of the United Nations University, Arundel (2002) presents an analysis of over 11 000 GM crop field trials carried out in the United States and the European Union which confirms that most of the field trials are conducted by private firms and that only a small number involves tropical crops and traits for stress resistance.

Abiotic stress (e.g. drought, frost, heat or salt) is a major limitation to agricultural production in parts of the developing world. A vast area of soils contains an excess of heavy metals in Brazil and Africa. Steadily increasing acreage of agricultural land in Asia and elsewhere is becoming sterile because of salinity from poorly managed irrigation practices. In many environments, crop performance is severely limited by drought. Research investments in these areas could have major impacts on food security and hunger. However, preliminary analysis of the data in FAO-BioDeC indicates that no GM crops resistant to abiotic stress have been released to date in developing countries and that only six GM varieties are currently under field testing in Bolivia (frost tolerant potato), China (cold tolerant tomato), Egypt (salt tolerant wheat), India (moisture tolerant Brassica) and Thailand (salt tolerant rice and drought tolerant rice). By comparison, for herbicide resistance, there are already three GM crop varieties commercially available and 50 under field testing in developing countries. The database shows that 28 research initiatives are underway for abiotic stress resistance in developing countries. Most of the research is being carried out in five Asian countries. Very little research is being carried out on drought resistance. Work on aluminium-resistant varieties is underway for wheat in Mexico and sugar beet in China. Little research is being carried out on cold tolerance, although Bolivia and China have progressed to field trials in potato and tomato respectively. The amount of research and testing devoted to abiotic stress resistance is insufficient compared with the real needs of developing countries.

3.1.3 This Conference

Biotechnology clearly offers tremendous promise for addressing key problems in food and agriculture. However, resources for agricultural research are very limited in developing countries and as a consequence, their policy-makers are faced with a series of very difficult choices. How much importance should they give to biotechnology research? How should they allocate the biotechnology research resources with respect to the different agricultural sectors or to the different kinds of biotechnologies available? How should they prioritize the different kinds of problems (and specifically those affecting poor farmers) that might be addressed by the research? How should developing countries carry out this research, by focusing on their NARS or in collaboration with other countries in their region or with the private sector or the universities in the developed world? These are the kinds of issues that should be raised and discussed throughout the conference. More specifically, the items that should be discussed are:

- of the limited resources (human and financial) dedicated to agricultural research in developing countries, how much should be devoted to biotechnology?
- of the resources devoted to agricultural biotechnology research in developing countries, what priorities should be given to the different agricultural sectors (crop, fishery, forest, agro-industry or livestock)? How should these priorities be set?
- of the resources devoted to agricultural biotechnology research in developing countries, which biotechnologies should be prioritized (e.g. use of molecular markers, tissue culture, genetic modification, etc.)?
- which objectives (e.g. increased production, better animal health, etc.) should biotechnology research be prioritizing within each of these sectors?
- at which level (regional, subregional or national) should the objectives of research in agricultural biotechnology be prioritized?
- should some (or all) of the biotechnology research in developing countries preferably be carried out within the NARS or through collaborative regional efforts?
- for agricultural biotechnology research in developing countries, how important should collaboration with the IARCs be?

- for agricultural biotechnology research in developing countries, how important should collaboration with the private sector or universities in developed countries be?
- should developing countries focus on developing the biotechnology products themselves or should they focus on adapting biotechnologies that have been developed elsewhere?
- individual developing countries differ greatly in their capacities to carry out biotechnology research and in the resources they have available for such activities. How important are these differences for the role and focus of biotechnology in the agricultural research agenda?
- the needs of small farmers are generally being ignored in the so-called "biotechnology revolution". How can the biotechnology research agenda in developing countries be focused towards their needs? What concrete actions can be taken?

3.1.4 References

Arundel, A. 2002. GM field trials: Relevance to developing countries. *Technology Policy Briefs* 1 (2): 4-5. Institute for New Technologies of the United Nations University. (also available at www.intech.unu.edu/publications/technology_policy/tpb_v1_02_2002.pdf)

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Huang, J., Rozelle, S., Pray, S. & Qinfang, W. 2002. Plant biotechnology in China. *Science* 295: 674-676.

Pardey, P.G. & Beintema, N.M. 2001. *Slow Magic: Agricultural R&D a Century after Mendel*. IFPRI Food Policy Report. (also available at www.ifpri.cgiar.org/pubs/fpr/fpr31.pdf).

3.2 SUMMARY DOCUMENT

Executive summary

The agricultural research agenda should be defined using a "bottom-up" approach, based on the needs of local communities in developing countries. The needs and realities of small farmers in developing countries require special attention in the research agenda. Research is very important for developing countries' agriculture and more public funding of biotechnology research is needed. There is general agreement on the positive role that non-GMO biotechnology research can play in developing countries but opinions are divided on the use of scarce agricultural research resources for GMO research. Biotechnology research can and should complement research into conventional technologies. Research collaboration, both within and amongst countries, is essential for developing countries but there are some reservations about public-private sector collaboration. Intellectual property rights are an issue of concern for biotechnology research in developing countries. With reduced national research budgets, regional collaboration has special importance. Opinions are divided on whether developing countries should develop their own biotechnology products and techniques or whether they should adapt those developed elsewhere. These were some of the outcomes of a moderated e-mail conference, entitled "What should be the role and focus of biotechnology in the agricultural research agendas of developing countries?", hosted by the FAO Biotechnology Forum from 13 November to 16 December 2002. During the five-week conference, 347 people subscribed and 128 messages were posted, about 60 percent from people living in developing countries. Most were from people working in research centres/organizations (35 percent), universities (25 percent) and NGOs (20 percent), with the remainder being from independent consultants (10 percent) or people working in government agencies or FAO.

3.2.1 Introduction

During the conference, a total of 128 messages were received and are numbered in the order of posting. Specific references to messages posted, giving the participant's surname and message number, are provided. All messages can be viewed at www.fao.org/biotech/logs/c8logs.htm. There was large interest in the subject of the conference. A total of 347 people joined and 67 (19 percent) of them submitted at least one message. Messages were received from all over the world, about 60 percent from participants living in developing countries. The conference was very successful, both in terms of the number of topics covered and, in particular, the quality of the messages posted. As Murphy (106) wrote in the final week, "The discussions have overwhelmingly been positive and constructive both in substance and tone and I have learned a lot from people with whom I would rarely have the chance to communicate".

Most of the discussions, when referring to specific agricultural situations, considered the crop sector, with few messages focusing solely on the agro-industry, fishery, forestry or livestock sectors. Although the term "biotechnology" in the FAO Biotechnology Forum covers a wide range of diverse technologies, used mainly in reproductive biology or in the manipulation and use of genetic material of living organisms, participants chose to focus on genetic modification and genetically modified organisms (GMOs). Thus, as in previous Forum conferences, GM crops were a major topic of discussion.

In Section 3.2.2 of this document, the main elements of the discussions are summarized under seven topics. Section 3.2.3 provides some information on participation in the conference and Section 3.2.4 gives the name and country of the people who sent referenced messages.

3.2.2 Main topics discussed

3.2.2.1 Bottom-up approach to agricultural research

There was a large consensus that research in developing countries should be intimately linked to the problems and requirements of local communities. The need for a "bottom-up" approach in agricultural research and development was therefore emphasized (Altieri [42, 94], Bhatia [53], Nishio [100], Ashton [102, 119], Dhlamini [105], DeGrassi [111] and Vazquez [128]). As Altieri (94) wrote, the approach should use and build upon the resources available i.e. the local people, their knowledge and native natural resources and "it must also seriously take into consideration, through participatory approaches, the needs, aspirations and circumstances of smallholders". Ashton (119) argued that breeding improvements (through biotechnology or conventional methods) can only succeed if a network exists to take the "needs of farmers to breeders and for the two to meaningfully interface".

Perera (76) referred to a practical application of the bottom-up approach when establishing agricultural biotechnology priorities for Sri Lanka. Institutes in the NARS and other related institutes held discussions with their relevant stakeholders and then informed a national committee of their future plans and priorities in the field of biotechnology. The committee then decided on the national priorities by considering the real problems faced by the farming community and deciding which techniques could help to solve/minimize these problems. Nwalozie (47) also described how a broad spectrum of stakeholders, including farmers and non-governmental organizations (NGOs), were involved in the development of agricultural research plans for West and Central Africa.

DeGrassi (111) agreed with Altieri (42) that the voice of the poor farmer was mostly absent when the agenda was being set for the poor and he advocated building basic grassroots democracy. Muralidharan (6) felt that even in developing countries with high biotechnology capacity, like China and India, "hardly any benefits have been realized which are specific to poor-farmer requirements". Altieri (8), supported by Sai (15), also argued that the CGIAR and Global Forum on Agricultural Research (GFAR), both important for defining the research agendas for the developing world, had little participation from farmers and NGOs. Badr (127) argued that because small farmers have their own expertise and local knowledge, researchers should work with them, a point also made by Nishio (100). Sanchez (126) indicated the need for biotechnology researchers to not only receive training in biology techniques but also to develop an "holistic view of the rural and agricultural situation of their countries".

3.2.2.2 How much of the limited resources available for agricultural research should be devoted to biotechnology?

As noted in the Background Document (and emphasized by participants throughout the conference), agricultural research is very important for developing countries, especially in the light of the challenges that farmers in developing countries will face in the coming decades, however, it receives relatively limited funding. One of the questions that participants were asked to address in the conference was how much of these limited resources should be devoted to biotechnology research. Traoré (39) felt it was not easy to answer the question. As Immonen (30) noted, "agricultural biotechnology may compete with many other research needs in agriculture and in other areas of research for benefit of the developing countries". There was a lively discussion on the topic, with considerable disagreement on the usage of research resources on GMOs (i.e. "GMO research"). There was, however, general agreement on the positive role that

biotechnology research, excluding GMOs (i.e. "non-GMO biotechnology research"), can play and that biotechnology research can and should complement research into conventional technologies.

Limitation of agricultural research resources was in some cases, however, seen to be an insurmountable problem. For example, Mayer (87) noted that in reality there were often few or no research funds available for allocation and that funding for international agricultural research had considerably decreased in recent years. Herbert (99) said that in Nigeria, less than 0.1 percent of the GDP was applied to agricultural research (crop and livestock together, with relatively fewer resources going to livestock), a situation which was not conducive to investments in livestock biotechnology research.

a) Biotechnology research complementing conventional research

Several participants emphasized the complementarity between biotechnology research and research into conventional technologies. Downes (9) argued for increased support for biotechnology research but said that this did not deny the need for better, more conventional technologies in food production. Beach (4), supported by Collard (24), also felt there was room for both conventional breeding and biotechnology and that it would be wrong to reduce support for conventional breeding and depend on biotechnology (i.e. "they must go together"). This was precisely the concern of Guimarães (3), who noted that many traditional rice breeding programmes had been dismantled and funds transferred to other research areas such as biotechnology, meaning that it was now more difficult to train a young scientist in conventional rice breeding methods than it was a couple of decades ago.

Traoré (39) estimated that in Mali, more than 80 percent of the agricultural research resources were allocated to applied and adaptive research, mostly to conventional research methodologies, and suggested that "some resources could be devoted to selective biotechnology tools like molecular markers or tissue culture which could efficiently complement the ongoing conventional research". Muir (72) proposed that given limited resources and time, optimal allocation of research resources could be found by defining the alternative technologies (e.g. conventional breeding, marker-assisted selection [MAS] or genetic modification), the costs of each and the likely benefits from each.

Izquierdo (19) favoured a "strict interdisciplinary complementation considering conventional breeding, advanced genetic plant improvement and integrated crop management" and urged that polarization be avoided. Altieri (42) also urged that truly interdisciplinary research be conducted, covering crop, soil, water and pest management aspects simultaneously and considering the specificity of the local farming systems, maintaining that biotechnology research treats the complex agrobiodiversity characteristics of small farming systems as a "black box". Murphy (48) emphasized the importance of having the basics in place first, i.e. metaphorically making the cake, and that GMO research might then be the "icing on the cake". His overall feelings about agricultural research in developing countries were that a) there was still a great dearth of basic knowledge about the agronomy, physiology and genetics of many major crops in these countries; b) an appropriate infrastructure, both for education and training and for advice and outreach to farmers was still being developed; c) dramatic yield benefits might be possible by simple improvements in management practices and by better use of existing germplasm; and d) in the longer term, developing countries would need to deploy the full range of modern agricultural biotechnology methods and they should therefore foster a modest research effort in this area.

b) Research on GMOs

There was considerable discussion and deep division, regarding how much research resources should be used on one biotechnology, genetic modification. Altieri (1) provided a number of reasons why he considered that very little public funds should be used for GMO research in developing countries, particularly in relation to small farmers, such as the costs of transgenic seeds, the long development time for GM crops (especially when modified for complex traits, like drought tolerance), the absence of acceptable biosafety regulations in some countries and intellectual property rights (IPR) issues. Howe (13) argued that substantial funding of GMO research by large companies meant that it was not carried out to benefit the poor and that (69) no public funding should be dedicated to GMO research. As an alternative to genetic modification, Altieri (8) proposed that there were "hundreds of other less risky, less costly agro-ecological technologies that are pro-poor, do not cause environmental degradation and that are culturally sensitive and socially activating". De Lange (16) agreed, citing integrated farming, mixed cropping and traditional soil and water conservation methods. Ferry (18) felt that promoting more GMO research "except in some exceptional cases, will be at best useless to the poor and more probably prejudicial for them", and argued that since money for research in developing countries was increasingly rare, biotechnology should not be a priority for the poor.

The issue of consumer concerns about "GM food" was raised by some participants (e.g. Verzola, 11; Mashava, 12) who felt the concerns should be a motive for reducing GMO research funding, while others (e.g. Infante, 17) suggested it was hindering the possibility of developing countries introducing new GM products to the world market. Vazquez (28) said that the healthy food production environment of developing countries should be further boosted and that alternatives to GM crops, such as research in the fields of agro-ecology, population ecology and community ecology, should be explored. Verzola (51) cautioned about the risks of gene flow from field testing GMOs and warned scientists to be aware that field testing could be used to carry out a hidden agenda of "deliberate contamination" of GMO-free countries. In this context, Mehra (70) noted that many developing countries do not have sufficient infrastructure to regulate the release/use of GM crops, while Halos (52) proposed that when a country decides to invest in GMO research it should also establish a biosafety regulatory system.

Other participants emphasized the potential benefits of GMO research. For example, Downes (9), while accepting the main arguments of Altieri (1, 8), came to a different conclusion, arguing for better support for GMO research (and teaching) "carried out on a broadly public-good model, in developing countries and in partnership with them". He felt that, although still at the early stages of its development, genetic modification "is generally judged to be at the beginning of extraordinary wealth (and health) creation in the rich world" and that poor regions of the world should not be allowed to fall behind in this area and should be assisted to access it for their own needs. Sai (7), like Muralidharan (6), also disagreed with Altieri (1) that very little public funds should be used for GMO research in developing countries, arguing that this would only support the cause of the multinational corporations (MNCs), which currently possess knowledge in the field, and that "successful public research can only counter monopolistic tendencies of private corporations".

c) Non-GMO biotechnology research

As Sabu (45) reminded participants, biotechnology is not just about GMOs. While the use of agricultural research funds for GMO research was a subject of considerable debate, the same was not true for other biotechnologies. Participants proposed a range of different non-GMO biotechnologies that should be included in the research agenda (although without specifying how

much resources should be devoted to them), often suggesting that this research would be more beneficial to developing countries than research involving GMOs.

Muralidharan (61), supported by Dollie (62) and Howe (64), felt that less sophisticated, cheaper biotechnologies were being neglected in the research agenda in favour of genetic modification because it was "new and fashionable". Dollie (62), therefore, suggested "perhaps it is time to pause and re-prioritise". Verzola (11) and Collard (24) also argued that biotechnology research was too skewed in favour of genetic modification while non-GMO biotechnologies received little attention and funds. Newman (86) felt that scarce funding should be allocated preferably to non-GMO biotechnology that "offers the same promises of disease, frost, drought and insect tolerance that we are needing". Collard (24) suggested that research into other biotechnologies (such as mutation breeding, tissue culture and use of markers) might be more relevant to developing countries than GMO research and that non-GMO biotechnologies should be considered on the research agenda, but only in conjunction with non-biotechnology areas of agricultural research. Datta (26), on the other hand, argued that each biotechnology has its own merits and disadvantages and that genetic modification, for example, could tackle some problems that other biotechnologies could not.

Edirisinghe (88) emphasized that there are many areas of research where there are "no arguments and which all can agree to work on", thoughts echoed by De Lange (118) who said "we should focus on biotechnologies that are acceptable for everybody". Muralidharan (92) supported Edirisinghe's (88) point, proposing 'lower biotechnologies' (such as biofertilizers) as one such research area. He also argued that they would benefit from the availability of cheap labour in developing countries and that additional research should be carried out to make micropropagation more accessible to farmers in developing countries. Scanlan (80) also supported research into the "lower biotechnologies", maintaining that substantial progress had been made in the development of biofertilizers and biopesticides and suggesting that, when associated with other desirable practices (including promotion of biodiversity, multiple cropping systems, indigenous plant species, improved germplasm and integrated production and protection), technologies such as these "can have much impact in addressing household food security and creating sustainable livelihoods in low-income food-deficit countries".

Sabu (45), like Nwalozie (31), described the benefits of tissue culture, where a plant tissue culture laboratory could be set up in public sector institutions with poor finances, and underlined the role that genomics could play in rice breeding. Immonen (30) also highlighted the importance of genomics research, arguing that it would be particularly important for crops in developing countries, while De Lange (118) underlined how much has yet to be learned about genomes. Rajmohan (84) also felt that tissue culture was an important biotechnology for developing countries, but stressed its limitations. He proposed that use of molecular markers was the most important area of biotechnology, given the rich plant genetic resources found in developing countries, and that GMO research (focused on specific-country needs) should be strengthened only in selected institutions, in collaboration with developed countries. Mayer (66) also underlined that apomixis in otherwise non-apomictic crops was a very important area of biotechnology research.

3.2.2.3 What should be the priorities for biotechnology research in developing countries?

Of the resources devoted to agricultural biotechnology research in developing countries, what priorities should be given to the different agricultural sectors (crop, fishery, forestry, agro-

industry or livestock) and which research areas should be prioritized within each of these sectors? In the conference, some participants attempted to answer these difficult questions.

Considering prioritization in general, Bhatia (53) suggested that when setting priorities in agricultural research, methods should be used to identify areas giving "maximum return in the shortest possible time, with minimum investment", although he pointed out that even in small farming communities, conflicts may arise amongst the needs of different groups of farmers (e.g. those with dry land or with irrigation facilities). He proposed that the most limiting constraint for production systems in an area be identified and then "the best available technology that can ameliorate the situation in the shortest time frame, at an affordable cost, should be used". Franco (120) argued that prioritizing the needs of developing countries should be on the basis of a case-by-case analysis, considering the kind of biotechnology research involved (GMO, tissue culture, molecular markers, etc.), the user (poor farmer for food subsistence, or large farmer for export of products) and the time horizon. Rajmohan (84) maintained that when allocating resources for biotechnology research, developing countries should have concrete ideas about the immediate and long-term benefits to their resource-poor farmers and they should not merely attempt to mimic the biotechnology research of developed countries.

Hong (101) noted that each country has to prioritize and evaluate areas of biotechnology that could be effectively and economically employed for its (agricultural) development, giving the example of Malaysia, where the Government has formed a National Biotechnology Secretariat to prioritize and coordinate suitable biotechnological applications for development of industries or processes, especially those using agricultural resources. Perera (76) described the outcome of an exercise to determine agriculture biotechnology priorities for Sri Lanka, considering the real problems of the farmers and deciding which techniques could help/minimize them. The seven priorities were improvement of crop and livestock productivity; reduction of costs of cultivation of crops and management of livestock; biodiversity; environment; genome analysis and transgenics; bioinformatics; and finally, nutrition.

a) Priorities amongst the different agricultural sectors

Badr (60) felt it was hard to generalize about this, as the agricultural sectors to be prioritized may differ amongst countries and even amongst regions of a country. Traoré (39) also noted that the prioritized sector will differ from country to country and suggested that prioritization should depend on the added value that biotechnology brings to the research programme. For Mali, research in the crop sector had been prioritized "due partly to the state of trained manpower and labour facilities", but that livestock and forestry biotechnology research had not been neglected. Similarly, Rajmohan (84) said crop biotechnology seems to have top priority in most developing countries and that priorities amongst the remaining sectors should be based on benefits to the farmers. Muhunthan (117), because of the importance of crops such as cereals, legumes, vegetables and tubers, proposed that first priority for agricultural biotechnology research should be given to the crop sector, followed by the forestry sector, then the livestock/fishery sectors and finally, agro-industry.

b) Priorities within the different agricultural sectors

When considering priorities for biotechnology research within specific agricultural sectors, most messages considered the crop sector, with participants proposing a range of different research areas and species to be prioritized.

Infante (17) pointed out that some crops of high economic and trade value, such as coffee or cocoa, had not been prioritized in the research agenda, but should be. He also proposed a number of areas where biotechnology would be invaluable for improving crop production because improvement through conventional breeding is difficult, such as crops with a narrow genetic base and/or long agronomic cycles. Sabu (21) mentioned specifically how the genetic diversity of rice had been eroded by genetic selection processes and that both the productivity and genetic diversity of rice had to be increased in Asia, proposing that biotechnology be used for the identification and incorporation of useful genes from wild rice germplasm. Immonen (30) in particular mentioned the need for research into the function of genes controlling important crop traits, such as tolerance to different abiotic stresses. Muhunthan (117) suggested the use of DNA markers, micropropagation and other *in vitro* technologies be prioritized with the aim of increasing productivity and the development of pest/disease resistant crop varieties. Owusu-Biney (93) suggested a number of specific examples of problems in West Africa that might be addressed by biotechnology, including those involving the cassava mosaic virus, the presence of arsenates in soils of mining areas and the need for fast growing trees for afforestation programmes and to satisfy demand for wood. Newman (86) said that priority in research should be given to addressing the impacts of seasonal variation, in particular due to drought, because farmers need consistency in income. Infante (17) suggested that research in South America should also consider the special circumstances of people living in regions above 3 000 metres in altitude.

For the forestry sector, Muralidharan (85) emphasized the "tremendous potential of biotechnology" for improving understanding of the genetics of forest trees in the tropics and thus accelerating their genetic improvement, but argued that the objectives of tree improvement programmes should move from the emphasis on a few, fast-growing clones grown in a sterile high-input environment to a "more people and eco-friendly forestry". Muhunthan (117) emphasized the need to preserve the valuable genetic resources of developing countries, where molecular markers and *in vitro* techniques, together with reproductive biological studies, could be used.

Regarding other sectors, Herbert (99) felt there was an urgent need to apply biotechnology to ensure maintenance of livestock biodiversity in the developing world, emphasizing the risk of erosion of animal genetic resources. Halos (52) proposed that biotechnology research should also focus on development of edible vaccines for humans and animals, an area also highlighted by Badr (95). Muhunthan (117) emphasized milk production of local livestock breeds, using conventional methods as well as reproductive and DNA technologies to increase production, while for aquaculture, he proposed that the focus be on genetic selection and hybridization, with maximum utilization of sea and inland water resources. For agro-industry, De Lange (40) suggested that biotechnology research should aim to improve fermentation techniques, especially at the household level, while Muhunthan (117) maintained that research should focus on "conventional biotechnologies", such as biofertilizers and biopesticides, and that village communities should be directly involved in the research work.

c) Impact of the time horizon on priorities

Ferry (90) pointed out the importance of considering the time perspective when discussing priorities in the research agenda, as new varieties (GM or not) might not be considered necessary for reducing the number of poor by the year 2015 but they might be if the time horizon was extended to 2050. He also proposed that research resources for regions with serious hunger problems (such as sub-Saharan Africa) should be focused on projects providing rapid solutions. Muralidharan (54, 67) also felt that, particularly for developing countries, research funding

should go towards meeting short-term goals. Collard (24) maintained that with so many food insecure people in the world, research providing short-term benefits was essential in agriculture and, since many areas of biotechnology may only provide medium- to long-term benefits, this research might not involve biotechnology.

Blanchfield (58) felt it was a mistake to try to weigh up short- versus long-term goals, as a "balance is needed between the two", so that the serious problems currently facing the poor, requiring short-term solutions, as well as the responsibility to future generations, would be addressed. Muir (104), supported by Murti (109) and Heisey (110), maintained that short-term solutions for poverty were not to be found in biology (or biotechnology) but in the economics and politics of the region involved, thus "there is no silver bullet such as biotechnology that is going to stop poverty - that requires a consistent and focused political structure to provide the infrastructure necessary to succeed". Infante (107) agreed with Muir (104) that the solution to poverty was social and not technological, and underlined the importance of education. Murti (109) highlighted the problems of building policy in this area when policy-makers are "scientifically illiterate" and scientists "politically clueless".

3.2.2.4 Focusing research towards the small farmer

Throughout the conference, participants placed special emphasis on the situation and needs of the small farmers in developing countries and the potential impact that biotechnology research could have on their lives. Thus, in the first message of the conference, Altieri (1) emphasized that "an estimated 850 million people live on land threatened by desertification. Another 500 million reside on terrain that is too steep to cultivate. Because of those and other limitations, about two billion people have been untouched by modern agricultural science. Most of the rural poor live in the tropics, a region that is the most vulnerable to the effects of global warming".

a) The needs of the small farmer

Izquierdo (19) highlighted traits important for small farmers in marginal areas, such as tolerance to drought, salinity, soil pH, pest resistance, food or fodder quality and post harvest keeping quality. Mayer (66), like Datta (36), underlined the importance of improved seed for the small farmer and argued that "it will be very important to accurately identify the special needs of small farmers with respect to germplasm improvement and then to decide which is the best technical path to achieve the desired results. Biotechnology will not always be the answer but it definitely will in some cases". Sharry (71) agreed, arguing that in Argentina, GM crops could help in some special situations. Badr (78) noted that the needs of small farmers differ from one country to another and gave examples of the problems facing small farmers in Egypt, such as high costs and fluctuations in market prices. She wrote (82) that in Egypt, small farmers want increased yields and income by applying biotechnology research, provided it is safe. Verzola (11) said the small farmers he works with in the Philippines need and want more research on organic, chemical-free agriculture. Ouf (115) maintained that small farmers need high-producing varieties tolerant to different environmental stresses.

Altieri (94) provided a list of eight topics that he thought would emerge in the research agenda if defined jointly with small farmers from developing countries, namely improved understanding of marginal agro-ecosystems; selection of local varieties that deliver stable yields in the face of environmental stress; technologies for water harvesting and drought management; small-scale, community-managed irrigation and water-conservation systems; more diversified, less risky and productive farming systems; synergetic, diversified and less risky cropping and

crop-livestock systems providing more stable yields; productive and sustainable agroforestry alternatives to shifting cultivation and finally, sustainable income- and employment-generating exploitation of forest, fisheries and natural resources, as well as research on land reform, access to local markets, etc. Based on his long experience with low-income rural families in India, Nazareth (46) listed the main causes (14 in total) of nutritional insecurity for rainfed, irrigated and urban areas and suggested that agricultural research systems should look at them and evaluate current agricultural biotechnologies "to see how much they are part of the problem and to what extent they can be solutions".

b) Can biotechnology research help the small farmer?

Although there were clear differences of opinion about genetic modification, there seemed to be general agreement (e.g. Ashton, 102) that specific non-GMO biotechnologies and biotechnology research could help small farmers.

Ashton (102) suggested that countries should follow the example of Zimbabwe where an independent biotechnology trust investigated problems among smallholder farmers that might be addressed by biotechnology. It identified no problems that could be mitigated by use of GM crops. He suggested that GM crops do not aim at meeting the needs of small farmers because they are directed towards intensive, industrial farming, a point also made by Ferry (18). Verzola (20) warned that farmers from developing countries who invest in GM crops would feel "the full brunt of reduced GM crop prices and market rejection", as there were no subsidy programmes for farmers. Altieri (42) stated that major peasant movements worldwide reject GMOs and "corporate control of biotechnology". Muralidharan (6) felt, however, that "poor-farmer biotechnology" could start with nutritional improvement of a staple food crop using genetic modification, as this would clearly illustrate benefits of the technology. Halos (14) described the conditions of small farmers in the Philippines, suggesting that GMOs might be important for them in some situations e.g. increasing their incomes by reducing crop losses due to pests or diseases.

Ashton (102) suggested that other biotechnologies, such as tissue culture or MAS, might successfully address the needs of small farmers. Badr (82) felt that biotechnology research to help small farmers should involve research to increase yields, preferably through small quick projects that could be run by women farmers at home, mentioning (114) in particular, the benefits of micropropagation. Looking at the past, Ferry (32) argued, however, that most high yielding varieties produced by the "green revolution" had been mainly useful to farmers with access to water resources and money to buy fertilizers and pesticides. In reply, Reece (34) accepted that larger farmers had been the first to benefit from the new varieties, but argued that there was evidence to suggest that smaller farmers also eventually increased their incomes by means of the new varieties.

Muralidharan (55) felt that the scarce public funds available should support research to improve and implement "modern, but relatively conventional, agricultural practices" (such as post-harvest protection, storage and equitably distributing food grains) that have a better chance of reaching poor farmers. Muhunthan (122) suggested that the "biovillage concept" could be important for small farmers, where the term "biovillage" is used to denote "the integration of biotechnology with the best in traditional techniques, in a manner that the livelihood security of rural people can be upgraded ecologically and economically". Scanlan (80) advocated the potential benefits of biotechnology research for small farmers in the context of conservation agriculture and other sustainable practices.

Many participants, including Badr (60), felt that any research agenda should be accompanied by training and education for farmers. Kambikambi (50) felt that in some countries, small farmers were not able to make informed decisions on biotechnology because of poor understanding of the subject. Badr (60) also felt that by seeing new technologies applied successfully in field experiments, small farmers would then try to use them. Herbert (99) argued that in rural Africa, where livestock serve as stores of cash, small farmers would accept reproductive technologies in the livestock sector if they were involved in development of the technologies.

3.2.2.5 National, regional and international research collaboration

Cooperation, cooperation, cooperation! With constraints in national research budgets, participants emphasized the importance of increased cooperation between researchers and research organizations, both within and amongst countries.

a) Research at the national and regional level

A point made in the Background Document was that there are large differences amongst developing countries with respect to biotechnology capacity and financial/human investments in biotechnology research. A small number of countries, such as Brazil, China, India, Mexico and South Africa, has well-developed biotechnology programmes. The majority has, however, relatively weak biotechnology capacity and very limited research resources. In this situation, there was strong support from participants for regional research initiatives. For example, Bhatia (53) claimed that NARS in most countries have very little of the expertise and infrastructure needed for advanced biotechnology research (a point also highlighted by Nwalozie [47]), and emphasized, therefore, the need for active collaboration amongst individuals, departments and institutions.

Mayer (6) advocated fostering regional collaboration based on strong NARS and international agricultural research centres (IARCs), and that major donors and advanced research institutes (ARIs) should also be involved. Traoré (39) argued that NARS in developing countries, in addition to other areas, needed to tackle some strategic issues in biotechnology research, focusing on the special needs of developing countries, and that this would help their scientific partners (including IARCs) to give more focus on pro-poor biotechnology research. He encouraged international cooperation on biotechnology research to complement the individual national or subregional research agendas and said that in the African region, the Forum for Agricultural Research in Africa (FARA), in conjunction with the subregional organizations, would play an important catalytic role in this. Muralidharan (6) admitted that, individually, NARS were no match for large corporate firms but emphasized that, collectively, they would have many advantages, such as their ability to focus on specific poor-farmer oriented technologies.

Nwalozie (47) informed participants about the existence of regional and subregional research organizations for developing countries, with the subregional organizations composed of NARS as the building blocks. He described the long consensus-seeking process by which strategic plans for agricultural research cooperation had been drawn up for the West and Central Africa subregion, from which biotechnology was identified as a key tool. Given the definition of regional priorities and the expensive nature of biotechnology, he concluded that “it makes partnership and economic sense to pool human, material and financial resources together at regional levels in respect of biotechnology research in developing countries. This does not mean that national biotech programmes should be stopped. A regional approach can undertake certain

research of common interest, and also strengthen national capacities in biotechnology". Rajmohan (84) also argued that prioritization of the research objectives should be made at the regional, rather than national level and highlighted the importance of regional cooperation amongst biotechnology research institutions, something he said was often missing.

Muhunthan (121) acknowledged that subregional and regional collaboration was very important, but felt that objectives for biotechnology research should be first prioritized at the national level within NARS, and that a body should monitor research within the country to avoid duplication of research efforts, a problem also mentioned by other participants (e.g. Abdel-Mawgood, 108). For a small country like Sri Lanka, he suggested that there was a lot to be gained from collaborating with "regional biotechnology giants", such as India. Ashton (102) also favoured a regional approach, proposing that "the limited resources available for agricultural research should therefore be regionally pooled and examine the simplest, most practical and preferably previously proven and tested technologies used in similar climatological, infrastructurally-deficient regions".

b) Collaboration involving NARS, IARCs, developed country research institutions and the private sector

International collaboration was generally seen in a very positive light, in particular collaboration involving different public sector institutes. Some participants, however, urged caution concerning public-private sector research collaboration.

Herbert (99) felt that cooperation amongst scientists in the north and south should continue as it was yielding good fruits, a point also emphasized by Abdel-Mawgood (108) who said that from his own experience, "the most successful work is that involving collaborative research projects with scientists from the developed world. So I am suggesting that developing countries set up agendas for their priorities and find an expertise from the developed world in that area of research to benefit from his/her experience, to speed up the research and hasten benefit from the technology".

Hong (101) emphasized that biotechnology research must be strategically planned and government supported, with the active participation of the private sector. Rajmohan (84) welcomed international collaboration and said that it was essential, particularly for human resource development and establishment of facilities, as was cooperation between public and private sector institutes within a country. The importance of training human resources in biotechnology was underlined by several participants. For example, Murphy (106) noted its importance for enabling informed decisions to be taken on the allocation of scarce research and development resources, while Dhlamini (105) maintained "capacity building and the ability to retain trained personnel is central to the adoption and utilisation of biotechnology in developing countries".

Some participants, however, expressed reservations about public-private sector biotechnology research collaboration for developing countries and urged increased investments in public sector biotechnology research as an alternative. For example, Muralidharan (6) felt that as private companies had a vested interest in developing technology/products that maximized their profit, this might often go against the interests of farmers in developing countries. Verzola (116) cautioned CGIAR institutes from opening themselves up to "greater corporate influence". Traoré (39) was also sceptical about the private sector properly addressing a pro-poor research agenda, and argued that the only alternative to this was to "build a strategy based on active cooperation among NARS and alliance between NARS and public sector research institutions

(IARCs, ARIs, universities) to enable NARS to have a certain research capacity to address issues important to them and to the poor". Similarly, Dhlamini (105) felt that "over-dependency on the donor community and private sector should be discouraged" as "different donors have different objectives and priorities and in most cases, these are not in line with the critical needs of the recipient countries". He therefore urged increased public sector financing of applied biotechnology activities. Immonen (30) also emphasized the public sector's role, when she called for publicly funded genomics research, involving developing country NARS, IARCs and universities, noting the several advantages the public sector had for engaging in such research. Muralidharan (55) also argued that publicly funded GMO research, unlike that of the private sector, could ensure that crop varieties strategically important for developing countries were included in the research priorities.

Morris (37), however, urged public funding bodies to "develop a mindset that encourages the growth of real wealth creating activities in the developing world", arguing that publicly funded research often "does not lead to the development of true globally competitive research capacity in the developing world, and is often not self sustaining because IPR may not be retained by the organization undertaking the research".

A number of participants underlined the role that international organizations, such as FAO, should have in this area, in: supporting development of infrastructure for public-good agricultural research (Datta ,74; Murphy, 106); providing knowledge and training to researchers from developing countries (Sabu, 21); assisting dialogue on GMOs (Infante, 17; Reddy, 89); providing access to intellectual property useful to developing countries (Datta, 36 and 74); and providing general support for national agricultural biotechnology (Acikgoz, 38).

3.2.2.6 Should developing countries adapt existing biotechnology products and techniques or develop their own?

Participants were divided on the subject of whether developing countries should, or would need to develop their own biotechnology products or techniques or, alternatively, whether they should rely on adapting the research results from industrialized countries. For example, Nwalozie (31, 47) and Morris (37) felt developing countries should be pro-active about biotechnology development, both referring specifically to their continent, Africa, with Nwalozie (47) maintaining "developing countries should not just adapt biotechnologies developed in other countries. These technologies should be developed in the developing countries or in the sub-region of the developing country!". Kershen (41) supported this stance, maintaining that Africa must invest in biotechnology if it is "to have any future hope of gaining independence from aid and food security, and health security".

Nassar (49) disagreed, saying "why should we developing countries spend hundreds of millions of dollars on research that can be made by developed countries?", proposing instead, like Mayer (66), adaptation of technology developed elsewhere. In a similar vein, Bhatia (53) compared development of GM crops to aircraft construction and asked rhetorically "how many countries have developed their own passenger aircrafts?". Given the high technology level and the long time required to develop a GM crop, he said he would personally seek to import the GM seeds from a private company, although he noted that in some cases (if the technology was unavailable/expensive or if the country wished to invest in capacity building), public funds should be used for local biotechnology development. Martinez (57) disagreed with Nassar (49), arguing that the farmer's vision, goals, needs and capabilities should be considered first and then solutions should be tailored to the farmer's specific set of constraints and goals, something "that won't be

achieved by simply importing technology developed for a different population target with different sets of goals and constraints".

Van Asselt (125), arguing that biotechnology research technologies have been developed in close interaction with specific research organisms and are therefore largely "context-dependent", also questioned whether adoption of research results from developed countries was an optimal strategy as the species cultivated in developing countries tended to differ from those used in biotechnology research in developed countries. He therefore supported Franco's (120) call for developing countries to be on the "biotechnology development train". Infante (96) also highlighted that some research problems are specific to developing country agriculture, so developing countries will have to develop the appropriate biotechnology solutions, if they want them.

Willemse (98) noted that most developing countries are net importers of technologies and argued that the need was evident for (a) local adaptation and extension of imported technologies and (b) development and enhancement of new technologies/competencies. In successfully developing the biotechnology sector, he emphasized (98, 103) the importance of the enabling environment for development and application. Rajmohan (84) emphasized the importance of international collaborative efforts, but argued that adoption of already-developed technologies should only be a short-term objective and that the ultimate aim for developing countries should be the generation of independent results and products.

Murphy (106) felt it might be better for developing countries to wait a few years before investing in GMO research, arguing that the technology is getting cheaper and simpler, many of the current applications will be superseded in the next five to ten years and that current technology may then be semi-obsolescent. Immonen (30), on the other hand, suggested that public sector genomics research initiatives, involving developing country NARS, were worthwhile right now, as "in a few years time, the private sector may have acquired a lot more of the so-called platform information which is needed for developing important breeding tools".

3.2.2.7 Intellectual property rights and biotechnology research in developing countries

In discussing research collaboration between developed and developing countries, concerns about the impacts of IPR on biotechnology research in developing countries and the private sector's importance in the IPR issue were often raised. For example, Altieri (8) felt an important issue to be addressed was how poorly-funded public research institutions would be able to conduct independent, pro-poor biotechnology research "in the midst of existing IPR regimes controlled by MNCs and also given that private sector funding of many public research centers and universities is increasingly biasing the research agenda?". Vazquez (28) also suggested that industrialized nations are advancing patent-like protection and/or plant breeders' rights for plant varieties and that "the introduction of GMOs as well as enforcement of IPR regimes globally can be seen as market expansion by corporations". Sai (15) shared the concerns of Altieri (8) and argued therefore that the public in developing countries should be educated that they should have IPR regimes suitable to their needs. He concluded that there was no need for developing countries to comply with the "dictats of MNCs" and that the WTO's agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides them with sufficient flexibility. Sullivan (77) also urged that available options under TRIPS be explored as they could, for example, leave open the possibility for countries to "adopt broad research exemptions to intellectual property infringement, which could be of benefit to developing country agriculture".

Beach (4), Mayer (5) and Young (44) were more optimistic about IPR issues and felt that agreements could be reached to benefit all parties, enabling developing countries to access technology and GM crops yet protecting the commercial interests of MNCs. Sullivan (77) stated that "the issue of proprietary claims to research products will not simply go away" and argued, like Young (44), that proper training of personnel in developing countries is necessary to "develop the capacity and sophistication to deal with modern IPR systems and to negotiate and do business with institutions and companies that hold vitally needed technology". Beach (4) also underlined that scientists in developing countries needed training in IPR and regulatory issues, in addition to knowing how to use the technology.

Mayer (5) also argued that the existence of patents did not mean all doors were closed, as licences at acceptable rates could be obtained, owners of key patents could be lobbied and, finally, patents have a time limit. Immonen (30) also suggested that IPR questions should not be avoided and that many solutions exist, noting that at least "patents are far better for information sharing and negotiation than trade secrets".

For developing countries to circumvent IPR problems, some participants (e.g. Mieschendahl, [29]; Immonen, [30]) proposed increasing public agricultural research to reduce the reliance on patented inputs from the private sector. For the same reason, Morris (37) proposed that Africa should rapidly engage in all facets of biotechnology development, which would allow it to generate its own intellectual property and solutions.

3.2.3 Participation in the conference

A total of 347 people subscribed to the conference and 67 of them (i.e. 19 percent) submitted at least one message, the highest number of active participants and the highest participation rate of all the ten conferences held so far in the FAO Biotechnology Forum, indicating the high interest that people have in this topic. Fifty-eight (58) percent of messages was from participants living in developing countries and 42 percent from developed countries.

All continents were represented, with 40 of the 128 messages posted (i.e. 31 percent) coming from participants living in Asia while the remainder came from Europe (30 messages - 23 percent), North America (18 messages - 14 percent), Africa (20 messages - 16 percent), Latin America and the Caribbean (11 messages - 9 percent) and Oceania (9 messages - 7 percent). People sent messages from 29 different countries, the largest proportion came from India (16 percent), the United States (14 percent), the Philippines (9 percent), Australia (7 percent), the United Kingdom (6 percent) and Egypt (5 percent), followed by the Netherlands, South Africa and Spain (each with six messages - 5 percent).

The largest proportion of messages came from people working in research centres or research organizations (38 percent, including seven messages from people in CGIAR research centres and its Science Council), which was not unusual given the theme of the conference. There were 32 messages from people in universities (25 percent), 13 messages (10 percent) each from NGOs and independent consultants and the remainder came from people in farmer organizations (7 percent), government agencies (5 percent) and FAO (4 percent).

3.2.4 Name and country of participants with referenced messages

Abdel-Mawgood, Ahmed. Saudi Arabia
Acikgoz, Nazimi. Turkey
Altieri, Miguel. United States
Ashton, Glenn. South Africa
Badr, Aisha. Egypt
Beach, Larry. United States
Bhatia, Chittranjan. India
Blanchfield, Ralph. United States
Collard, Bert. Australia
Datta, Swapan. The Philippines
DeGrassi, Aaron. United Kingdom
De Lange, Wytze. The Netherlands
Dhlamini, Zephaniah. Italy
Dollie, Farida. South Africa
Downes, Martin. Ireland
Edirisinghe, Udeni. Sri Lanka
Ferry, Michel. Spain
Franco, Javier. Bolivia
Guimarães, Elcio. Italy
Halos, Saturnina. The Philippines
Heisey, Paul. United States
Herbert, Udo. Nigeria
Hong, Lay Thong. Malaysia
Howe, Bob. United States
Immonen, Sirkka. Italy
Infante, Diogenes. Venezuela
Izquierdo, Juan. Chile
Kambikambi, Tamala. Zambia.
Kershen, Drew. United States
Martinez, Alejandro. Australia
Mashava, Dakarai. Zimbabwe
Mayer, Jorge. Australia
Mehra, K.L. India.
Mieschendahl, Martin. Germany
Morris, Jane. South Africa
Muhunthan, Rajarathan. Australia
Muir, William. United States
Muralidharan, E.M. India
Murphy, Denis. United Kingdom
Murti, J.R. India
Nassar, Nagib. Brazil
Nazareth, Jagdish. India
Newman, Julie. Australia
Nishio, John. United States
Nwalozie, Marcel. Senegal
Ouf, Atef. Egypt
Owusu-Biney, Alex. Ghana
Perera, Athula. Sri Lanka
Rajmohan, K. India

Reddy, P. Chengal. India
Reece, David. United Kingdom
Sabu, K.K. Malaysia
Sai, Y.V.S.T. India
Sanchez, Myriam. Colombia
Scanlan, Fintan. Italy
Sharry, Sandra. Argentina.
Sullivan, Shawn. Mexico
Traoré, Adama. Mali
Van Asselt, Bert. The Netherlands
Vazquez, Chela. United States
Verzola, Roberto. The Philippines
Willemse, Gert. South Africa
Young, Terry. United States

CHAPTER 4.
REGULATING GMOS IN DEVELOPING AND TRANSITION COUNTRIES

4.1 BACKGROUND DOCUMENT

4.1.1 Introduction

As observers of the biotechnology debate will be very aware, the subject of genetically modified organisms (GMOs) in food and agriculture is highly controversial. Although, genetic modification is generally seen as a tool offering potential benefits to farmers and consumers in a wide range of food and agriculture areas, there is concern about the potential impacts on human health and the environment.

The significance of the potential benefits it offers can be appreciated by considering the tremendous progress that has been made in recent years in the field of genetics and the realization that, as the identity, location, impact and function of the majority of genes affecting traits of importance for food and agriculture are still unknown, this is only the tip of the iceberg. In the future, it will be possible to better understand the genetic mechanisms behind a whole range of key traits in the agro-industry, crop, fisheries, forestry and livestock sectors and to use this information to produce GMOs with the desired characteristics.

Human health issues have been raised because GMOs can be a direct source of food (by eating a GM plant, animal or fish) or an indirect source, where ingredients in processed foods may be GM (e.g. soybeans are widely used in processed foods, including margarine, biscuits and sausages) or where domestic animals or fish, eaten by humans, may be raised on GM feed. Currently, GMOs are primarily an indirect food source, as the dominant crops in commercial use are used in livestock feed and food processing and GM fish or livestock are not commercially available for food consumption.

Environmental issues have been raised because of potential consequences of gene flow from GM to non-GM individuals of the same species (a topic covered in Chapter 2) or because GMOs may have a negative impact on unrelated species (e.g. crops genetically modified for insect resistance might harm non-target organisms, such as soil microbiota and beneficial insects).

Regulation of GMOs has therefore always been a central part of the general GMO debate i.e. What kind of regulations should they be? What exactly should they regulate? How strict should they be? How should GMOs be regulated compared with their conventionally-bred counterparts? etc. The theme is especially important because of the impacts of regulation on the trade of GM products and on the research and development climate for GMOs, in what is still a relatively new field. For example, an FAO report (2003a) prepared for the biennial session of FAO's Committee on Commodity Problems notes the current impacts on trade of crops: “the presence of GM products has affected trade, both in commercial transactions and in food aid deliveries. Segregated markets are developing for non-GM products to accommodate consumer preferences, with some countries focusing on supplying the markets for non-GM commodities and some major importers sourcing part of their products in countries known to be free of GM varieties”. The issue of GMO regulation has also engaged policy-makers at the highest international level, where for example, 103 countries in 2000-2001 signed the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, an important international agreement concerning GMOs.

In this Background Document, Section 4.1.2 provides a brief overview of the current status regarding GMOs in food and agriculture. In Section 4.1.3 the areas that might be regulated are covered while Section 4.1.4 considers some key factors concerning regulation of GMOs. Section 4.1.5 lists some specific questions that should be addressed in the conference.

Note, this Forum hosts conferences about specific topics concerning biotechnology in food and agriculture for developing countries. As a simplification, the term "developing countries" in this context has always been intended to include the "transition" countries (i.e. the central and eastern European countries and the new independent states of the former Soviet Union), although there has been little participation from these countries in the Forum so far. To encourage their participation, the conference title for the first time specifically mentions transition countries.

4.1.2 Background and current status regarding GMOs in food and agriculture

A GMO is an organism that has been transformed by the insertion of one or more genes (called transgenes). The genes may be from a different kingdom (e.g. a bacterial gene into plant genetic material), a different species within the same kingdom or even from the same species. For example, two genes from the daffodil *Narcissus pseudonarcissus* and one gene from the bacteria *Erwinia uredovora* were inserted into the genetic material of rice to produce the transgenic rice variety commonly known as "Golden Rice", which produces a precursor of vitamin A.

Active research into genetic modification of living organisms has been ongoing since the 1980s. However, large-scale production of GMOs in agriculture has only become a reality in the past few years, with the commercial planting of GM crops. The current status of GMOs in the crop, forestry, animal, fisheries and agro-industry sectors is looked at here. GMOs are currently commercially available in two sectors, crop and agro-industry.

4.1.2.1 GM crops

Estimates indicate that the global area planted with transgenic crops increased from 2 to 59 million hectares from 1996 to 2002, respectively (James, 2002). Each year, four countries (Argentina, Canada, China and the United States) and four crops (soybean, maize, cotton and canola) have dominated the transgenic acreage statistics. For example, in 2002, the four countries were responsible for 66, 23, 6 and 4 percent, respectively of the global transgenic acreage, with the four crops covering 62, 21, 12 and 5 percent, respectively of the transgenic area planted. Of the 59 million hectares planted with transgenic crops in 2002, 75 percent contained crops modified for herbicide tolerance, 17 percent were modified for insect resistance while 8 percent were modified for both traits.

4.1.2.2 GM forest trees

There is no reported commercial-scale production of GM forest trees. However, there is much active research in the area of genetic modification of trees and a large number of laboratory and field trials, involving a range of tree species, has taken place since the 1980s. The traits of interest for GM forest research include herbicide tolerance and pest resistance (as for crops), but also other features, such as delayed flowering (so that trees can be harvested before they pollinate) or lowered amounts of lignin (to reduce the costs and environmental pollution associated with paper-making). Breeding trees for drought, flooding or salt tolerance may find

useful applications in environmental rehabilitation, and soil and water restoration. A study commissioned by FAO to review the global status and trends regarding genetic modification of forest trees is currently underway.

4.1.2.3 GM animals

Although transgenic animals (especially mice) are used routinely for research purposes, no GM animals are commercially produced for food purposes. Regulatory approval for GM food animals (excluding fish that are covered below) has only been sought in a single case, namely, for a GM pig in Australia containing a growth hormone transgene allowing the animals to produce meat more efficiently, however, the meat never reached the market. The kinds of transgenes currently being studied for potential use in commercial populations include the growth hormone gene (to increase growth rates), the phytase gene from bacteria (to reduce phosphorous emissions from pigs) or keratin genes (to improve the properties of wool in sheep).

4.1.2.4 GM fish

There is much research and commercial interest in the production of GM fish. The trait of major interest is increased growth rate, although disease resistance and improved environmental tolerance are also being researched. Transgenic fish from about 20 species, including carp, catfish, salmon and tilapia, have been produced for experimental purposes. Two transgenic fish species are awaiting regulatory approval for food purposes, namely a GM salmon in the United States and a GM tilapia in Cuba. The GM salmon is the AquAdvantage Atlantic salmon which contains the Chinook salmon growth hormone gene together with a promoter from the ocean pout's antifreeze protein gene, allowing the salmon to continue to grow well in winter when, in non-GM salmon, growth would slow down. The GM tilapia is a hybrid containing a modified tilapia growth hormone gene to improve growth and conversion efficiency.

4.1.2.5 GM micro-organisms

The genetic modification of micro-organisms offers considerable prospects for the food industry in the production of food additives (amino acids, peptides, flavours, organic acids, polysaccharides and vitamins) and processing aids (enzymes, micro-organisms). Genetic modification of micro-organisms is already applied for the purpose of increasing efficiency and reducing cost in the production of a number of food additives (artificial sweeteners, amino acids). GM yeasts are applied for flavour development in brewery applications. Recombinant enzymes which are the products of GM micro-organisms are also widely applied in the food industry in the areas of baking, brewing and in dairy and fruit juice processing. For example, GM chymosin, a crucial enzyme for cheese-making, was first approved in 1990 in the United States and is currently used in several countries. Current applications of genetic modification in the agro-industry sector are taking place primarily in developed countries.

4.1.3 Areas for regulation

Regulations governing GMOs can potentially act at a number of key stages:

4.1.3.1 Research and development (R&D)

Development of GM individuals or a GM variety can be a long process. It begins in the laboratory, where the GMOs are produced and where presence of the transgene is confirmed, etc.,

and proceeds to field testing of the organisms produced to ensure that they have the desired characteristics. Regulations here may cover the conditions under which laboratory experiments take place; exchange of GM material amongst laboratories and conditions for testing GMOs in greenhouses, other contained facilities or in the field.

4.1.3.2 Seeking approval for commercialization

After the R&D stage, there may be interest in bringing the GM product to the market. Regulations here may cover assessment of the potential human health and environmental risks, to be carried out prior to eventual approval.

4.1.3.3 Commercial release

If approval is granted, the next stage is the commercial release of the GMOs. Regulations may cover aspects such as how and where GMOs may be released (e.g. minimum distance of GM crops from organic agriculture or non-GM fields; need for GM-free refuges) and if used for food, the kind of labelling needed, if any; whether post-commercialization monitoring of the impacts of GMOs is necessary or what kinds of sanctions should be imposed following eventual violation of the regulations.

4.1.3.4 Imports of GM material or food

Applications may be made to import GMOs or their genetic material (semen, seeds, etc.) for release in the environment. Similar GM varieties may or may not already be approved in the importing country. Regulations may cover the kind of information required for approval e.g. whether information on potential environmental impacts from the exporting country is sufficient or whether new tests are required in the importing country.

Applications may also be made to import "GM food", food from GMOs (e.g. GM fish) or food that contains ingredients from GMOs (e.g. chocolate containing GM soybean). Regulations may cover the kind of information required for approval e.g. whether new food safety data is needed or whether data from the exporting country may be used.

Phillips (2003) points out that the GM crops currently commercialized are extensively traded internationally and that the countries growing them are also major exporters of these crops. For example, in 2000, a total of 168 countries imported maize, with 85 percent of the trade coming from the main countries growing GM maize. Although many developing countries may not be actively involved in developing their own GM products, they may nevertheless wish to introduce regulations to cover the import of GM material or food.

4.1.4 Some key factors concerning regulation of GMOs

4.1.4.1 The majority of developing countries does not currently have a regulatory system for GMOs in place

Whereas European and North American countries have been at the forefront in developing regulatory systems for GMOs (see e.g. Nap *et al.,* 2003), the majority of developing countries currently lack them, although many are now being established. Nap *et al.* (2003), and Phillips (2003) point out that there are significant differences amongst the kinds of regulatory systems already in place in developed countries. Some countries have taken a cautious approach

regarding regulation with the result that only a few GMOs have been commercially released. Others instead have approved most of the new GM products for production and consumption. As a clear example of divergences in existing systems, Philips (2003) points out that some countries have adopted, or are developing, provisions requiring mandatory labelling of products derived from GMOs, whereas others have opted for voluntary labelling systems.

4.1.4.2 Key elements in developing a regulatory framework

Development of a regulatory framework may be a costly, time-consuming process involving extensive consultation and effort. For example, the web-based "Decision Support Toolbox for Biosafety Implementation" (see www.isnar.cgiar.org/ibs/biosafety/regulatory.cfm), developed by the International Service for National Agricultural Research (ISNAR) and FAO in consultation with UNEP/GEF, describes four key elements to be considered when developing a regulatory framework. The first concerns the legislative framework, including whether to use voluntary guidelines or legally binding regulations and whether to modify existing legal instruments or introduce new ones. The second concerns the criteria making a product subject to regulatory assessment e.g. whether the determining factor should be that the organism is produced by genetic modification (as in almost all current GMO regulatory frameworks) or, as in Canada, that the organism contains novel traits, irrespective of whether genetic modification or traditional plant breeding methods were used to introduce the novel traits. The third element concerns transparency and public involvement in the decision-making processes e.g. whether there should be public participation in the development of the regulatory framework and whether the public should be informed about products being evaluated and whether any supporting data should be made public.

The fourth element is potentially quite contentious and concerns approaches to risk assessment and risk management. This includes how to assess the risk from GMOs, how to decide when the human health and environmental risks posed by the GMOs are too great (e.g. should they first be compared with potential risks from their conventionally-bred counterparts?) and whether the regulatory framework should weigh up the potential benefits, as well as the risks of GMOs. It also includes decisions on whether economic issues and market potential, social impacts or ethical concerns should be considered in the risk assessment and management. In this context, it is important to note that the Cartagena Protocol on Biosafety (see below), while asserting that assessments are to be undertaken in a scientific manner based on recognized risk assessment techniques, also recognizes the right of importing countries to take into account socio-economic considerations, such as the value of biological diversity to its indigenous and local communities, in reaching a decision on import of GMOs.

4.1.4.3 International instruments

A number of existing international agreements has direct relevance to GMOs and can be of assistance to developing countries in establishing appropriate regulatory structures that deal with potential concerns while, at the same time, promoting harmonization of national regulations at the international level. In a recent study commissioned by FAO, Glowka (2003) reviewed the legal instruments available in this area. He showed that at the international level there is no single comprehensive legal instrument that addresses all aspects of GMOs or its products and that in the biosafety area (i.e. addressing the risks posed to the environment and human health when GMOs are released into the environment [for research or commercial purposes]), there are at least 15 international instruments. Seven of these are legally binding, namely the UN Convention on the Law of the Sea (1982), the Convention on Biological Diversity (1992), the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (1995), the WTO Agreement on

Technical Barriers to Trade (1994), the International Plant Protection Convention (1997), the Aarhus Convention (1998) and the Cartagena Protocol on Biosafety (2000).

The Cartagena Protocol on Biosafety, which seeks to protect biological diversity from the potential risks posed by living modified organisms (LMOs, i.e. living GMOs), specifically focusing on transboundary movements, is due to enter into force after it has been ratified by 50 countries (as of 4 April 2003, just five countries were lacking). It has provided an important stimulus to the development of national GMO regulatory frameworks in developing countries. In June 2001, a three-year US$38 million UNEP/GEF project was launched to help participating countries to set up their national frameworks for the management of LMOs, allowing them to meet the requirements of the Protocol. As of 15 March 2003, there were 33, 35, 17 and 28 countries from the Africa, Asia-Pacific, Central and Eastern Europe and Latin America and the Caribbean regions, respectively, participating in the project.

The Joint FAO/WHO Codex Alimentarius Commission is the principal forum in which the food safety aspects of GMOs are addressed. A number of Codex committees deals with matters related to GM foods. In 1999, the Commission established the ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology to consider the health and nutritional implications of GM foods. The Commission is developing a series of guidelines covering areas such as the labelling of GM foods or food safety assessment of foods derived from GM plants.

4.1.4.4 Biosecurity

The development and enforcement of a regulatory framework for GMOs may need to be coordinated within cross-sectorial national approaches to the management of biological risks associated with food and agriculture and the development of national institutions for these purposes. This concept is referred to as *Biosecurity* by FAO (see FAO, 2003b). It covers food safety, plant life and health, animal life and health and the environment, including the introduction and release of GMOs and their products. National regulatory and export certification systems are being challenged by large increases in the volume of food and agricultural products being traded internationally, by the expanding variety of imported products and by the growing number of countries from which these imports originate. Increased travel is also creating more pathways to spread pests, diseases and other hazards that are moving faster and further than ever before, both amongst and within countries. Investments (infrastructure and human resources) in regulatory frameworks are high, with high recurrent costs. Improved coordination is therefore being sought among national bodies responsible for enforcing sanitary, phytosanitary and zoosanitary measures to better protect human, animal and plant life and health. Models for rationalizing relevant regulatory functions among sectors are appearing in a number of countries. For example, in Belize, food safety, animal and plant quarantine and environmental issues are dealt with by a single authority.

4.1.4.5 GMOs are very heterogeneous

When considering the kinds of GMO regulatory systems that might be appropriate for developing countries, it is important to consider that GMOs for food and agriculture are a very heterogeneous group, covering crops, fish, forest trees, livestock and micro-organisms, and thus they may present a range of different challenges. The potential environmental risks from GM forest trees that may live 100 years and grow to large heights differ, for example, from the release of a GM yeast to make bread. In addition, within each of these five sectors, GMOs may vary considerably, requiring different kinds of regulations. For example:

- some species (e.g. cotton or forest trees) are not grown for food, so food safety regulations are not strictly an issue. (Although, it should be kept in mind that some material, e.g. pollen/honey derived from GM trees, may still enter the food chain);
- the same species may be modified for very different traits e.g. an agricultural crop or animal may be modified to produce human pharmaceuticals (e.g. tomatoes producing vaccines against the Norwalk virus or sheep producing proteins for treatment of cystic fibrosis). "Pharmed" products under development include vaccines, antibodies and industrial proteins and in the crop sector, involve banana, maize, potato and tomato plants. Special regulations covering potential gene flow to their conventional counterparts may be necessary;
- regulations may vary depending on whether the GM species is produced for export or domestic use. For example, a study by Burachik and Traynor (2002) on Argentina's GMO regulations highlights this point: "the Argentine economy depends strongly on exports of primary agricultural commodities; consequently, maintaining and protecting markets is a major economic concern. For this reason, GMO commercialization is subject to a strict marketability requirement. GMOs intended for export are approved if and when they are accepted in Argentina's export market, primarily European countries. Otherwise, GMO varieties are not approved for commercialization. When exports are not a significant factor (e.g. in the case of cotton), commercial release can be approved irrespective of the regulatory status elsewhere, since there are no 'sensitive' markets for the product".

4.1.4.6 Balancing costs and benefits of regulation

The goals of GMO regulatory frameworks are to ensure safe release and use of these products. While developing the frameworks, policy-makers have to consider the play off between the need to minimize risk and to promote technology development. Strict regulatory frameworks will act to minimize the potential risks associated with GMOs but they may also act as a barrier to investments in GMO research and to the development of potentially useful GM products. If the costs (in terms of finances, time and human resources) of complying with the regulations are substantial they will obviously act as a disincentive for parties with limited resources.

As mentioned in previous Forum conferences (see e.g. Chapter 3.1), the agricultural biotechnology field is currently dominated by developed countries and by the private sector in these countries, with the result that the research and the biotechnology products being developed or released are directed primarily to farmers in the developed (and not developing) countries and of richer (and not poor) farmers that can afford the products. Establishment of strict regulatory regimes in developing countries may therefore exacerbate this situation as they have fewer available resources. This is expressed dramatically by Nap *et al.* (2003) i.e. "the cost of meeting regulatory requirements is currently a significant negative impact on the release of GM crops compared with the release of cultivars from traditional breeding. Excessive regulatory reviews will frustrate and curtail research and application to such an extent that only a few large multinational companies can afford to make progress. In this manner, over-regulation will help to promote a situation that is a concern of many: corporate control of agriculture. This trend is already clearly apparent and may result in the creation of a single (or a few) companies dominating world food production and increasing world dependence". On the other hand, relaxed regulations, allowing rapid and easy approval of GMOs, may not effectively protect citizens and the environment from potential risks. Policy-makers have therefore to carefully balance these costs and benefits.

Costs and benefits have also to be weighed up when considering the monitoring and enforcement aspects of GMO regulations. Strict measures, involving frequent, long-term and careful checks and inspections of GMOs, strain the limited resources of developing countries. Relaxed measures may, on the other hand, encourage parties to flout the rules.

4.1.5 Some topics to be considered in this conference

This conference considers the subject of regulating GMOs, for food and agriculture, in developing countries (including transition countries). More specifically, some items that should be discussed are:

- how strict should the framework be in developing countries i.e. how should policy-makers balance the need to guard against potential environmental and health risks with the need to economize on resources to monitor/enforce the regulations and the wish to promote development of appropriate products for their own country?
- GM varieties may be exported worldwide. How appropriate is it to use environmental and food safety data from one country when seeking approval for commercialization in a second country? Is the sector involved (agro-industry, crop, fisheries, forestry or livestock) important in this context?
- developing countries are facing increasing challenges in regulating to better protect human, animal and plant life and health. Given this situation, and given the limited resources (financial and personnel) available, what priority should they give to the development of regulatory frameworks for GMOs?
- a regulatory framework can be quite detailed and cover a number of different areas (see Section 4.1.3). For developing countries with limited resources wishing to establish a GMO regulatory framework, what are the key areas that should first be prioritized?
- how useful is the *Biosecurity* concept, involving a cross-sectorial national approach to the management of biological risks associated with food and agriculture (see Section 4.1.4.4), for developing countries wishing to establish or enforce a GMO regulatory framework?
- monitoring of the development, import, release and use of GMOs to ensure compliance with the laws or guidelines can be expensive for developing countries with limited finances and qualified human resources. How can monitoring be carried out efficiently in this situation?
- when addressing risk analysis and risk management in the regulatory framework, should:
- the risks associated with GMOs be compared with those from their conventionally-bred counterparts?
- economic, social and ethical factors be included, in addition to potential human health and environmental impacts?
- different issues are raised by the application of genetic modification in the agro-industry, crop, forestry, animal or fisheries sectors. Are different sets of regulations required for each sector?

4.1.6 References

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4.2 SUMMARY DOCUMENT

Executive summary

It is important for developing countries to regulate genetically modified organisms (GMOs). Two main motivations are that GMO regulation allows developing countries to protect consumer health and the environment and/or to harness the benefits of these new technologies. While there is agreement about the need for a GMO regulatory framework, there are differences in opinion about how strict it should be, as this is influenced by issues such as costs, perceived risks and benefits of GMO release, enforceability and credibility of the regulatory framework. Regulation of some stages or components of the process can be stricter than others. Developing countries currently lack the resources and capacity to adequately regulate GMOs, although there are notable differences between individual countries in this respect, and there is an important need for capacity building activities in this area. Methodology for risk assessment is well described, but there is disagreement whether it can be appropriately applied to GMOs, given their novelty. The social, ethical and economic aspects of GMOs are important but it is not certain that they should be included in the regulatory framework. The risks of GMOs should be weighed against their benefits as well as the risks of alternative options. There is strong division over whether GMOs should be regulated differently to non-GM varieties, with participants disagreeing whether it is the process (i.e. genetic modification or not) or the product (the kind of traits expressed) that should be the "regulatory trigger". Particular attention is needed for regulation of GMOs in countries that are also the centres of origin or diversity of agricultural species. There is general consensus that harmonization of regulatory systems across countries is important (and that existing international agreements/guidelines can assist in this context), but that it should also be possible to retain some country-specific elements in the systems. Coordination and harmonization of GMO regulation between the different relevant government ministries within a country is also important. Developing countries wishing to establish a GMO regulatory framework can learn a lot from, but do not need to model it on, the existing regulatory frameworks in developed countries. There is general support for involving the public in GMO regulatory processes; informing the public about GMOs (including labelling of GM products); and ensuring transparency of the regulatory processes. Monitoring implementation of a GMO regulatory framework may be especially difficult in developing countries due to lack of resources, although some issues are difficult to monitor even for resource-strong developed countries. The cost of regulation, including post-release monitoring of GMOs, is an issue of concern for developing countries, although strategies to reduce it can be considered. The question of liability is important and should be covered in the GMO regulatory framework.

These were some of the main themes and outcomes of a moderated e-mail conference entitled "Regulating GMOs in developing and transition countries", hosted by the FAO Biotechnology Forum from 28 April to 1 June 2003. About 400 people subscribed to the conference and 93 messages were posted over the five-week period by 44 participants from 20 countries, with half of the messages coming from people living in developing countries. Most messages came from people working in research centres, universities, NGOs and as private consultants, with the remainder from people working in government bodies, UN agencies or farmers' organizations.

4.2.1 Introduction

During the five-week conference, 93 messages were posted, each one numbered in order of posting. In this document, specific references to messages posted are provided, giving the participants' surname and message number. All of the messages can be viewed at

www.fao.org/biotech/logs/c9logs.htm. A total of 401 people subscribed, which was the highest number for any of the conferences held up to that date, reflecting the large interest in this subject, and roughly half of the messages posted came from participants living in developing countries. Although the conference aimed at covering the agro-industry, crop, fisheries, forestry and livestock sectors, most of the discussions, when referring to specific agricultural situations, considered the crop sector. The large areas cultivated with GM crops, and the resultant public and media debate about them, are no doubt responsible for this focus. In GM livestock for example, Wollny (87) said they are lagging far behind the scientific and public discussion in crops.

In Section 4.2.2 of this document, the main elements of the discussions are summarized under 11 topics. Section 4.2.3 provides some information about participation in the conference and Section 4.2.4 gives the name and country of the people that sent referenced messages. Note, the term 'developing countries' used in this document includes countries with transition economies.

4.2.2 Main topics discussed

4.2.2.1 Is it important for developing countries to regulate GMOs?

Participants agreed that development of a regulatory framework for GMOs was important for developing countries. Two main motivations were provided. The first was that it would allow developing countries to harness the benefits of these new technologies i.e. to avoid being bypassed by the "gene revolution", countries needed "the stable and predictable regulatory regimes necessary to create an enabling environment for the application of agricultural biotechnology"(MacKenzie, 5). Similarly, Morris (73) felt that if developing countries saw potential benefit from introducing GM technology, then the effort of developing a regulatory framework would be worth it. She also suggested that subsequent familiarization with GM technology could benefit science in the country as a whole.

The second, more frequently cited, motivation was protection of consumer health and the environment in developing countries (e.g. Bhat, 34; Rajaratnam, 80). According to Villaverde (25), if the regulatory framework of a developing country was weak or inexistent "its consumers could be exposed to potential risks, and this is unacceptable". Particular mention was made of the importance of protecting consumers in developing countries from non-approved GMOs in food aid (Vasanthi, 8; Bhat 14, 34). Kambikambi (31) also highlighted the situation in her country, Zambia, when GM maize provided as food aid was refused, writing "I suppose that underscores the importance of having a regulatory framework because what really happened is that we did not know how to handle that product in the absence of appropriate legislation". McCowen (93) noted that developing countries might be affected by foreign assistance policies of donor countries linking acceptance of medical aid to acceptance of food aid that might be GM.

4.2.2.2 How strict should the regulatory framework be in developing countries?

While participants agreed about the need for a regulatory framework for GMOs, they disagreed about how strict it should be. Several participants warned that strict regulation in developing countries, requiring substantial financial and human resources inputs, would penalize public sector GMO research initiatives directed towards developing country needs and would allow multinational corporations (MNCs) to continue dominating the area with their focus on major crops and traits (Strauss, 1; Quemada, 4; MacKenzie, 6; Morris, 13). Quemada (4) pointed out that in the United States the cost of regulatory data collection and compliance had already

driven most small players out of GM crop work, so that it was now being carried out by "major companies who can afford to spend the money and who have the appropriate staff to deal with the regulatory requirements". While not suggesting that regulation be abandoned he, supporting Strauss (1), proposed streamlining the process for traits that could be considered low risk and for crops with traits that could solve major problems. Morris (13) argued that there was enormous potential in Africa for improvement of crops such as sorghum and millet using GM technology, but asked "who will carry the cost of undertaking the biosafety research to ensure their safe introduction?". Morris (73) concluded that the regulatory framework should not be "large and cumbersome" because it only introduces extra costs and because the number of applications for use/release of GMOs in developing countries was likely to be relatively low, at least in the beginning.

Other participants, while recognizing that GMOs have a lot of potential, felt that rigorous regulation was nevertheless needed in developing countries (Ombori, 75; Muralidharan, 88; Pena-Neira, 89). In addition, Muralidharan (57) pointed out that as an alternative to relaxing regulations and allowing ready access to GMOs in developing countries, other "simple, cheap and safe" technologies were available. Richardson (79) was adamant about the need for strict regulation, arguing that, because of the harm they could cause if released into the ecosystem and found to be detrimental, introduction of new GMOs "requires more conservative regulation than either novel pesticides or novel medical treatments". The differences in perspective on this issue were also reflected in the exchange between Ashton (56) and Blanchfield (58) about current GMO regulations in different countries, with Ashton (56) arguing that most merely facilitate introduction of GM crops, whereas "regulations must regulate, not facilitate" and Blanchfield (58) responding that they should regulate but also facilitate.

A couple of participants also raised the issue of the relationship between strictness of the regulations and the ability to enforce them. Prakoso (50) argued the strict regulations could be adopted but, given financial and technical limitations of developing countries, they might not be enforceable. Similarly, Jackson (33) maintained it was important to have legal regulations that stipulate conditions for production or marketing of GMOs, but felt that "if these conditions are unenforceable then the regulatory framework has only limited relevance to what is occurring on the ground". Prakoso (50) argued therefore for regulation that should be practical, low cost and implementable. Also related to this issue of enforceability is the question of whether legislation governing the subject is binding or non-binding (Vapnek, 22; Kambikambi, 31; Jackson, 33).

For Willemse (17), the question of how strict regulatory frameworks should be in developing countries was not a simple one to answer and "would mostly be determined by each country's specific needs and circumstances". He felt that one of the most important aspects of a national regulatory framework was the credibility that the implementation of such a framework would enjoy at national level and that, to achieve this, regulatory frameworks in developing countries would probably need to be, at least initially, stricter than in developed countries to ensure acceptance not only of the framework, but also of subsequent approvals and/or refusals. He suggested that over time the framework might then evolve to become less strict.

As mentioned in Chapter 4.1.3, regulations governing GMOs can cover activities at a number of key stages, including research and development (R&D) of GMOs, commercialization of GM products or the import of GM material or food. It can be a lengthy process. According to Rao (37), "it takes about 11-13 years for a specific transgenic variety to get into commercial cultivation. Five years to develop the transgenic event, such as pest resistance or herbicide resistance, two or three years of controlled greenhouse trials on approval by a regulatory agency, and three or more years of controlled field trials". Regulation of some stages or components of

the process could be stricter than others. For example, MacKenzie (5) argued for a clear distinction to be made between experimental field trials, allowing GM crops to be assessed prior to commercial release, and the subsequent commercial release of GMOs into the environment, maintaining that the focus for the former should be on implementation of risk mitigation strategies (the terms and conditions necessary to safely permit confined trials) instead of on rigorous risk assessment, which should be the case for the latter. He argued that a "permissive environment for the conduct of experimental trials" was important for local R&D investment and for providing biosafety committees and regulatory officials with experience and expertise. Rao (37, 46) also argued that if a given GM event had been approved for commercial release in a given crop, then GMOs with the same GM event in different varieties of the same crop should be allowed to follow a shorter trial stage. Muralidharan (57) agreed with this, although McCowen (41) argued that such a system might deter companies from being the first to introduce new traits onto the market. Strauss (1) also proposed that GMO regulations should distinguish between GM products resulting from modification of native genes and GMOs expressing novel proteins or antipest toxins, arguing that the former should not be regulated as if they were 'potential environmental menaces'. While not opposing this proposal, MacKenzie (6) noted that incorporating this "categories of risk" argument into regulatory systems required a fundamental rethink of the existing approach to risk assessment of GM plants.

4.2.2.3 Developing countries lack the resources and capacity to adequately regulate GMOs

This was a common refrain from participants in the conference (e.g. Mog, 16; Kuhn, 29), with Bhat (48) suggesting that individual developing countries might not have the "resources, infrastructure and technical manpower" to even review the regulatory data.

The poor financial resources of developing countries and the potentially high costs of regulation were issues of concern. Ashton (35, 56) described the cost of rigorous regulation as "onerous", involving payments for inspectors, transport, laboratory procedures and consultations. Badr (38) suggested that developed countries could assist by providing funding while Morris (73), in a similar vein, proposed that developing countries should make maximum use of available resources internationally and in the developed world to assist them with risk assessment. Ashton (35, 56) also felt it was important to consider who should pay. He argued that it was wrong for the taxpayer in developing countries to foot the bill and proposed, instead, that parties wishing to introduce GM products onto the market should pay for the costs of regulation.

The lack of knowledge, experience and capacity required for GMO regulation was raised on many occasions throughout the conference. In addition, capacity levels can differ greatly between developing countries. As Morris (13) wrote, many developing counties, "do not have the basic tools of molecular biology in place", while Bhat (34) suggested that for GM crop/food issues, developing countries could be placed in two categories, those with 1) infrastructure for biotechnology (e.g. Brazil, China, Egypt, India, Malaysia, Mexico, South Africa); or 2) practically no work or expertise in the area of biotechnology. In contrast to most developed countries that could build their regulatory expertise together with advances in biotechnology, Lekoape (12) pointed out that developing countries lack this advantage, although Willemse (21) suggested that it was becoming more frequent for technological capacity and regulatory framework development to go hand in hand in developing countries. Prakoso (50) described some of the technical difficulties (lack of suitable equipment, reagents) developing countries face for detecting GMOs, while Vasanthi (8) and Bhat (48) also emphasized the importance of developing countries having functional laboratory facilities for detection of GMOs. Kuta (45) said that Nigeria lacked "the required quantity and quality of human capacity for scientific assessment of

possible environmental and health risks associated with GE-products". Bhat's (14) conclusion was therefore that "the expertise and infrastructure needed to undertake a critical, transparent, valid scientific assessment of the food and environmental safety [of GMOs] are either not existing or are in a rudimentary state of development in most of the [developing] countries".

Given this situation, some participants emphasized the need for capacity building activities (e.g. Lekoape, 12; Olutogun, 15; Kuta, 45; Nath, 77). There were, however, different ideas about how this should be done. Olutogun (15) stressed the contribution that the developed world could make in helping the developing world with capacity building. Willemse (21) also noted that most capacity building initiatives currently modelled development of regulatory frameworks on the existing frameworks in developed countries. Lekoape (23), however, argued that most developing countries did not have the resources, or perhaps the need, to establish similar regulatory frameworks to those in developed countries and concluded "it is therefore imperative that capacity building initiatives are demand-driven. Developing countries should not feel obliged to follow in the footprints of the developed nations". This viewpoint was supported by Mog (26), calling for "locally-controlled and demand-driven" capacity building initiatives, who noted that developing countries could learn from the experiences of other countries but did not have to follow their model. Rajaratnam (91), echoing Acikgoz (83), proposed that international organizations like FAO could help developing countries to draft their regulations by providing expertise, advice and training.

4.2.2.4 The approach to risk assessment and risk management

As described in the Background Document, one of the main elements to be addressed in a GMO regulatory framework is the approach to risk assessment and risk management, involving issues such as how to assess the risk from GMOs, whether to weigh potential risks against potential benefits and whether (in addition to environmental and human health aspects) to consider economic issues, social impacts or ethical concerns. These topics were amply discussed in the conference. Methodology for risk assessment was described, but there was disagreement whether it could be appropriately applied in this situation, given the novelty of GMOs. While some participants argued that social, ethical and, in particular, economic, aspects should be included in the regulatory framework, a small number argued this was not appropriate. Several participants also noted that the risks of GMOs should be weighed against possible benefits of GMOs and the risks of alternative options.

a) Risk assessment methodology

Muir (59) reminded participants that there was an entire field of science devoted to methodology for risk assessment, whereby a number of ways were available to estimate risks of potential hazards before eventually releasing any new product onto the market. His mention of cars and airplanes in this context, evoked a series of comments regarding the differences and similarities between their risk assessment and those of GMOs (Doebel, 62; Blanchfield 63; Wuerthele, 66; Willemse, 86). Muir (59) noted that there is no such thing as a zero risk of anything and that risks are expressed in terms of probabilities, e.g. there is an 80 percent probability of rain (if rain is identified as a hazard). Doebel (62) argued, however, that because genetic modification was new, there were no precedents that would allow the probabilities to be established and so proper risk assessment could not be carried out. Similarly, Muralidharan (88) felt it was too early to claim that a fairly good assessment of risks was possible. Muir (70) maintained, however, that probabilities of environmental hazards could be quantified, based on knowledge of how natural selection works. Phillips (82) also argued that the environmental impact of releasing a GM crop "could vary widely depending on the indigenous flora and fauna and on the nature of the

cultivated and uncultivated areas, and their interaction", thus requiring location-specific assessments. Regarding the probabilities associated with human health hazards, Phillips (82) suggested these should be assessed within cultural-economic-social populations, as diets and susceptibility to allergens can vary widely between populations.

Wuerthele (66), on the other hand, agreed with Doebel (62) that the lack of experience with genetic modification meant there was no basis for proper assessment of the risks associated with GMOs, arguing, in addition, that all of the hazards of GMOs were not yet known. Phillips (82) maintained, however, that characterization of the hazards related to GMOs was unlikely to vary greatly between populations or ecosystems, and that it would seem appropriate to carry out one good characterization effort. Regarding human health, he proposed that the key hazards are toxicity, allergenicity and compositional change. Regarding environmental impacts, he proposed that invasiveness, outcrossing and harm to non-target organisms would be examples of the hazards. His conclusion was that "regulation of the health and safety aspects should rely fundamentally on internationally characterized hazards, generally accepted methods and locationally relevant assessments of exposure".

b) Whether to include economic, social and ethical aspects in the risk assessment

Several participants mentioned the importance of including these aspects, in addition to human health and environmental impacts, in the regulatory framework. For Morris (73), while they might not be safety issues *per se*, they were important for the cost-benefit equation as well as ensuring the long-term acceptance of the technology. Bucchini (74) argued that safety issues regarding GMOs could be resolved at the international level whereas social, economic and ethical issues should be debated and decisions made at the national level. Villaverde (72) argued that regulation of socio-economic risks from GM foods and organisms was the main regulatory gap in developing countries, emphasizing the need to consider seed monopolies held by MNCs and the economic cost/benefits of introducing GM crops. Newman (2) felt that as introduction of a GM variety to a country was supposedly based on economic reasons, it was essential to include a "comprehensive, unbiased economic assessment as part of the risk analysis process. This risk assessment must include the impact on the non-GM grower and associated industries that may be affected". She was appalled that developed countries had excluded this aspect in their GMO legislation. Vasanthi (9) agreed with her on the need for economic risk assessment of GMOs, arguing that it could be included as part of the post-market monitoring procedures where, ideally, "data on the economics of the entire process of cultivation, harvesting, marketing, traceability and consumption of GM crops would be needed".

Richardson (51) also felt that a regulatory framework should include the aspect of "who benefits", a point considered in detail by Mog (16, 84), who maintained that because GMOs developed for profit might "make poor farmers dependent upon GM products that have been designed to increase the profits of foreign corporations", the regulatory framework should be stricter on these GMOs (potentially restricting their access to domestic markets) than on GMOs not developed for profit. Willemse (86) disagreed. Arguing that regulation should be risk-based, he maintained that a distinction between for-profit and not-for-profit GMOs for regulatory purposes would incorrectly assume that the risk lies with the objective or purpose of the GMO rather than the technology or the product. Phillips (82) felt these kinds of concerns should not be added to health and safety regulations as this would raise the risk that safe and possibly beneficial GMOs would be rejected or that unsafe GMOs would be approved by the regulatory framework in developing countries. He concluded that "most other aspects that concern people about GM foods--e.g. industrial structure; distribution of winners and losers; social impacts; moral aspects--

while raised in the context of GM foods are not unique to GM foods and probably are better handled in the context of a broader development policy".

c) Weighing up the risks

Several participants noted that carrying out a risk assessment of GMOs was not the final result. On the one hand, risks should be weighed against possible benefits (Richardson, 11; Muir, 59; Efaw, 67), with Blanchfield (78) arguing that potential benefits should be measured primarily for those suffering hunger and malnutrition. On the other hand, they should be weighed against possible alternatives, such as doing nothing (Muir, 59; Blanchfield, 78) or using a different technology (Richardson, 51; Muir, 59; Blanchfield, 78; Hongladoram, 92). For example, Richardson (51) suggested that a regulatory framework needed to consider whether alternative solutions that cost little with less risk had been examined.

4.2.2.5 Regulation of GM versus non-GM products

In most current regulatory systems, GM crops are more strictly regulated than non-GM crops. This can be an incentive for employing other biotechnologies (such as genomics or tissue culture) instead of genetic modification (Newman, 7). In addition, if GM crops require lengthy trial periods this may give enough time to non-GM varieties to overtake them (Rao, 37). Participants were strongly divided on whether GMOs should be regulated differently to non-GM varieties.

Muir (65) referred to a 2002 publication from the United States National Academy of Sciences which concluded that specific traits produced by either conventionally bred or GM plants could pose unique risks and that conventionally bred plants should therefore be evaluated using the same regulatory process as GM plants. He noted that it was possible to use the same methodology to evaluate the risks from GM and conventional plants and that the regulatory framework could be the same. Willemse (86) highlighted the negative impacts that some non-GMO related activities could have, such as the import of invasive alien species or the introduction of agricultural pests carried by crops. For him, this showed that "the same regulatory criteria are not being applied for GMOs and for their non-GMO equivalents" and he argued "if we continue to apply different criteria in risk assessment and risk management based on our perceptions and individual likes and dislikes, we will continue to generate disasters, while stifling development that is needed above all by developing countries".

A number of participants pointed out that the range of potential techniques available for conventional breeding included some with potentially large effects on the genetic material, such as hybridization, mutagenesis (e.g. using irradiation) and polyploidization and that crop products developed using these techniques should not be regulated differently than GMOs (Rao 28, 43; Blanchfield, 63; Muir, 65). Doebel (69) disagreed arguing, *inter alia*, that mutagenesis and polyploidization were not part of traditional or conventional breeding. Regarding hybridization, Richardson (51) argued that the consequences (at the cell and organism level) of genes moved by hybridization were not equivalent to those introduced by molecular techniques (and so the regulatory implications/consequences were not the same).

Some participants maintained that the process of genetic modification was unique, requiring special regulation, and was not comparable with conventional breeding (e.g. Muralidharan, 88). Richardson (51) argued that insertion of a DNA segment "cannot be assumed to be neutral or equivalent to any normal cellular process until appropriately tested" and that GMOs should be strictly regulated because they could cause non-reversible damage

(Richardson 51, 79). Doebel (62, 69) maintained that genetic modification was not similar to conventional breeding as non-targeted insertion of DNA from one species into the DNA molecule of another species was "problematic in an unprecedented way" because of uncertainty about interaction of the inserted DNA with the recipient DNA molecule and interaction between the resulting DNA molecule and the environment. Regarding regulation, he therefore urged caution. Blanchfield (63, 78), however, argued that conventional breeding resulted in random insertion of unspecified and unknown numbers of genes and therefore "whatever the problems of genetic modification, they are at least matched if not surpassed by those of 'breeding'". Efaw (67) maintained instead that conventional breeding randomly combined genes already present in the species and that the genes had already been through countless iterations of checks and balances.

As seen above, discussions basically come down to whether it is the process (i.e. genetic modification or not) or the product (the kind of traits expressed) that is the "regulatory trigger" i.e. the criteria making a product subject to regulatory assessment. Participants arguing for GMOs and non-GM products to be regulated in the same way, obviously felt that "product" should be the trigger (Muir, 65, 70; Prakoso, 76), whereas those arguing for stricter regulation of GMOs than non-GM products (even if the traits produced [e.g. herbicide tolerance] are the same) felt "process" should be the trigger. Most existing regulatory systems use process rather than product as the trigger (MacKenzie, 24; Willemse, 30). This distinction has interesting implications for a specific case raised in the conference. If a "stacked" GMO variety (i.e. with two or more transgenes inserted) is developed by crossing two GM parental lines that are already approved, it was argued that to have a consistent regulatory policy, the stacked variety should not require regulatory approval (Willemse 17, 21, 30; MacKenzie, 24). As MacKenzie (24) concluded, "for countries with "process-based" regulatory systems to invoke the "product risk" argument only for the special case of stacked events, is confusing at the least".

4.2.2.6 Centres of origin or diversity

Some specific attention was given during the conference to the topic of regulating GMOs in countries that are also the centres of origin or diversity of crop species. Specific examples mentioned were work on development of GM potatoes in the Andean regions of Peru (Buijs, 49) and, especially, reports of GM maize in Southern Mexico (Bucchini, 74; Pena-Neira, 89). Willemse (21), echoed by Diaz (39), felt that the latter example could influence development of regulatory frameworks in countries with centres of origin of agricultural species (as well as the revision of existing frameworks of countries exporting to such countries). For Acikgoz (83), centres of genetic diversity should be considered as a key point in GMO legislation, although he felt it would be difficult to decide whether to ban or permit cultivation of economically useful GMOs in these areas. Willemse (86) argued, instead, that no compromise should be made on the principle of "not allowing a GMO into the species center of origin". Morris (13), supporting Quemada's (4) comments about the high cost of getting adequate data for regulatory purposes, argued this was becoming a critical issue in any developing country where crops have their centre of origin and where there is little documentation of the potential for cross-pollination with wild relatives.

4.2.2.7 Coordination and harmonization of GMO regulations between countries

As mentioned in the Background Document, the majority of developing countries, in contrast to developed countries, currently lack regulatory systems for GMOs. Should developing countries aim to establish similar and harmonized systems or can they be unique and country-specific? Should they be modelled on existing systems in developed countries and what role can international agreements play? In discussions on these issues, most participants seemed to feel

that harmonization of regulatory systems across countries was important (and that existing international agreements/guidelines could assist in this context), but that it should also be possible to retain some country-specific elements in the systems.

a) The need for cross-country harmonization

For Villaverde (25), a strong reference regulatory framework was needed worldwide because "this discussion on GM foods is global, and [we] therefore need to have global solutions". A number of different arguments were provided in favour of cross-country harmonization. Due to the widely divergent views held regarding safety of GM foods, Vasanthi (8) argued that international harmonization of risk assessment procedures was needed urgently. Bucchini (74) felt that as prevention of gene flow and movement of GM material within and between countries was not feasible in most parts of the world (i.e. "low level flow of GMOs cannot be prevented"), appropriate safety levels should therefore be determined at the international or regional level. Regional cooperation was also promoted by Morris (73) as a way of pooling limited resources and reducing the necessity for creating individual regulatory mechanisms in each country. Phillips (82) argued that the hazards related to GMOs and GM food were unlikely to vary greatly between ecosystems or human populations and that international harmonization should therefore be the standard.

b) How harmonization can be achieved

In order to achieve harmonization of GMO regulations across countries, some participants proposed that existing international agreements/guidelines could be used, such as the Principles and Guidelines adopted by the Codex Alimentarius Commission in July 2003 regarding GM foods (Olutogun, 90; Phillips, 82; Villaverde, 25, 55, 64; Vasanthi, 44) and the Cartagena Protocol on Biosafety (Villaverde, 25). Vasanthi (8, 44) and Rao (52) pointed out that uncertainty exists about the relationship between a number of multilateral agreements that are relevant for GMOs. Referring to the Codex Guidelines, the Cartagena Protocol and the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, Vasanthi (44) wondered whether international harmonization of GM food safety standards might help in reducing such conflicts. Bhat (34), supported by Rajaratnam (80), called on FAO, IAEA, UNEP and WHO to work together to develop a model regulatory framework that individual developing countries could then adapt for their purposes. Similarly, Olutogun (90) called for development of a global regulatory mechanism, involving the Codex Alimentarius Commission and CGIAR centres, to assist developing countries.

c) Retaining country-specific elements

Although promoting development of harmonized regulatory systems in developing countries, participants maintained that it should be possible to include some country-specific elements/needs in the framework (e.g. Vasanthi, 8; Mog, 26; Bhat, 34; Rajaratnam, 80). Willemse (17) argued that flexibility for individual country needs should be allowed, given the importance of credible implementation of the framework at the national level, a point also made by Mog (26). Bucchini (74) proposed that whereas human health and environmental safety of GMOs should be decided at the international level, the social, economic and ethical issues regarding GMOs should be debated and decisions made at the country level. Hongladarom (92) concluded that "no matter what kind of regulatory schemes be put in place in the so-called Third World countries, those schemes need to be in accordance with the need for those countries to find a way to flourish and prosper in their own terms".

Lekoape (23) emphasized the importance of each country's unique set of circumstances, i.e. their "level of development, capabilities, aspirations, cultures and traditions", and that these should influence adoption and regulation of any technology. Willemse (27) supported this, proposing that "adoption of technologies (or their products) and regulation should always be driven by domestic demand and influenced by domestic circumstances". Willemse (30) was also adamant that for countries receiving GMOs "one principle that should not be negotiable is the right of the recipient country to decide its own criteria and level of biosafety". McCowen (32), however, responding to Lekoape (23), questioned how independent and individual the regulatory systems of developing countries could be, given their reliance on trade and the importance of WTO agreements on trade. Similarly, Villaverde (25) maintained that for a developing country wishing to export GM food to the developed world, "the regulatory framework in a developing country does not have much degree of freedom in relation to the regulatory framework of the importing country".

d) Developing countries learning from, and modelling their system on developed countries

As mentioned earlier, most current regulatory frameworks have been established in developed and not developing countries. For developing countries wishing to establish a regulatory framework, there was consensus that, although they could learn a lot from the experiences of developed countries, they did not have to follow in their footsteps (e.g. Lekoape, 23).

Bhat (48) provided some details about differences between the regulatory systems established in the United States and the European Union (systems that were increasingly diverging, according to Hongladarom [92]), the two primary regulatory models available in developed countries. He concluded that "developing countries need general comprehensive regulations and separate regulations evolved on a case-by-case basis depending on the need of each country". Participants emphasized that experience with implementation of GMO regulatory systems in developed countries could provide valuable information for developing countries wishing to establish their own systems (Mog, 26; Ashton, 56; Bucchini, 74). For example, Wuerthele (66) suggested a number of possible lessons that developing countries could learn from experiences in the United States, such as the need to consider legal frameworks which will be flexible enough to regulate the wide range of GMOs that might be developed in the future. In addition, Willemse (21, 27) pointed out that the experiences and developments in developing countries with existing regulatory frameworks could also provide some important lessons for other developing countries in establishing regulatory frameworks as well as benefiting subsequent evolution of frameworks in developed countries. Willemse (27) concluded therefore that "the global GMO regulatory scenario is evolving into a dynamic interdependent network that could only benefit from cross-fertilization of all experiences and lessons learnt".

4.2.2.8 Coordination and harmonization of GMO regulations within a country

In the same way that participants felt that harmonization of regulatory systems across countries was important, there was also an appreciation of the need for regulatory harmonization within countries. Regulation of GMOs touches on issues relevant to several different government ministries within a single country. According to Bhat (14), the issues of GM food/feed/crops "cannot be tackled by a single ministry and coordination between ministries of agriculture, health, environment, science and technology, commerce is essential". For example, Kuta (45) pointed out that there would be five major federal agencies, from four different ministries, involved in regulation of GM crops in Nigeria. Rajaratnam (91) suggested that the GMO regulatory

framework would need to be drafted by a body involving ministries and experts working in areas such as agriculture, forestry, livestock, health, nutrition and environment. This may present some challenges, as different ministries or ministerial committees may differ in their approaches to GMOs (e.g. Rao, 28) leading to situations where "one ministry is pushing for more research on GMOs, while the other is trying to put a damper on it" (Hongladarom, 92).

Wuerthele (66) argued that the experiences from GMO regulation in the United States demonstrated the importance of determining in advance who will review the health, environmental, food safety and social effects of GMOs and how those reviews will be coordinated. Bhat (14) suggested that a single coordinating agency be established that would "act as a single window for interacting with the risk assessors, risk managers and risk communicators and all the stakeholders, including the industry, farmers and consumers". Similarly, Rajaratnam (91) argued for a single body to monitor GMO regulation rather than having different monitoring body systems for different aspects of GMOs. In the Background Document, it was suggested that development and enforcement of a GMO regulatory framework might need to be coordinated within a cross-sectorial national approach to the management of biological risks associated with food and agriculture, a concept referred to as Biosecurity by FAO. Willemse (17, 86) supported the suggestion, arguing that the 'one-stop-shop' envisaged in the concept could provide a solution to the issue of capacity constraints.

4.2.2.9 Public participation/awareness and GMO regulations

As described in the Background Document, one of the key elements to be considered when developing a regulatory framework relates to transparency and public involvement in the decision-making processes. In the conference there was general support for involving the public in these processes; informing the public about GMOs (including labelling GM products); and ensuring transparency of the regulatory process.

For Lekoape (23) the most important lesson that developing countries could learn from developed country experiences with GMO regulation was to engage the public at all levels, from drawing up a research policy to making decisions about individual approvals, arguing that "this bottom-up approach means consumers are not only a part of the process, they identify with it and assume responsibility for the end result, thus endorsing the credibility of a regulatory framework". Mog (26), based on his research and experiences in southern Philippines, was convinced of the importance of involving local people in the process of researching and developing both technologies (like GMOs) and the policy measures necessary to regulate them because it tailors them to local circumstances; increases local credibility; and helps the local people to face unknown future challenges in this area. Morris (73) pointed out that in Africa, the traditional decision-making processes were community-based, and decisions made in this way were more likely to achieve buy-in than decisions imposed by scientists.

Although the importance of public involvement in regulating GMOs was supported during the conference, Kuta (60) also noted that, at least in his country Nigeria, there was still low public awareness about issues surrounding GM crops. He therefore called for more funding to be provided for public awareness projects in this area. Nath (77) also urged that farmers and the public be provided with information to enable them to make an informed choice about the use of GM crops and that the information should not come only from GMO firms. Regarding public awareness about GMOs, there was also specific discussion in the conference about the importance of labelling GM products, where there was general agreement that labelling was needed in developing countries (e.g. Bhat, 34, 38; Ombori, 75). For example, Nath (77) argued that labelling was essential because, if unlabelled, GM crops could enter the markets without a

conscious decision being made about them by the agro-intermediaries. Labelling practices can vary between countries (Prakoso, 50; Wuerthele, 66; Rao, 68) and Ashton (56) and Rao (68) supported international harmonization of labelling requirements. Prakoso (50) noted the technical difficulties that developing countries with limited resources face regarding GMO detection and proposed that reasonable enforceable labelling requirements should cover GMOs as raw materials but not as food products. Prakoso (78) also proposed that consumers should be informed about the safety of released GMOs so that labelling of GM materials would not negatively impact their marketing.

Many participants called for transparency in the regulatory processes (e.g. Bhat, 14; Ashton, 35; Muralidharan, 88). For Rao (54), regulatory data should be made available to scientists and the interested public and not considered in secrecy, arguing that there were anti-technology lobbies throughout the world which pressurized governments and regulatory committees to impede the import or release of GMOs. Similarly, Ashton (35, 56) complained about closed and secretive regulatory processes, arguing that powerful lobby groups were operating to facilitate introduction of GM crops. Diaz (39) and Ashton (56) emphasized that regulators and regulatory bodies should not have any conflicts of interest. Diaz (39) was also concerned about the use of confidential information in the regulatory processes concluding that, for any GMO application, the public had the right to know as much as possible about the GMO involved.

4.2.2.10 Monitoring implementation of GMO regulations

Once a regulatory framework has been put in place (defining the procedures for GMO approval; the kinds of GMOs that might be approved; how and where they may be released etc.) and applications for release of individual GMOs have been approved, monitoring of implementation of the regulations is needed. Participants highlighted the fact that monitoring may be especially difficult in developing countries due to lack of resources, although some issues can be difficult to monitor even for resource-strong developed countries.

Among others, Vasanthi (8) pointed out the importance of monitoring of GMOs, particularly in the field during and after cultivation, and during marketing, and that attention needed to be given to the kind of methods required, particularly approaches for preventing/checking unapproved cultivation of GM crops and checking for compliance with cultivation procedures of GM crops. Morris (73) noted, however, that the costs of monitoring compliance with any legislation could be high, and that GMOs were no exception in this respect. Ashton (35) argued that even for an "advanced developing nation" such as South Africa, there was insufficient capacity to properly and independently monitor or regulate all the trials and general releases of GM crops. A number of solutions to this problem of resources was proposed. Kuhn (29) suggested "industry self-policing" for developing countries that lack the necessary resources and expertise, whereby biotechnology companies selling GM crops would provide some oversight of post-market use of GM crops by farmers. He argued that this could be used at least until the developing country's government was able to assume a greater oversight role. McCowen (40), however, was not convinced that such a proposal might be suitable for countries other than the United States. Another potential solution came from Morris (73) who proposed that, to avoid duplicating functions and incurring additional costs due to monitoring GM crops, people working in the existing agricultural inspection service, as well as extension officers, could be trained in issues regarding GM technology to take over these tasks. Another solution proposed was that the costs could be met by the GMO producer. For Richardson (79), the regulatory agencies should be responsible for enforcement, but they should charge the seller for the costs of testing and enforcement. Similarly, Rajaratnam (81) suggested that any party who imports GM

seeds/seedlings or micro-organisms into a country should have the responsibility for setting up the monitoring system.

Although lack of resources was considered a problem for monitoring implementation of GMO regulations in developing countries, participants noted that some areas of GMO regulations were hard to monitor regardless of the resources available. One area is implementation of a refuge strategy, where Bt crops (i.e. producing insecticidal toxins using genes from the bacterium *Bacillus thuringiensis* [Bt]) are planted together with non-Bt 'refuge' areas of the same crop, to delay the development of resistance to Bt toxins among the pests. According to McCowen (10), implementing refuge strategies in North America had proven to be "basically impossible" as, although the seed dealers ensured that farmers buy the correct ratio of Bt and non-Bt seeds, planting was ultimately left up to the farmers and many did not know the correct refuge size or shape (McCowen, 93). Morris (13) and Muralidharan (88) pointed out that implementation might be even more problematic in developing countries, where illiterate or poor farmers on small farms might ignore the need for adequate non-Bt refuges. Monitoring the implementation of refuge strategies is, however, burdensome at the farm level as there is no quick mechanism for distinguishing GM from non-GM products (Jackson, 33). A second area concerns regulations covering tolerable limits for GM material in products identified as "non-GM". The regulations might be difficult to implement and monitor because of the diversity of products that could contain GM material (Jackson, 33) and because of technical limitations of procedures for detection of GM material (Prakoso, 50; Muralidharan, 57). A third area concerns regulations covering GMO gene flow, where Ramsaroop (42), supported by Buijs (49), noted that in developing countries such as Guyana there was prolific exchange of plant genetic materials between farmers making it difficult to control the movement of GM crops.

4.2.2.11 GMO regulations and liability

If GMO regulations have been infringed and some economic damage has been done, who is liable? Participants argued that the issue of liability is important and should be covered in the GMO regulatory framework.

Diaz (39) argued that the national solution to issues about legal responsibility for GMO introduction and payment for potential environmental or health damage should be given in the regulatory framework and that it was important to clearly assign such responsibilities before any undesirable events occurred. Wuerthele (66) bemoaned that in the United States, many legal, ethical and societal issues raised by GMOs were still unresolved, so for example, there were no regulations on liability for the consequences of GMO gene flow to non-GM crops. In South Africa, Ashton (35) maintained that the responsibility for negative impacts (financial, environmental) of GMOs fell on 'the user' (i.e. farmers, retailers and consumers) while Newman (2, 61) said non-GMO farmers in Australia were responsible for any negative consequences resulting from GMO gene flow to their crops. She (61), like Bhat (48), concluded that "the GM product provider must be legally responsible for containing and controlling their product and for any economic damage that would occur". While Efaw (78) suggested the GMO producers seemed to be very deliberate about avoiding responsibility for negative economic or environmental consequences, Blanchfield (78) noted that in a recent case (involving the finding of Starlink corn, a variety approved for animal feed but not for human consumption, in food products in 2000) the company involved accepted full liability. Blanchfield (78) also predicted that in the future the nature of the GMO producers would change as there would be more GMO R&D by government agencies, charitable foundations and international organizations and less by the private sector. Mog (84) disagreed, predicting that in the future private companies would continue to dominate, with governments struggling to respond adequately to the technologies they introduce.

4.2.3 Participation in the conference

The conference ran for five weeks, from 28 April to 1 June 2003, and a total of 401 people subscribed. Of the 401 people, 44 (i.e. 11 percent) submitted at least one message. Messages came from all major regions of the world - 27 of the 93 messages posted (i.e. 29 percent) came from participants in North America, 23 percent from Asia, 19 percent from Africa, 13 percent from Europe, 9 percent from Oceania and 8 percent from Latin America and the Caribbean. Messages came from people in 20 different countries - the greatest proportion coming from India and the United States (18 percent each), South Africa (12 percent), Canada (11 percent) and Australia (9 percent). A total of 46 (i.e. 49 percent) messages were from participants in developing countries and 47 (51 percent) from developed countries. The greatest proportion of messages came from people working in research centres (27 percent) and universities (26 percent), with the remainder from private consultants (16 percent) and from people in NGOs (15 percent), government bodies (8 percent), farmers' organizations (4 percent) and UN organizations (4 percent).

4.2.4 Name and country of participants with referenced messages

Acikgoz, Nazimi. Turkey
Ashton, Glenn. South Africa
Badr, Aisha. Egypt
Bhat, Ramesh. India
Blanchfield, Ralph. United Kingdom.
Bucchini, Luca. Italy
Buijs, Jasper. Peru
Diaz, Humberto Peralta. Mexico
Doebel, Reinald. Germany
Efaw, Clark. United States
Hongladarom, Soraj. Thailand
Jackson, Lee Ann. Australia
Kambikambi, Tamala Tonga. Zambia
Kuhn, Mark. United States
Kuta, Danladi Dada. Nigeria
Lekoape, Kelebohile. Switzerland
MacKenzie, Donald. Canada
McCowen, Tracey. Canada
Mog, Justin. United States
Morris, Jane. South Africa
Muir, Bill. United States
Muralidharan, E.M. India
Nath, Vikas. United States
Newman, Julie. Australia
Olutogun, Olusanya. Nigeria
Ombori, Omwoyo. Kenya
Pena-Neira, Sergio. Japan
Phillips, Peter. Canada
Prakoso, Budi. Thailand
Quemada, Hector. United States
Rajaratnam, Muhunthan. Australia
Ramsaroop, Raymond. Guyana

Rao, Kameswara. India
Richardson, Dick. United States
Strauss, Steven. United States
Vapnek, Jessica. Italy
Vasanthi, Siruguri. India
Villaverde, Héctor. Chile
Willemse, Gert. South Africa
Wollny, Clemens. Germany
Wuerthele, Suzanne. United States

CHAPTER 5.
MOLECULAR MARKER-ASSISTED SELECTION AS A POTENTIAL TOOL FOR GENETIC IMPROVEMENT OF CROPS, FOREST TREES, LIVESTOCK AND FISH IN DEVELOPING COUNTRIES

5.1 BACKGROUND DOCUMENT

5.1.1 Introduction

Having reached the landmark of ten conferences in this FAO Biotechnology Forum, it is a pleasure to dedicate an entire conference to biotechnology involving the use of DNA markers, in particular to their use in market-assisted selection (MAS) for genetic improvement of domestic plant and animal populations in developing countries.

The potential benefits of using markers linked to genes of interest in breeding programmes have been obvious for many decades. However, realization of this potential has been limited by the lack of markers. With the advent of DNA-based genetic markers in the late 1970s, the situation changed and researchers could, for the first time, begin to identify large numbers of markers dispersed throughout the genetic material of any species of interest and use the markers to detect associations with traits of interest, thus allowing MAS to finally become a reality. This led to a whole new field of academic research, including the milestone paper by Paterson *et al.* (1988) which showed, given the availability of large numbers of genetic markers for their species of interest (tomato), how the effects and location of marker-linked genes impacting a number of quantitative traits (fruit traits in their case) could be estimated, using an approach that could be applied to dissect the genetic make-up of any physiological, morphological and behavioural trait in plants and animals.

Most of the traits considered in animal and plant genetic improvement programmes are quantitative traits i.e. they are controlled by many genes, together with environmental factors and the underlying genes have small effects on the observable phenotype. Milk yield and growth rate in animals or yield and seed size in plants are typical examples of quantitative traits. In classical genetic improvement programmes, selection is carried out based on observable phenotypes (of the candidates for selection and/or their relatives) but without knowing which genes are actually being selected. The development of molecular markers was therefore greeted with great enthusiasm as it was seen as a major breakthrough promising to overcome this key limitation. As Young (1999) wrote in a recent review, “Before the advent of DNA marker technology, the idea of rapidly uncovering the loci controlling complex, multigenic traits seemed like a dream. Suddenly, it was difficult to open a plant genetics journal without finding dozens of papers seeking to pinpoint many, if not most, agriculturally relevant genes”.

However, despite the considerable resources that have been invested in this field and despite the enormous potential it still represents, MAS, with few exceptions, has not yet delivered its expected benefits in commercial breeding programmes for crops, animals, forest trees or farmed fish in the developed world. This is just one of the aspects that should be considered in this e-mail conference which aims to examine the appropriateness and potential of MAS as a tool for genetic improvement in developing countries.

This Background Document aims to provide information that participants will find useful for the debate. Firstly, a brief overview of the technical aspects of molecular markers and MAS is

provided. Then, the current status of the application of MAS in crops, forest trees, livestock and fish is summarized. Section 5.1.4 then raises some important issues that might be relevant to applications of MAS in developing countries. In Section 5.1.5 some of the topics that should be discussed throughout the conference are highlighted. Finally, Section 5.1.6 provides references to articles mentioned in the document.

From 17 to 18 October 2003, the Fondazione per le Biotecnologie, the University of Turin and FAO organized an international workshop in Turin, Italy, entitled "Marker-assisted selection: A fast track to increase genetic gain in plant and animal breeding?". The proceedings of the workshop (available at www.fao.org/biotech/Torino.htm), with 11 papers covering crops, livestock, fruit trees and farmed fish, provide an excellent overview of the current status of MAS and can be consulted by anyone looking for more detailed technical information on this subject.

In conferences hosted by the FAO Biotechnology Forum, clearly defined topics of relevance to agricultural biotechnology in developing countries are discussed for a limited amount of time. In defining the topic for this conference, it can be noted that although molecular markers may be used for a wide range of different tasks, such as to quantify the genetic diversity and relationships within and amongst agricultural populations (e.g. livestock breeds), to investigate biological processes (such as mating systems, pollen movement or seed dispersal in plants) or to identify specific genotypes (e.g. cloned forest trees), these applications will not be considered in the conference and instead focus will be on the use of molecular markers for genetic improvement of populations through MAS, including marker-assisted introgression.

5.1.2 Background to MAS

5.1.2.1 Molecular markers

To begin at the beginning, it should be said that all living things are made up of cells that are programmed by genetic material called DNA. This molecule is made up of a long chain of nitrogen-containing bases (there are four different bases: A, C, G and T). Only a small fraction of the DNA sequence typically makes up genes, i.e. they code for proteins, while the remaining and major share of the DNA represents non-coding sequences the role of which is not yet clearly understood. The genetic material is organized into sets of chromosomes (e.g. five pairs in Arabidopsis thaliana; 30 pairs in cattle), and the entire set is called the genome. In a diploid individual (i.e. where chromosomes are organized in pairs), there are two alleles of every gene, one from each parent.

Molecular markers should not be considered as normal genes, as they usually do not have any biological effect and instead, can be thought of as constant landmarks in the genome. They are identifiable DNA sequences, found at specific locations of the genome and transmitted by the standard laws of inheritance from one generation to the next. They rely on a DNA assay, in contrast to morphological markers, based on visible traits and biochemical markers, based on proteins produced by genes.

Different kinds of molecular markers exist, such as RFLPs, RAPDs, AFLPs, microsatellites and SNPs. They may differ in a variety of ways, such as their technical requirements (e.g. whether they can be automated or require use of radioactivity); the amount of time, money and labour needed; the number of genetic markers that can be detected throughout the genome; and the amount of genetic variation found at each marker in a given population. The information provided by the markers for the breeder will vary depending on the type of marker

system used. Each one has its advantages and disadvantages and in the future, other systems are also likely to be developed. A brief overview of the major marker systems is given below.

a) RFLPs

Restriction Fragment Length Polymorphisms (RFLPs) are markers detected by treating DNA with restriction enzymes (enzymes that cut DNA at a specific sequence). For example, the EcoR1 restriction enzyme cuts DNA whenever the base sequence GAATTC is found. Differences in the lengths of DNA fragments will then be seen if, for example, the DNA of one individual contains that sequence at a specific part of the genome (e.g. tip of chromosome 3) whereas another individual has the sequence GAATTT (which is not cut by EcoR1). RFLPs were the first molecular markers to be widely used. Their use is, however, time-consuming and expensive and simpler marker systems have subsequently been developed.

b) RAPDs

Random amplified polymorphic DNA (RAPD) markers were first described in 1990. They are detected using the polymerase chain reaction (PCR), a widespread molecular biology procedure allowing the production of multiple copies (amplification) of specific DNA sequences. The analysis for RAPD markers is rapid and simple, although results are sensitive to laboratory conditions.

c) AFLPs

In the mid 1990s, another PCR-based method of generating molecular markers was described, giving rise to amplified fragment length polymorphism (AFLP) markers. With this technique, DNA treated with restriction enzymes is amplified with PCR. It allows selective amplification of restriction fragments giving rise to large numbers of useful markers which can be located on the genome relatively quickly and reliably. Unlike other methods described here, the technique is patented.

d) Microsatellites

These are simple DNA sequences (e.g. AC), usually two or three bases long, repeated a variable number of times in tandem. They are easy to detect with PCR and a typical microsatellite marker has more variants than those from other marker systems. Initial identification of microsatellites is time-consuming.

e) SNPs

In recent years, single nucleotide polymorphisms (SNPs), i.e. single base changes in DNA sequence, have become an increasingly important class of molecular marker. The potential number of SNP markers is very high, meaning that it should be possible to find them in all parts of the genome, and micro-array procedures have been developed for automatically scoring hundreds of SNP loci simultaneously at a low cost per sample.

Korzun (2003), considering the case of cereals, provided a good comparison of these marker systems (Table 5.1.1).

Table 5.1.1. Comparison of the most commonly used marker systems in cereals (Korzun, 2003)

Feature	RFLPs	RAPDs	AFLPs	Microsats	SNPs
Amount of DNA required (in micrograms)	10	0.02	0.5-1.0	0.05	0.05
Quality of DNA required	high	high	moderate	moderate	high
Is it PCR-based?	no	yes	yes	yes	yes
Number of polymorphic loci analysed per analysis	1.0-3.0	1.5-50	20-100	1.0-3.0	1.0
Ease of use	not easy	easy	easy	easy	easy
Amenable to automation	low	moderate	moderate	high	high
Reproducibility	high	unreliable	high	high	high
Development cost	low	low	moderate	high	high
Cost per analysis	high	low	moderate	low	low

5.1.2.2 From markers to MAS

The molecular marker systems described above allow high-density DNA marker maps (i.e. with many markers of known location, interspersed at relatively short intervals throughout the genome) to be constructed for a range of economically important agricultural species, thus providing the framework needed for eventual applications of MAS.

The next step is that using the marker map, putative genes affecting traits of interest can be detected by testing for statistical associations amongst marker variants and any trait of interest. These traits might be genetically simple, for example, many disease resistance traits in plants are controlled by one or a few genes (Young, 1999). Alternatively, they could be genetically complex quantitative traits, involving many genes (i.e. so-called quantitative trait loci [QTLs]) and environmental effects. (Most economically important agronomic traits tend to fall into the second category). For example, Babu *et al.* (2003), using 280 molecular markers (comprising 134 RFLPs, 131 AFLPs and 15 microsatellites) and recording populations of rice lines for various plant water stress indicators, phenology, plant biomass, yield and yield components under irrigated and water stress conditions, detected a number of putative QTLs for drought resistance traits.

Having identified markers physically located beside (or, even, within) genes of interest, it is now possible, in the next step, to carry out MAS, i.e. to select identifiable marker variants (alleles) in order to select for non-identifiable favourable variants of the genes of interest. For example, consider a hypothetical situation where a molecular marker M (with two alleles M1 and M2), that can be identified using a DNA assay, is known to be located on a chromosome close to a gene of interest Q (with a variant Q1 that increases yield and a variant Q2 that decreases yield), that is as yet unknown. Then, if a given individual in the population has the alleles M1 and Q1 on one chromosome and M2 and Q2 on the other chromosome it is known that any of its progeny receiving the M1 allele will have a high probability (how high it is depends on how close M and Q are to each other on the chromosome) of also carrying the favourable Q1 allele, and thus would be preferred for selection purposes, while those that inherit the M2 allele will tend to have inherited the unfavourable Q2 allele, and so would not be preferred for selection. With conventional selection, relying on phenotypic values, it is not possible to use this kind of information.

The success of MAS is influenced by the relationship between the markers and the genes of interest. Dekkers (2004) distinguished three kinds of relationship:

- the molecular marker is located within the gene of interest (i.e. within the gene Q, using the example above). In this situation, the term gene assisted selection (GAS) can be referred to. This is the most favourable situation for MAS since, by following inheritance of the M alleles, inheritance of the Q alleles is directly followed. On the other hand, it is most difficult to find these kinds of markers;
- the marker is in linkage disequilibrium (LD) with Q throughout the whole population. LD is the tendency of certain combinations of alleles (e.g. M1 and Q1) to be inherited together. Population-wide LD can be found when markers and genes of interest are physically very close to each other and/or when lines or breeds have been crossed in recent generations. Selection using these markers can be called LD-MAS;
- the marker is not in linkage disequilibrium (i.e. it is in linkage equilibrium [LE]) with Q throughout the whole population. Selection using these markers can be called LE-MAS. This is the most difficult situation for applying MAS.

Due to the universal nature of DNA, molecular markers and genes, MAS can, in theory, be applied to any agriculturally important species and active research programmes have been devoted to building molecular marker maps and to detecting QTLs for potential use in MAS programmes in a whole range of crop, livestock, forest tree and fish species. In addition, MAS can be applied to support existing conventional breeding programmes. These programmes use strategies such as: recurrent selection (i.e. using within-breed or within-line selection, important in livestock); development of crossbreds or hybrids (by crossing several improved lines or breeds) and introgression (where a target gene is introduced from a low-productive line or breed [donor] into a productive line [recipient] that lacks the target gene [a strategy especially important in plants]). See Dekkers and Hospital (2002) for more details. MAS can be incorporated into any one of these strategies (e.g. for marker-assisted introgression, by using markers to accelerate introduction of the target gene). Alternatively, novel breeding strategies can be developed to harness the new possibilities that MAS raises.

5.1.3 Current status of applications of MAS in agriculture

A brief summary is provided of the current status regarding application of MAS in the different agricultural sectors.

5.1.3.1 Crops

The promise of MAS has possibly been greeted with most enthusiasm and expectation in this particular agricultural sector, stimulating tremendous investments in the development of molecular marker maps and research to detect associations between phenotypes and markers. Molecular marker maps have been constructed for a wide range of crop species. Information on major plant projects (such as the sequencing of the entire rice genome) can be found at www.ncbi.nlm.nih.gov/genomes/PLANTS/PlantList.html.

Dekkers and Hospital (2002), however, in a recent review noted that “as theoretical and experimental results of QTL detection have accumulated, the initial enthusiasm for the potential genetic gains allowed by molecular genetics has been tempered by evidence for limits to the precision of the estimates of QTL effects” and that “overall, there are still few reports of

successful MAS experiments or applications". They reported that marker-assisted introgression of known genes was widely used in plants, particularly by private breeding companies, whereas marker-assisted introgression of unknown genes had often proved to be less useful in practice than expected. As Young (1999) wrote: "even though marker-assisted selection now plays a prominent role in the field of plant breeding, examples of successful, practical outcomes are rare. It is clear that DNA markers hold great promise, but realizing that promise remains elusive".

There is also considerable divergence amongst different crop species with respect to their applications of MAS. For example, Koebner (2003) highlights the relatively fast uptake of MAS in maize compared with wheat and barley, arguing that it largely reflects the breeding structure, where maize breeding in industrialized countries is dominated by a small number of large private companies that produce F1 hybrids, a system allowing protection from farm-saved seed and competitor use, while for the other major cereal species breeding is primarily by public sector organizations and most varieties are inbred pure breeding lines, a system allowing less protection over the released varieties. Progress in arable crops is nevertheless quite advanced compared with horticultural crop species, such as apples and pears, where development of molecular marker maps has been slow and only a few QTLs have been detected (Tartarini, 2003), even if MAS can potentially be very useful for genetic improvement of such long-cycle plants.

5.1.3.2 Forestry

As for crops, extensive efforts have been devoted to the construction of molecular marker maps for the major commercial genera, such as eucalypts, pines and acacia. RFLPs, RAPDs, microsatellites and AFLPs have been extensively used. The web site http://dendrome.ucdavis.edu/index.php provides updated information on the status regarding molecular marker maps in forestry.

The molecular maps have been used to locate markers associated with variation in forestry traits of commercial interest, such as growth, frost tolerance, wood properties, vegetative propagation, leaf oil composition and disease resistance. A major incentive for using molecular techniques in tree breeding is to improve the rate of genetic gain by reducing the long generation interval since MAS allows early selection before the traits of interest (e.g. wood quality) are expressed. However, Butcher (2002) noted that "MAS has yet to be incorporated in operational breeding programs for plantation species" and she referred to the high costs of genotyping, the large family sizes required to detect QTLs and the lack of knowledge of QTL interactions with genetic background, tree age and environment as explanatory factors.

In a recent review of biotechnology in forestry, Yanchuk (2002) also highlighted the potential advantage of early selection using MAS, but again pointed out that MAS is not yet being routinely applied in tree breeding programmes, largely "because of economic constraints (i.e. the additional genetic gains are generally not large enough to offset the costs of applying the technology). Thus it is likely that MAS will only be applied for a handful of species and situations, e.g. a few of the major commercially used pine and Eucalyptus species. Molecular markers are therefore primarily an information tool and are used to locate DNA/genes that can be of interest for genetic transformation, or information on population structure, mating systems and pedigree confirmation".

5.1.3.3 Livestock

Again, much effort has been put into the development of molecular marker maps in this sector. The first reported map in livestock was for the chicken in 1992 which was rapidly

followed by the publication of maps for cattle, pigs and sheep. Since then, the search for useful markers has continued and further species have been targeted, including the goat, horse, rabbit and turkey (see www.thearkdb.org/ for the current status regarding some major farm animal species). Microsatellite markers have been of major importance.

Dekkers (2004) recently reviewed commercial applications of MAS in livestock and showed that several gene or marker tests are available on a commercial basis, in different species and for different traits and that the majority of uses involve GAS, where an important gene (e.g. responsible for a congenital defect) has been identified or, to a lesser degree, LD-MAS. He pointed out that documentation is poor since although several genetic tests are available, the extent to which they are used in commercial applications is unclear, as is the manner in which they are used and whether their use leads to greater responses to selection. He concluded that "opportunities for the application of MAS exist, in particular for GAS and LD-MAS and, to a lesser degree, for LE-MAS because of greater implementation requirements. Regardless of the strategy used, successful application of MAS requires a comprehensive integrated approach with continued emphasis on phenotypic recording programs to enable QTL detection, estimation and confirmation of effects, and use of estimates in selection. Although initial expectations for the use of MAS were high, the current attitude is one of cautious optimism".

5.1.3.4 Aquaculture

Molecular marker maps have been constructed for a number of aquaculture species e.g. tilapia, catfish, giant tiger prawn, kuruma prawn, Japanese flounder and Atlantic salmon, although their density is generally low. Density is highest for the rainbow trout, where the map published in 2003 has over 1 300 markers spread throughout the genome, the vast majority are AFLPs but also include over 200 microsatellite markers. Some QTLs of interest have been detected (e.g. for cold and salinity tolerance in tilapia; for specific diseases in rainbow trout and salmon). Sonesson (2003), in a recent review of MAS in fish breeding schemes, suggested that MAS would be especially valuable for traits that are impossible to record on the candidates for selection, such as disease resistance, fillet quality, feed efficiency and sexual maturation and concluded that MAS is not used in fish breeding schemes today and that the lack of dense molecular maps is the limiting factor.

5.1.3.5 Summary

Molecular marker maps, the necessary framework for any MAS programme, have been constructed for the majority of agriculturally important species. Density of the maps varies considerably amongst species. Currently, MAS does not play a major role in genetic improvement programmes in any of the agricultural sectors. The enthusiasm and optimism concerning the potential contributions that MAS offers for genetic improvement still remains. However, they seem to be tempered by the realization that it may take longer than originally thought and that genetic improvement of quantitative traits using MAS may be more difficult than previously considered. The conclusions from the review by Dekkers and Hospital (2002) are a good reflection of this: "Further advances in molecular technology and genome programmes will soon create a wealth of information that can be exploited for the genetic improvement of plants and animals. High-throughput genotyping, for example, will allow direct selection on marker information based on population-wide LD. Methods to effectively analyse and use this information in selection are still to be developed. The eventual application of these technologies in practical breeding programmes will be on the basis of economic grounds, which, along with cost-effective technology, will require further evidence of predictable and sustainable genetic advances using MAS. Until complex traits can be fully dissected, the application of MAS will be

limited to genes of moderate-to-large effect and to applications that do not endanger the response to conventional selection. Until then, observable phenotype will remain an important component of genetic improvement programmes, because it takes account of the collective effect of all genes".

5.1.4 Some factors relevant to applying MAS in developing countries

In the debate on the role or value of MAS as a potential tool for genetic improvement in developing countries, some of the potential factors that should be considered are briefly described below, as they may influence applications of the technology.

5.1.4.1 Economic factors

As with any new technology promising increased benefits, the costs of application must also be considered. According to Dekkers and Hospital (2002), "economics is the key determinant for the application of molecular genetics in genetic improvement programmes. The use of markers in selection incurs the costs that are inherent to molecular techniques. Apart from the cost of QTL detection, which can be substantial, costs for MAS include the costs of DNA collection, genotyping and analysis". For example, Koebner (2003) suggested that the current costs of MAS would need to fall considerably before it would be used widely in wheat and barley breeding. In practice, therefore, although MAS may lead to increased genetic responses, decision-makers need to consider whether it may be cost-effective or whether the money and resources spent on developing and applying MAS might instead be more efficiently used on adopting other new technologies or on improving existing conventional breeding programmes.

Little consideration has been given to this issue. Some results have, however, been recently published from studies at the International Maize and Wheat Improvement Center (CIMMYT) in Mexico on the relative cost-effectiveness of conventional selection and MAS for different maize breeding applications. One application, considered by Morris *et al.* (2003), was the transfer of an elite allele at a single dominant gene from a donor line to a recipient line. Here, conventional breeding is less expensive but MAS is more rapid. For situations like this, where the choice between conventional breeding and MAS involves a trade-off between time and money, it was suggested that the cost-effectiveness of using MAS depends on four parameters: the relative cost of phenotypic versus marker screening; the time saved by MAS; the size and temporal distribution of benefits associated with accelerated release of improved germplasm and finally, the availability to the breeding programme of operating capital. It was concluded that "all four of these parameters can vary significantly amongst breeding projects, suggesting that detailed economic analysis may be needed to predict in advance, which selection technology will be optimal for a given breeding project".

In the different applications considered by CIMMYT, the costs of developing molecular markers associated with the trait of interest were not considered, as it was assumed that they were already available. There is a distinction between development costs (e.g. identifying molecular markers on the genome, detecting associations between markers and the traits of interest) and running costs (typing individuals for the appropriate markers in the selection programme) of MAS. Development costs can be quite expensive, so developing countries need to consider whether to develop their own technology or, alternatively, to import the technology developed elsewhere, if available.

Another aspect to be considered here is how to evaluate the economic benefits of MAS. For a publicly funded breeding programme, it should include economic benefits to farmers from

genetic improvement of their plants or animals. For private companies instead, the impacts of using MAS on their market share, and not on rates of genetic improvement, would be of greatest interest.

5.1.4.2 MAS versus conventional methods

Although conventional breeding programmes, relying on phenotypic records, have their limitations, they have shown over time that they can be highly successful. Application of MAS will not occur in a vacuum and the potential benefits (genetic, economic, etc.) of using MAS need to be compared with those achieved or expected from any existing conventional breeding programmes.

In the different agricultural sectors, this question has received much attention from researchers. There seems to be general consensus that the relative success of MAS compared with conventional breeding may depend on the kind of trait (or traits) to be genetically improved. If the trait is difficult to record or is not routinely recorded in conventional programmes, MAS will offer more advantages than if it is routinely recorded. Similarly, if the trait is sex-limited or can only be measured late in life then MAS is favoured, as marker information can be used in both sexes and at any age.

5.1.4.3 MAS versus other biotechnologies for genetic improvement

The relative costs and benefits of applying MAS should be compared not only with conventional breeding but also with potential use of other new technologies that can genetically improve agricultural populations. These include tissue culture in crops and forest trees; reproductive technologies (e.g. embryo transfer or cloning) in livestock and triploidization or sex-reversal in farmed fish. These also include genetic modification, a technology that can be applied to all sectors. Compared with genetic modification, regulation of MAS, be it at the level of research and development, field testing, commercial release or import/export of developed products, is more relaxed and in addition, acceptance of the technology by the public is not an issue.

5.1.4.4 IPR issues

As discussed in Conference 6 of this Forum (FAO, 2001), the issue of intellectual property rights (IPR) is playing an ever greater role in food and agriculture in developing countries. Participants in Conference 6, among other things, suggested that the issue of IPR was influencing, generally in the negative sense, the quality of agricultural research carried out and the nature of research collaboration between the public and private sector and between developing and developed countries.

It is therefore obvious that IPR may also impact MAS in developing countries. The impact may be felt at a number of steps involving development and application of markers for genetic improvement. For example, the AFLP molecular marker mapping technique is patented. Molecular markers can be patented, although this can often be overcome by using other markers near the gene of interest. Individual genes can also be patented. With IPR, however, there is nevertheless public disclosure of the invention or information. Non-disclosure of information, where patents are not sought but the information on markers or detected QTLs is nevertheless kept secret, can also have negative impacts, by denying developing countries' access to potentially useful information.

5.1.5 Topics to be discussed in the conference

This conference considers the subject of molecular MAS as a potential tool for genetic improvement of crops, forest trees, livestock and fish in developing countries. In particular, some items which should be discussed are:

- how useful is MAS as a tool for genetic improvement in developing countries?
- for which traits and types of species is it most appropriate?
- for which agricultural sectors (crops, forestry, livestock, aquaculture) is it most appropriate?
- for which production systems is it most appropriate?
- what are the current limiting factors to its successful application in developing countries?
- how can these limiting factors be overcome?
- what impacts are IPR having on development of MAS tools and applications of MAS in developing countries?
- when should developing countries play an active role in the development of MAS technology (construction of molecular marker maps, detection of association between molecular markers and traits of interest, etc.) or when, instead, should they aim to import the technology developed elsewhere?
- when is it appropriate for developing countries to use MAS? Should the previous establishment of a successful conventional breeding programme be a prerequisite?
- how appropriate is MAS as a tool for genetic improvement in developing countries compared with other biotechnologies?
- what role should international organizations, like FAO or the World Bank, or the Consultative Group on International Agricultural Research (CGIAR) centres have in this area?

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5.2 SUMMARY DOCUMENT

Executive summary

MAS is a complementary technology, for use in conjunction with more established conventional methods of genetic selection, for plant and animal improvement. It has generated a good deal of expectations, many of which have yet to be realized. Although documentation is limited, the current impact of MAS on products delivered to farmers seems small. While the future possibilities and potential impacts of MAS are considerable, there are also obstacles to its use, particularly in developing countries. Principal among these are issues relating to current high costs of the technology and its appropriateness, given that publicly funded agricultural research in many developing countries is suboptimal and development priorities do not necessarily include genetic improvement programmes. Other potential obstacles to the uptake of MAS in developing countries include limited infrastructure, the absence of conventional breeding programmes, poor private sector involvement and lack of research on specific crops of importance in developing countries. Intellectual property rights may also be an important constraint to development and uptake of MAS in the developing world. It is hoped that through partnerships amongst developing and developed country institutions and individuals, including public-private sector collaboration, MAS costs can be reduced, resources pooled and shared and capacity developed. With the assistance of the CGIAR and international organizations such as FAO, developing countries can benefit more from MAS. These were some of the outcomes of a moderated e-mail conference, entitled "Molecular marker-assisted selection as a potential tool for genetic improvement of crops, forest trees, livestock and fish in developing countries", hosted by the FAO Biotechnology Forum from 17 November to 14 December 2003. During the four-week conference, 627 people subscribed and 85 messages were posted, about 60 percent coming from people living in developing countries. The majority of messages came from people working in research centres and universities. The remainder worked as consultants, in development agencies, for farmer organizations, government agencies, NGOs or UN organizations.

5.2.1 Introduction

The number of subscribers (627) was far higher than for any of the other conferences hosted by the Forum since its launch in March 2000 and during the four-week conference, a total of 85 messages were received, numbered in the order of posting. Specific references to messages posted, giving the participant's surname and message number, are provided in the document. All the individual messages can be viewed at www.fao.org/biotech/logs/c10logs.htm.

Contributions were not evenly spread across the four agricultural sectors of the conference. MAS in crop and livestock genetic improvement dominated the discussions and issues relating to forest trees and aquaculture were mentioned much less, possibly indicating differences in uptake of this relatively new technology among the four sectors. Nonetheless, many of the issues and concerns raised were general in nature and applicable across sectors. These issues included considerations of costs and gains, intellectual property rights and the benefits of partnerships to allow developing countries greater participation in development and use of MAS.

Murphy (1) began the conference with a request that MAS be viewed dispassionately as a potential tool for crop improvement to be deployed alongside conventional methods. Sokefun (64) referred to conventional selection methods as "soft" technologies and the newer technologies, such as MAS, as "hard" technologies, and suggested that the hard would not replace the soft technologies and that a fusion of both would achieve the best results. In contrast to more

upstream technologies (including genetic modification, mutagenesis and protoplast fusion), which generate additional variation in plant populations, Murphy (1) described MAS as a "downstream technology" that, like conventional phenotypic selection, can be used to select the optimal variants in a population.

The conference discussion was balanced and the topic of the potential of MAS did not evoke strong reaction among the participants, although many had reservations about it. There was consequently little indication of a substantial dichotomy of opinion whereby participants could be put into pro- and anti-MAS camps. This is in sharp contrast to discussions about genetic modification in previous conferences of this Forum (see for example www.fao.org/biotech/logs/C1/sum.htm). As stated by Muralidharan (7), MAS differs from genetic modification in being more widely acceptable.

There was considerable agreement among the participants on the perceived opportunities and constraints associated with MAS and the usefulness and applicability of the technology in developing countries. Olori (21) thought that successful application of MAS in a well structured breeding programme in any developing country would yield the same benefits as in developed countries. However, as suggested by Montaldo (18) for genetic improvement in animals, it would be necessary to make case-by-case studies, taking into account not only biological issues, but also social, political and economic ones, before making recommendations on application of MAS.

In Section 5.2.2 of this document, the main elements of the discussions are summarized under 11 headings. Section 5.2.3 provides some information about participation in the conference and Section 5.2.4 gives the name and country of the people that sent referenced messages.

5.2.2 Main themes discussed

5.2.2.1 Whether MAS should be a priority in developing countries

The general opinion was that MAS could be usefully applied for genetic improvement of plants and animals in developing countries, but that it would not necessarily represent a priority. Gianola (6) pointed out that in order for MAS to be taken up in developing countries, because of the scarcity of resources, the returns to investment should be far superior compared with those for a developed country, given the significant opportunity costs. Africa was mentioned as facing major constraints to agricultural production, including drought stress, low soil fertility and pests, which were not easily and economically amenable to MAS (Koudande, 68), and Seth (26) stressed the importance of priority setting in the context of national agricultural economies. Crop diversification and research on underutilized species were also mentioned as other possible priorities for addressing problems of the expanding human population (Priyadarshan, 11 and 71). Murphy (1) suggested that tremendous gains could be made in agricultural development without resorting to applications of biotechnology, by addressing issues of management and infrastructure. For example, in the case of Brazil, a priority might be improvements in the road system to facilitate export crops reaching the ports (Murphy, 1).

5.2.2.2 Costs of MAS

The cost associated with MAS was a common theme during the conference and several participants, including Collard (9), considered it to be the most important issue for developing countries. It was pointed out (e.g. De Koning, 13) that although costs associated with MAS can be high, conventional genetic improvement programmes can also be expensive. Gianola (2) called for an economic analysis of MAS in comparison with conventional methods, specifically requesting estimates of internal rates of return. He (6) also warned that there was a risk that some investments in MAS might be wasted given the advances being made in post-genomics. For Weller (4), "with respect to the economic questions, MAS is no different from any other technology that increases rates of genetic gain, but also increases costs", concluding that the investments required for MAS could be massive, but so also could the long-term economic gains. However, as pointed out by Montaldo (18), the economics of MAS is based on the value of the selected traits and most importantly, each case should be looked at individually. De Koning (13) highlighted the major economic benefits that could be gained by breeding livestock for resistance to trypanosomiasis.

Various stages in the MAS development and application process were regarded as being costly. Labour and DNA extraction were viewed by Williams (37) as representing the major costs, but Collard (45) considered equipment, consumables and infrastructure to be among the most costly items in a MAS programme. Genotyping (Toro, 67), marker development (El Ouafi, 77; Wallwork, 59) and patenting (Ganunga, 69) were other areas that represented large costs that might constrain MAS use in developing countries. It was suggested that farmers in the developing world could not be expected to pay for MAS (Chavez, 33), while Muralidharan (74) suggested that costs in a country like India would eventually be a lot cheaper than in developed countries.

Participants, including Buijs (58), pointed out that technologies become cheaper as knowledge accumulates and capacity is built up, citing the example of tissue culture. Buijs (22) also felt that the costs of MAS should be put in perspective with those from other related research areas, pointing out that plant varieties or animals bred by MAS do not require costly safety regulation, in contrast to those bred using genetic modification. Toro (50) and Muralidharan (74) suggested that MAS would become cheaper due to automation/robotics, and Varshney (82) reported that microsatellite marker development has become cheaper as a result of bioinformatics. Many participants suggested that developing countries could make best use of MAS through collaborative ventures (Olori, 21, 65; Acikgoz, 66; Saravanan, 73), formation of multidisciplinary teams (Sridhar, 76; William, 70; Muchugi, 49) and within national and regional frameworks (Montaldo, 18). Collaboration would spread resources and reduce costs.

Figures for the costs of genotyping mentioned in the conference ranged from US$4 per marker for MAS in pigs (Toro, 79) to under US$0.2 for durum wheat (El Ouafi, 77). Robert Koebner, in the pre-conference workshop (www.fao.org/biotech/Torino.htm), suggested costs of around US$0.4 for wheat, while noting that more extensive calculations put the full economic cost at US$1-2. Discussion of such exact figures for costs is at best indicative in the face of continuous changes in the world economy, particularly in exchange rates and purchasing power. Suffice it to say that as costs are reduced, the value of MAS rises and possibly becomes more widely applicable.

5.2.2.3 Putting MAS into context

Although MAS has generated a good deal of expectations, which in some cases has led to over-optimism and in others to disappointment because many of the expectations have not yet been realized, participants in the conference aimed to consider MAS rationally and to put it into context of the whole agricultural picture. As Murphy (1) wrote, MAS "should be viewed dispassionately as a potential tool for crop improvement to be usefully deployed alongside conventional phenotype selection for certain crops and for certain characters".

Good genetic improvement strategies were considered by many to be among the most important prerequisites for successful implementation of MAS. Montaldo (18) said that with respect to livestock improvement, MAS would not substitute for choosing the right breeding objectives and the starting point of a programme incorporating MAS should be a sound breeding strategy founded in traditional selection methodology. Wallwork (59) thought that many of the criticisms of MAS (e.g. see De Lange, 57) stemmed from poor research and development strategies and not necessarily from shortcomings in the technology. El Ouafi (77) stated plainly that if a successful conventional breeding programme could not be established, MAS would not help, and Olori (21) suggested that the absence of "any real sense of the need for a genetic improvement program" in developing countries would hinder application of MAS. Such practical strategic considerations balance the hyperbole and over-optimism that has sometimes been associated with MAS. De Lange (57) argued that because of its high costs and relatively moderate results to date, MAS seemed to be "yet another over-hyped gene technology" and questioned, like Ackigoz (66), whether MAS should be a primary consideration for developing countries. Bhatia (8) was among several participants to comment on this issue and believed that the hyperbole to some extent reflected fashion and vendor bias, as for all new technologies.

5.2.2.4 MAS in relation to conventional breeding programmes

The need for an established breeding programme to be put into place for MAS to be usefully introduced represented one of the main points debated in the conference. Many participants (e.g. Montaldo, 18) explicitly stated the need for a conventional programme to be operational prior to implementation of MAS and others inferred it. Notter (25), on the other hand, suggested that animal recording need not precede implementation of MAS; he proposed that they could be implemented together.

Referring to animal trypanosomosis in Africa, De Koning (13) commented that lack of routine recording of production and health traits, with limited national molecular research facilities, presented a structural problem to implementing a breeding programme using MAS. De Koning (20) also said that when livestock were mainly kept by smallholders, each with a handful of animals, there would be no routine recording. Makkar (52) also suggested that in low input systems, which characterize many developing countries, phenotype and pedigree information were often not available, and this would make it difficult to realize the value of MAS. Notter (25) proposed, however, that MAS (or related technologies) could act as a lever to promote implementation of animal recording. He also noted that "MAS without recording is unlikely to be very beneficial for most traits".

For crops, Singh (61) suggested that MAS should be an integral part of the breeding strategy, but Acikgoz (66) was critical of situations where scientists without any experience of traditional plant breeding programmes entered directly into MAS. Sridhar (76) and El Ouafi (77), while acknowledging the importance of MAS, both suggested that meaningful breeding programmes were necessary to make progress with MAS and Dulieu (23) doubted that traditional

selection methods could easily be replaced by MAS. Priyadarshan (11) also believed that more basic biological knowledge about the intricacies of nature was needed to improve selection procedures for plants and Montaldo (18) pointed out that knowledge of genetic control of some important traits remained incomplete.

MAS in aquaculture in developing countries was only briefly discussed in the conference, although Priyadarshan (71) argued that aquaculture merited more emphasis. Martinez (63) suggested that for aquaculture, application of DNA technologies and MAS was scarce even in developed countries because of the lack of integration between quantitative and molecular genetics, and that the only successful application in aquaculture was that described by Toro (50), who said that molecular markers could be used to assist classical genetic improvement programmes by constructing pedigrees needed for genetic evaluation in trees and fish where otherwise pedigree information was lacking. Martinez (63) noted, however, that economic analysis of this strategy compared with individually identifying fish using electronic devices was scarce. Krause (75) gave an example where molecular marker information could be used to reduce the costs of a fish breeding programme. Normally, electronically-tagged back-up copies of nucleus breeding populations of fish are made as an insurance against loss of a deployed population. This is an expensive process that can be avoided by taking tissue samples from sires and dams that are analysed for the presence of established molecular markers if a nucleus stock is destroyed. This allows a nucleus stock to be regenerated relatively easily and cheaply, if and when necessary.

While the merits of applying MAS to genetic improvement of trees in developing countries were appreciated (e.g. Muralidharan, 7), participants suggested that there are many problems that detract from its usefulness. Principal among these is the poor state of current tree breeding in general, and in developing countries in particular. Simons (28) listed a number of problems concerning genetic improvement of tropical trees, including dioecy, undocumented origins and uncertainty of genetic control of traits. However, Galvez (10) mentioned that MAS had been used to assist in selection of coconut parents for breeding. Priyadarshan (11) considered MAS to be helpful for rubber improvement, at least theoretically, and Badr (47) seemed to be looking forward to MAS reducing the time needed for evaluation of fruit trees in Egypt, obviating the need for grafting to see the products of breeding efforts. Forest trees, perhaps more than any other genetic resources used by humans, are at, or still very near, their wild state (Muralidharan, 7), which indicates that tremendous improvement can probably be made quite rapidly based on selection among existing genotypes. Muchugi (49) recognized the potential of MAS for tree species improvement, seeing it as a technique best placed to help select and upgrade tropical tree species where the first fruiting may take as long as twenty years.

5.2.2.5 Technical details of MAS use

There were several contributions to the conference regarding technical aspects of MAS and how to use MAS effectively in genetic improvement programmes. Mota (14) raised the issues of molecular markers located far from the target gene, increasing the probability of recombination taking place amongst them, resulting in reduced efficiency of MAS and secondly, of false-positive marker-gene associations. Dulieu (23) also emphasized the importance of tight marker-gene linkage to minimize losses through recombination. Weller (15) acknowledged the importance of both issues raised by Mota (14) and proposed that the best solution to the problem of false-positives is to employ the false-discovery rate, to get an idea of the expected number of false positives. De Koning (16) supported the use of the false-discovery rate and also referred to recent research results suggesting there were benefits in MAS from using a relaxed threshold for QTL detection. Mota (36) concluded that developing countries should only use MAS in their

breeding programmes when there is complete linkage between the marker and the gene of interest, to avoid wasting precious resources. Dulieu (42) commented on this, pointing out the advantages of using flanking markers (i.e. where markers are located on either side of the gene of interest) in MAS.

Singh (44) described the usefulness of MAS in backcrossing programmes, by growing large BC1 populations (BC1 is the first backcross generation), rejecting 50-60 percent based on phenotype (conventional screening) and analysing the remainder with MAS. This could be repeated in the second backcross population, saving considerable time and resources. The usefulness of this approach was confirmed by Dulieu (53) and Sridhar (54) explained how three genes for rice bacterial blight resistance were pyramided into adapted germplasm using MAS in a backcrossing programme.

5.2.2.6 Which traits for MAS?

Referring to crop improvement, Murphy (1) noted that not all crops and traits were amenable to MAS. A perspective from the Netherlands on the type of traits amenable to MAS to date was provided by De Lange (57), who indicated that single gene controlled traits had received most attention, but little progress had been made with multiple gene traits. Makkar (52) stated that many MAS studies had adopted a single trait approach, pointing out that with a multitrait breeding objective, a response for one trait is often made at the expense of another. He also suggested the utility of MAS when heritability for the trait was low. Singh (41) indicated that "breeders are not much thrilled about MAS for simply inherited traits, and not many QTL (especially the productivity related ones) with tightly linked markers are available".

Several other participants mentioned traits that would be amenable to MAS, including Priyadarshan (11) working with rubber trees, Williams (37) who provided the case of root nematodes and William (70) who mentioned work being carried out on barley yellow dwarf virus resistance in cereals, rust diseases, nematode resistance and root health. Rakotonjanahary (78) also suggested that MAS be used when conventional approaches to selection were difficult or impossible. For example, Reddy (62) proposed MAS be used for traits where it is difficult to obtain phenotypic data, like quality traits, and William (70) indicated that protein assays to develop quality protein maize were expensive compared with marker assays. Slaughter traits in livestock were also considered to be amenable to MAS as the desired traits are otherwise difficult to measure without killing the animal (Makkar, 52). Muchugi (49) suggested the potential usefulness of MAS in selecting for medicinal traits and growth rates in tropical trees.

Introgression of genes from wild into cultivated germplasm was proposed to be a good use of MAS (Bhagwat, 46). Notter (25) also commented on the opportunities molecular markers provide for screening populations for animals with favourable or unfavourable genotypes, giving as an example, scrapie in sheep. Krause (75) mentioned other genetic examples, such as a sperm defect in pigs and the halothane gene implicated in low pork quality, that could be screened out using MAS. Sex-linked traits were also mentioned as being suitable for MAS (Makkar, 52).

Galvez (10) suggested that molecular markers could also be useful for work with transgenic crops, for characterizing GM plants and tracking movement of the transgene in the gene pool. William (70) also mentioned the use of MAS for transferring a desirable transgene, such as a gene from *Bacillus thuringiensis*, from one cultivar to another.

In addition to discussing traits considered amenable to MAS, mention was also briefly made of traits not considered amenable to MAS. It was realized that more progress had been

made with single genes, relatively easily transferred, but that there was potential for facilitating QTL transfer, although this was still relatively undeveloped. Traits that are highly influenced by the environment or production system, including crop yield (Priyadarshan, 11), were not considered easily amenable to MAS. Williams (37) pointed out that a major problem associated with MAS was lack of polymorphism at the DNA level, which would render a trait not amenable to MAS. Inadequate coverage of the genetic map with molecular markers was viewed by Dulieu (23) as an obstacle to applying MAS. He also detailed other conditions relating to the nature of the trait that should be considered for MAS to be efficient: single versus multigene, additive versus dominant, expressivity and penetrance.

5.2.2.7 Practical applications of MAS

Some participants considered the actual impact of MAS on genetic products delivered to farmers. Although documentation was limited, the current impact seemed small while the future impact was likely to be far more substantial.

Priyadarshan (11) indicated that biotechnology research had been actively supported for over 17 years in India, but was doubtful about the impact on varieties released to farmers. He believed that research on MAS and other biotechnologies had largely remained in journal articles and it had not significantly boosted conventional plant breeding efforts on the ground. Kirti (12) lamented that there was no comprehensive documentation regarding the successful use of MAS for breeding new crop varieties or developing breeding material, as this information would be important for evaluating the technology. Collard (45), while noting that MAS had been successful in cereal crops in Australia, said he was not aware of many examples of MAS-derived cultivars grown in Australia despite the wealth of publications from Australian institutions on the technology. Sridhar (48) suggested that in India, most products of MAS are still in the hands of research institutions undergoing evaluation. He suggested that MAS products require a "fast track" evaluation system to expedite the release of promising germplasm.

According to Makkar (52), success in demonstrating genetic gain in the laboratory did not always equate with success under field conditions. However, some real successes were reported, including transfer of important resistance genes into adapted rice germplasm for Indian farmers (Sridhar, 35 and 54), indicating that more successes might be in the pipeline. Williams (51) said that molecular markers had been used for at least five years in Australia in some wheat and barley improvement programmes and that "it is likely that in Australia all breeding programs with industry funding and probably also the private breeding companies are currently using MAS to some extent". However, the potential of the new technology has to be weighed against the success achieved using traditional methods. Acikgoz (66) pointed out that the Turkish rice cultivar Tokak was still being sold despite having been released in 1937, and questioned how much impact population genetics studies, popular 20-30 years ago, had had on cultivar development, let alone the impact of biotechnology applications.

Buijs (58) mentioned tissue culture, once regarded as a modern, relatively expensive technology, which is now relatively inexpensive and widely used in developing countries. It will only be known retrospectively whether MAS evolves similarly to become a standard tool of the plant and animal breeder in developing countries.

5.2.2.8 Intellectual property rights (IPR) issues

Some participants felt that IPR were an important constraint to development and uptake of MAS in the developing world. Corva (29) raised the issue of the use of licensed genomic

technology by public institutions in developing countries, mentioning that many useful cattle markers were becoming available, but were patented, and that there was therefore a demand for practical information about IPR and violation of IPR. Weller (30) pointed out that patents are only valid in the country where they are granted, that research tends to be exempt from patent restrictions and that there can be long delays between filing of patent claims and their eventual granting. Saravanan (31) argued strongly for the freedom of researchers to use patented biotechnology tools. Storlie (32) argued that farmers in the developing world should be concerned about being constrained by "corporate patents on particular genes, which may require a company's authorization for possession and use". William (70) noted that development of useful markers for MAS was already a significant challenge in developing countries and felt that if their use was restricted due to IPR "their use would be really limited". Both Williams (51) and Sarla (80) stressed that new genetic information has to be kept as much in the public domain as possible to ensure that there is equal access to it.

Fairbanks (60) described a case demonstrating how some of the limitations imposed by intellectual property issues, including transfer of germplasm across international boundaries, could be overcome, while also avoiding some of the economic obstacles faced by scientists in developing countries. Microsatellite markers for quinoa were being developed at an American university, in a joint programme with a Bolivian foundation, to be then sent to Bolivia for use by Bolivian scientists in their quinoa breeding and conservation programmes.

5.2.2.9 Differences in capacity amongst developing countries

From the conference it was clear that there is enormous diversity in terms of capacity, opportunities and constraints among developing countries that would have a bearing on development and application of MAS. There are substantial differences in factors including the state of public sector research, the involvement of the private sector in research, development and marketing capabilities, perceived priorities for development, the social and agricultural systems of the country, the state of educational systems and the degree to which information and technology remain in the public domain.

Many participants in the conference, including Buijs (22) and Corva (29), commented on developing countries lagging behind developed countries in the uptake of new technologies, and Sokefun (3) expressed concern that a lack of resources should not result in the developing world being by-passed. Davila (81) suggested that developing countries like Brazil, where MAS can be used relatively easily, could help other developing countries with MAS development, through south-south collaboration. Roughly a quarter of messages posted in the conference came from India, and it was apparent that it is another developing country that has invested substantially in MAS, among other biotechnologies. Such are the trends in capacity and infrastructure there that it was indicated that Indian institutions might be able to provide MAS services more cheaply than in developed countries (Muralidharan, 74). This is an important consideration, as Bhatia (8) suggested that breeders should ask whether MAS-related analytical work could be outsourced. Reddy (62) believed that MAS would only be economical in developing countries like India.

5.2.2.10 Role of the CGIAR and international organizations

Collaboration amongst the developing and developed world was inferred to be the only way for the developing world to realistically participate in development of MAS and avail itself of the opportunities it represented (Sokefun, 3; Galvez, 38). Fasoula (84) expressed the need for developing countries to play an active role in developing MAS, particularly in making the associations between markers and traits, although Koudande (68) considered that for economic

reasons developing countries could simply import required technology. Many other participants in the conference voiced the need for international cooperation. One demonstration of the extent to which scientists from developing countries are contributing to research on, and application of, MAS is that many participants in the conference were from developing countries but studying and/or working abroad. Contributions came from national institutions hosting foreign researchers and also from centres of the CGIAR that promote collaborative research and training. Olori (65) pointed out the many ways that developing country individuals and institutions are contributing to development of MAS by participating in international agricultural research. Gianola (24), however, questioned the apparent altruism of developed countries in sponsoring collaborative MAS efforts, fearing that it might hide motives for developing biomedical applications from the results.

Partnerships between CGIAR and national researchers led to some successes in MAS mentioned in the conference. Sridhar (35) reported on the collaboration between an Indian rice research institute and the International Rice Research Institute, and Wallwork (59) on cooperation amongst an Australian institution, the International Center for Agricultural Research in the Dry Areas and the International Maize and Wheat Improvement Center.

There was a strong call from many participants for the CGIAR and international organizations such as FAO to play an active role in the area of MAS development and application. For example, Murphy (1) suggested that the CGIAR and FAO should facilitate international collaboration in this area. Priyadarshan (11) suggested that the CGIAR might manage a centralized facility for routinely carrying out MAS. Acikoz (66) envisaged a role for FAO in addressing issues of classical plant breeding at regional and national level, which he saw as being more of a priority than MAS, while Muralidharan (74) thought FAO to be suited to playing the role of coordinator for MAS research among laboratories working on the same crop. Rakotonjanahary (78) proposed a similar role for CGIAR and FAO as facilitators in the exchange of information and genetic material obtained from MAS. Sarla (80) suggested that FAO could play a catalytic role in marker-aided allele mining and facilitate capacity building for applying MAS, especially to crops of regional importance.

5.2.2.11 Public-private sector linkages

Various additional constraints to using MAS in plant and animal improvement programmes in developing countries were discussed in the conference. Notter (25) stated that the history of public funding in developing countries was not good and Fairbanks (60) commented that agricultural research in developing countries was not well coordinated. Australia has invested heavily in MAS in its breeding programmes, but as pointed out by Collard (45) regarding plant breeding, the major target crops have been cereals produced for export. Moreover, there has been considerable support from private industry to research and development of MAS. For example, the Grains Research and Development Corporation (GRDC) of Australia was set up to serve farmers and is maintained through a levy collected from them. In contrast, in the developing world, the most important crops are usually produced for subsistence and there is often little private-public cooperation (Murphy, 1). Developing country farmers are unlikely to be able to support the activities of a dedicated research and development organization equivalent to the GRDC (Collard, 45). Similarly, Notter (25) pointed out that there was a scarcity of private animal breeding initiatives in developing countries and little or no commercial sector. MAS, in his opinion, would not change this situation. Nicol (19) highlighted the importance of extension agencies in assisting uptake of commercially available DNA marker tests.

Koudande (68) noted that in developed countries, most of the applied MAS in breeding is undertaken by companies, and wondered which companies in Africa would be wealthy enough to support MAS development and application. An additional factor is that MAS requires that molecular markers are available for particular crops and important traits, but most of the publicly available markers are for the major crops (Collard, 9), which are not necessarily of primary importance in developing countries. Some crops are also very region-specific, such as black gram mentioned by Gopalakrishna (72), and are unlikely to be the target of research leading to the development of MAS technologies. There seemed to be general support for a collaborative approach to MAS research and application, including public-private sector linkages, which would represent the best opportunity to facilitate development of, and access to, MAS in developing countries. Unfortunately, private sector contributions to this e-mail conference were limited and the discussion would have benefited from more of them.

5.2.3 Participation

The conference ran for four weeks, from 17 November to 14 December 2003, and 627 people subscribed, the highest number for any of the Biotechnology Forum conferences held so far. Of the 627 people, 52 (8 percent) submitted at least one message. Messages were received from all over the world, 28 of the 85 messages (33 percent) were posted from Asia, 26 percent from Europe, 14 percent from Latin America and the Caribbean, 9 percent each from Africa and Oceania and 8 percent from North America.

Messages were posted from people living in 26 different countries, the largest proportion was from India (25 percent), followed by Australia (9 percent), United States (8 percent), United Kingdom (7 percent) and Peru (6 percent). Fifty messages (59 percent) were contributed from people in developing countries and 35 (41 percent) in developed countries. The majority of messages came from people working in research centres (52 percent), including CGIAR centres, and in universities (37 percent). The remainder worked as consultants, for farmer organizations, government agencies, NGOs or UN organizations.

The figures for relative contributions from the developing versus developed world and from different regions of the world are only approximate as people from developing countries live and work in developed countries and vice versa. Similarly, results on participants' workplaces are only approximate as people may have several concurrent duties.

5.2.4 Name and country of participants with referenced messages

Acikgoz, Nazimi. Turkey
Badr, Aisha. Egypt
Bhagwat, Anjali. India
Bhatia, C.R. India
Buijs, Jasper. Peru
Chavez, Juan. Peru
Collard, Bert. Australia
Corva, Pablo. Argentina
Davila, Alberto. Brazil
De Koning, Dirk-Jan. United Kingdom
De Lange, Wytze. The Netherlands
Dulieu, H.L. France
El Ouafi, Ismahane. Syria
Fairbanks, Daniel. United States

Fasoula, Dionysia. Cyprus
Galvez, Hayde. The Philippines
Ganunga, Rosan. United States
Gianola, Daniel. United States
Gopalakrishna, T. India
Kirti, P.B. India
Koudande, Delphin. Benin
Krause, Antti. Finland
Makkar, Harinder. Austria
Martinez, Victor. Chile
Montaldo, Hugo. Mexico
Mota, Adilson. Brazil
Muchugi, Alice. Kenya
Muralidharan, E.M. India
Murphy, Denis. United Kingdom
Nicol, Don. Australia
Notter, David. United States
Olori, Victor. Ireland
Priyadarshan, P.M. India
Rakotonjanahary, Xavier. Madagascar
Reddy, V.L.N. India
Saravanan, S. India
Sarla, N. India
Seth, Ashok. United Kingdom
Simons, Tony. Kenya
Singh, Kuldeep. India
Sokefun, Olusola. Nigeria
Sridhar, R. India
Storlie, Eric. Australia
Toro, Miguel. Spain
Varshney, Rajeev. India
Wallwork, Hugh. Australia
Weller, Joel. Israel
William, Manilal. Mexico
Williams, Kevin. Australia

CHAPTER 6.
BIOTECHNOLOGY APPLICATIONS IN FOOD PROCESSING: CAN DEVELOPING COUNTRIES BENEFIT?

6.1 BACKGROUND DOCUMENT

6.1.1 Introduction

Biotechnology includes a wide range of diverse technologies and they may be applied in each of the different food and agriculture sectors. It includes technologies such as gene modification (manipulation) and transfer; the use of molecular markers; development of recombinant vaccines and DNA-based methods of disease characterization/diagnosis; *in vitro* vegetative propagation of plants; embryo transfer and other reproductive technologies in animals or triploidization in fish. It also includes a range of technologies used to process the raw food materials produced by the crop, fishery and livestock sectors. This is the area that will be considered in this conference, the 11th one to be hosted by the FAO Biotechnology Forum since it was launched in March 2000. It is an area that receives relatively little attention from the media, but which is very important for food security in many developing countries.

Biotechnology in the food processing sector targets the selection and improvement of micro-organisms with the objectives of improving process control, yields and efficiency as well as the quality, safety and consistency of bioprocessed products. Micro-organisms or microbes are generic terms for the group of living organisms which are microscopic in size and include bacteria, yeasts and moulds.

Fermentation is the process of bioconversion of organic substances by micro-organisms and/or enzymes (complex proteins) of microbial, plant or animal origin. It is one of the oldest forms of food preservation which is applied globally. Indigenous fermented foods such as bread, cheese and wine, have been prepared and consumed for thousands of years and are strongly linked to culture and tradition, especially in rural households and village communities. It is estimated that fermented foods contribute to about one-third of the diet worldwide.

During fermentation processes, microbial growth and metabolism (the biochemical processes whereby complex substances and food are broken down into simple substances) result in the production of a diversity of metabolites (products of the metabolism of these complex substances). These metabolites include enzymes which are capable of breaking down carbohydrates, proteins and lipids present within the substrate and/or fermentation medium; vitamins; antimicrobial compounds (e.g. bacteriocins and lysozyme); texture-forming agents (e.g. xanthan gum); amino acids; organic acids (e.g. citric acid, lactic acid) and flavour compounds (e.g. esters and aldehydes). Many of these microbial metabolites (e.g. flavour compounds, amino acids, organic acids, enzymes, xanthan gums, alcohol, etc.) are produced at the industrial level in both developed and developing countries for use in food processing applications. A considerable volume of current research both in academia and industry targets the application of microbial biotechnology to improve the production, quality and yields of these metabolites.

Fermentation is globally applied in the preservation of a range of raw agricultural materials (cereals, roots, tubers, fruit and vegetables, milk, meat and fish, etc.). Commercially produced fermented foods which are marketed globally include dairy products (cheese, yogurt,

fermented milks), sausages and soy sauce. Certain micro-organisms associated with fermented foods, in particular strains of the *Lactobacillus* species, are probiotic i.e. used as live microbial dietary supplements or food ingredients that have a beneficial effect on the host by influencing the composition and/or metabolic activity of the flora of the gastrointestinal tract. Probiotic bacterial strains are also produced and commercially marketed in many developed countries.

In developing countries, fermented foods are produced primarily at the household and village level, where they find wide consumer acceptance. Food fermentations contribute substantially to food safety and food security, particularly in the rural areas of many developing countries. Traditional fermentation processes used in the production of these foods are uncontrolled and are dependent on micro-organisms from the environment or the fermentation substrate for initiation of the fermentation processes. Such processes, therefore, result in products of low yield and variable quality. Micro-organisms and metabolic pathways associated with the production of fermented foods are the subject of considerable research, targeting strain isolation and identification; improvement of the efficiency of fermentation processes and the quality, safety and consistency of fermented foods. Much of this research incorporates the use of genetic technologies for strain development and improvement, and for diagnostic studies.

While micro-organisms are beneficial in most fermentation processes, some may pose the risk of food contamination and can cause food-borne illness. Diagnostic methodologies which integrate the use of molecular genetic techniques, enhance the speed and sensitivity of microbial testing and are increasingly being applied in developing countries.

In conferences hosted by the FAO Biotechnology Forum, clearly defined topics of relevance to agricultural biotechnology in developing countries are discussed for a limited amount of time. The topic here is the application of biotechnology to the processing of food (including beverages) produced from agriculture. This e-mail conference discusses biotechnological tools and options that are applicable to the study and improvement of micro-organisms which offer potential for improving the quality, safety and consistency of fermented foods; improving efficiency in the production of fermented foods, food ingredients, food additives and food processing aids (enzymes); diversifying the outputs of fermentation processes and finally, improving diagnostic and identification systems applicable to foods. Applications of biotechnology to plants or animals to improve their food processing properties (e.g. development of the Flavr Savr tomato variety, genetically modified to reduce its ripening rate) or to produce proteins from genetically modified (GM) micro-organisms to improve plant or animal production (e.g. production of bovine somatotropin [BST], a hormone increasing milk production in dairy cows, by GM bacteria) are not considered here. Finally, the conference topic covers applications of biotechnology to processing of food and not to processing of non-food agricultural products (e.g. timber) or to applying biotechnology to micro-organisms for environmental purposes (bioremediation and biofuels, etc.).

6.1.2 Current status of biotechnology in food processing

6.1.2.1 Biotechnology in food fermentation

Micro-organisms are an integral part of the processing system during the production of fermented foods. Microbial cultures can be genetically improved using both traditional and molecular approaches, and improvement of bacteria, yeasts and moulds is the subject of much academic and industrial research. Traits which have been considered for commercial food applications in both developed and developing countries include sensory quality (flavour, aroma, visual appearance, texture and consistency), virus (bacteriophage) resistance in the case of dairy

fermentations and the ability to produce antimicrobial compounds (e.g. bacteriocins, hydrogen peroxide) for the inhibition of undesirable micro-organisms. In many developing countries, the focus is on the degradation or inactivation of natural toxins (e.g. cyanogenic glucosides in cassava), mycotoxins (in cereal fermentations) and anti-nutritional factors (e.g. phytates).

a) Traditional approaches

Traditional methods of genetic improvement such as classical mutagenesis and conjugation have been the basis of industrial starter culture development in bacteria (a culture used to start a food fermentation is known as a starter culture), while hybridization has been used in the improvement of yeast strains which are widely applied industrially in baking and brewing applications.

i) Classical mutagenesis

This involves the production of mutants by the exposure of microbial strains to mutagenic chemicals or ultraviolet rays to induce changes in their genomes. Improved strains thus produced are selected on the basis of specific properties such as improved flavour-producing ability or resistance to bacterial viruses. Such mutants may, however, show undesirable secondary mutations which can influence the behaviour of cultures during fermentation.

ii) Conjugation

This is a natural process whereby genetic material is transferred among closely related microbial species as a result of physical contact between the donor and the recipient micro-organism. Conjugational gene exchange allows both plasmid-localized and chromosomal gene transfer (a plasmid is a circular self-replicating non-chromosomal DNA molecule found in many bacteria, capable of transfer amongst bacterial cells of the same species, and occasionally of different species).

iii) Hybridization (i.e. sexual breeding or mating)

Sexual reproduction in yeasts and thus genetic recombination, has led to improvements in yeasts. For example, crossing of haploid yeast strains with excellent gassing properties and with good drying properties could yield a novel strain with both good gassing and drying properties.

b) Molecular approaches

i) Genetic modification

Recombinant DNA approaches have been used for genetic modification of bacterial, yeast and mould strains to promote expression of desirable genes, to hinder the expression of others, to alter specific genes or to inactivate genes so as to block specific pathways. The successful application of genetic modification for food bioprocessing applications requires the development and use of food grade vectors, i.e. plasmids which do not contain antibiotic resistance genes as markers and which consist of DNA sequences from micro-organisms which are generally recognized as safe (GRAS).

GM yeasts appropriate for brewing and baking applications have been approved for use (e.g. approval was granted in the United Kingdom for use of a GM yeast [*Saccharomyces cerevisiae]* in beer production, containing a transferred gene from the closely related

Saccharomyces diastaticus, allowing it to better utilize the carbohydrate present in conventional feedstocks). None of these GM yeasts is however, used commercially.

ii) Genetic characterization

The genetic characterization of microbial strains through the use of molecular diagnostic techniques can contribute tremendously to the understanding of fermentation processes. Molecular diagnostics provide outstanding tools for the detection, identification and characterization of microbial strains for bioprocessing applications and for the improvement of fermentation processes. The application of these and other related techniques, together with the development of molecular markers for bacterial strains, greatly facilitates understanding of the ecological interactions of microbial strains, their roles, succession, competition and prevalence in food fermentations and allows the correlation of these features to desirable quality attributes of the final product.

iii) Genomics

In recent years, the genome sequences of many food-related micro-organisms have been completed (e.g. *Saccharomyces cerevisiae,* commonly known as baker's or brewer's yeast, was the first eucaryote to have its genome sequenced, in 1996) and large numbers of microbial genome sequencing projects are also underway (see for example, www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=Genome for an update). Functional genomics, a relatively new area of research, aims to determine patterns of gene expression and interaction in the genome, based on the knowledge of extensive or complete genomic sequence of an organism. It can provide an understanding of how micro-organisms respond to environmental influences at the genetic level (i.e. by expressing specific genes) in different situations or ecologies, and should therefore allow adaptation of conditions to improve technological processes. For a range of micro-organisms, it is now possible to observe the expression of many genes simultaneously, even those with unknown biological functions, as they are switched on and off during normal development or while an organism attempts to cope with pathogens or changing environmental conditions. For example, a recent paper by Cooper *et al.* (2003) describes their use of DNA macroarrays to analyse expression of all 4 290 genes of the model bacterium *Escherichia coli* after 20 000 generations of evolution in a glucose-limited medium. Functional genomics can, for example, shed light on common genetic mechanisms which enable micro-organisms to use certain sugars during fermentation, as well as on genetic differences allowing some strains to perform better than others. It holds great potential for defining and modifying elusive metabolic mechanisms used by micro-organisms. Moving from the gene to the protein level, it should also be mentioned that proteomics, an approach aiming to identify and characterize complete sets of protein, and protein-protein interactions in a given species, is also a very active area of research which offers potential for improving fermentation technologies.

6.1.2.2 Biotechnology in the production of enzymes

Enzymes are biological catalysts used to facilitate and speed up metabolic reactions in living organisms. They are proteins and require a specific substrate on which to work. Their catalysing conditions are set within narrow limits, e.g. optimum temperature, pH conditions and oxygen concentration. Most enzymes are denatured at temperatures above 42°C. However, certain bacterial enzymes are tolerant to a broader temperature range. Enzymes are essential in the metabolism of all living organisms and are widely applied as processing aids in the food and beverage industry.

In the past, enzymes were isolated primarily from plant and animal sources, and thus a relatively limited number of enzymes were available to the food processor at a high cost. Today, bacteria and fungi are exploited and used for the commercial production of a diversity of enzymes. Several strains of micro-organisms have been selected or genetically modified to increase the efficiency with which they produce enzymes. In most cases, the modified genes are of microbial origin, although they may also come from different kingdoms. For example, the DNA coding for chymosin, an enzyme found in the stomach of calves, that causes milk to curdle during the production of cheese, has been successfully cloned into yeasts (*Kluyveromyces lactis*), bacteria (*Escherichia coli*) and moulds (*Aspergillus niger* var. *awamori*). Chymosin produced by these recombinant micro-organisms is currently commercially produced and is widely used in cheese manufacturing.

The industrial production of enzymes from micro-organisms involves culturing the micro-organisms in huge tanks where enzymes are secreted into the fermentation medium as metabolites of microbial activity. Enzymes thus produced are extracted, purified and used as processing aids in the food industry and for other applications. Purified enzymes are cell free entities and do not contain any other macromolecules such as DNA.

Genetic technologies have not only improved the efficiency with which enzymes can be produced, but they have increased their availability, reduced their cost and improved their quality. This has had the beneficial impact of increasing efficiency and streamlining processes which employ the use of enzymes as processing aids in the food industry.

In addition, through protein engineering, it is possible to generate novel enzymes with modified structures that confer novel desired properties, such as improved activity or thermostability or the ability to work on a new substrate or at a higher pH. Directed evolution is one of the main methods currently used for protein engineering. This technique involves creating large numbers of new enzyme variants by random genetic mutation and subsequently screening them to identify the improved variants. This process is carried out repeatedly, thus mimicking natural evolution processes.

6.1.2.3 Biotechnology in the production of food ingredients

As described in the Introduction, flavouring agents, organic acids, food additives and amino acids are all metabolites of micro-organisms during fermentation processes. Microbial fermentation processes are therefore commercially exploited for production of these food ingredients. Metabolic engineering, a new approach involving the targeted and purposeful manipulation of the metabolic pathways of an organism, is being widely researched to improve the quality and yields of these food ingredients. It typically involves alteration of cellular activities by the manipulation of the enzymatic, transport and regulatory functions of the cell using recombinant DNA and other genetic techniques. Understanding the metabolic pathways associated with these fermentation processes, and the ability to redirect metabolic pathways, can increase production of these metabolites and lead to production of novel metabolites and a diversified product base.

6.1.2.4 Biotechnology in diagnostics for food testing

Many of the classical food microbiological methods used in the past were culture-based, with micro-organisms grown on agar plates and detected through biochemical identification. These methods are often tedious, labour-intensive and slow. Genetic based diagnostic and identification systems can greatly enhance the specificity, sensitivity and speed of microbial

testing. Molecular typing methodologies, commonly involving the polymerase chain reaction (PCR), ribotyping (a method to determine homologies and differences between bacteria at the species or subspecies [strain] level, using restriction fragment length polymorphism [RFLP] analysis of ribosomal ribonucleic acids [rRNA] genes) and pulsed-field gel electrophoresis (PFGE, a method of separating large DNA molecules that can be used for typing microbial strains), can be used to characterize and monitor the presence of spoilage flora (microbes causing food to become unfit for eating), normal flora and microflora in foods. Random amplified polymorphic DNA (RAPD) or amplified fragment length polymorphism (AFLP) molecular marker systems can also be used for the comparison of genetic differences amongst species, subspecies and strains, depending on the reaction conditions used. The use of combinations of these technologies and other genetic tests allows the characterization and identification of organisms at the genus, species, subspecies and even strain levels, thereby making it possible to pinpoint sources of food contamination, to trace micro-organisms throughout the food chain or to identify the causal agents of food-borne illnesses. Monoclonal and polyclonal antibodies can also be used for diagnostics, e.g. in enzyme-linked immunosorbent assay (ELISA) kits.

Microarrays are biosensors which consist of large numbers of parallel hybrid receptors (DNA, proteins, oligonucleotides). Microarrays are also referred to as biochip, DNA chip, DNA microarray or gene arrays and offer unprecedented opportunities and approaches to diagnostic and detection methods. They can be used for the detection of pathogens, pesticides and toxins and offer considerable potential for facilitating process control, the control of fermentation processes and monitoring the quality and safety of raw materials.

6.1.3 Some issues relevant to developing countries

This conference deals with the application of biotechnology to food processing in developing countries. Biotechnological research as applied to bioprocessing in the majority of developing countries, targets development and improvement of traditional fermentation processes. In this section, some areas specifically relevant to developing countries are considered and some key issues that should be discussed are listed.

6.1.3.1 Socio-economic and cultural factors

Traditional fermentation processes employed in most developing countries are low input, appropriate food processing technologies with minimal investment requirements. They make use of locally produced raw materials and are an integral part of village life. These processes are, however, often uncontrolled, unhygienic and inefficient and generally result in products of variable quality and short shelf lives. Fermented foods, nevertheless, find wide consumer acceptance in developing countries and contribute substantially to food security and nutrition.

- How will applications of biotechnology to fermented foods impact on these socio-economic and cultural factors?

6.1.3.2 Infrastructural and logistical factors

Physical infrastructural requirements for the manufacture, distribution and storage (e.g. by refrigeration) of microbial cultures or enzymes on a continuous basis is generally available in urban areas of many developing countries. However, this is not the case in most rural areas of developing countries.

- Should research be oriented to ensure that individuals at all levels can benefit from applications of biotechnology in food fermentation processes, i.e. should logistical arrangements for starter culture development be integrated into biotechnological research targeting improvement of traditional fermentations? What is required for the level of fermentation technologies and process controls to be upgraded in order to increase efficiency, yields and the quality and safety of fermented foods in developing countries?

6.1.3.3 Nutrition and food safety

Fermentation processes enhance the nutritional value of foods through the biosynthesis of vitamins, essential amino acids and proteins, through improving protein and fibre digestibility; enhancing micronutrient bioavailability and degrading antinutritional factors. Many bacteria in fermented foods also exhibit functional properties (probiotics).

The safety of fermented food products is enhanced through reduction of toxic compounds, such as mycotoxins and cyanogenic glucosides, and production of antimicrobial factors, such as bacteriocins, carbon dioxide, hydrogen peroxide and ethanol, which facilitate inhibition or elimination of food-borne pathogens.

- Are the nutritional characteristics (and safety aspects) of fermented foods adequately documented and appreciated in developing countries? Is there a need for consumer education on the benefits of fermented foods?

6.1.3.4 Intellectual property rights (IPR)

The processes used in the more advanced areas of agricultural biotechnology tend to be covered by IPR and these rights tend to be owned by parties in developed countries. This applies also to biotechnology processes used in food processing. On the other hand, many of the traditional fermentation processes applied in developing countries are based on traditional knowledge.

In addition to biotechnology processes, microbial strains may also be the object of IPR. For example, an era of massive private investment in biotechnology was initiated when the United States Supreme Court ruled in 1980 (in the Diamond versus Chakrabarty case) that a live GM bacterium (of the genus *Pseudomonas*, modified to degrade components of crude oil) could be patented. Many of the micro-organisms associated with traditional fermentation processes in developing countries are unique. Issues of ownership will become increasingly important as bacterial strains are characterized and starter cultures are developed in developing countries.

- How should food scientists, researchers, industry and governments in developing countries approach these issues?
- A considerable volume of research into the development and improvement of fermentation processes is currently taking place worldwide. Are the research results from developing countries adequately documented? Who owns this information? Are cell banks being developed to protect microbial strains characterized in developing countries?

6.1.3.5 Commercial opportunities

Biotechnological innovations have greatly assisted in industrializing production of certain indigenous fermented foods. Indonesian tempe and Oriental soy sauce are well known examples of indigenous fermented foods that have been industrialized and marketed globally. The results of biotechnology research will lead to fermented foods of improved quality, safety and consistency.

- Should biotechnology developments in developing countries target commercialization? Should they target diversification into new value-added products? Should biotechnology development be linked to technological developments in food processing?
- Can the application of biotechnology to food processing allow farmers in developing countries to add value to their agricultural products (for export or for local consumption) and improve their revenues?

6.1.3.6 Appropriateness of food processing biotechnology in developing countries

As with any commitment of resources, investments in biotechnology for food processing should be weighed up against other potential uses of these resources in developing countries.

- How relevant and worthwhile can such investments be for developing countries?

6.1.4 References

Cooper, T.F., Rozen, D.E. & Lenski, R.E. 2003. Parallel changes in gene expression after 20 000 generations of evolution in Escherichia coli. *Proc. Natl. Acad. Sci.*100(3): 1072–1077. (also available at www.pnas.org/cgi/content/full/100/3/1072).

6.2 SUMMARY DOCUMENT

Executive summary

Biotechnology in food processing includes numerous traditional methods for making fermented foods and beverages such as bread, cheese, yogurt and wine. Many fermented food products are integral, nutritious components of diets around the globe and also generate income. A wealth of information was contributed to this conference on traditional fermented foods and beverages, particularly from West Africa and India. The importance of documenting this information was highlighted and it was noted that considerable work remains to be carried out in the documentation, characterization and basic research of these traditional products and processes. The issues of control and variable quality of traditional fermentation processes were raised, and the use of well designed starter cultures was recommended. There was discussion of the merits and demerits of scaling up production processes through increased commercialization and industrialization. Potential loss of important food characteristics through standardization of production processes was also addressed. It was suggested that there was potential for small-scale rural-based commercialization that would build local capacity and ensure that the benefits from increased production were retained by the local communities in developing countries. It was recognized that modern biotechnologies, such as use of molecular typing to characterize micro-organisms, could be successfully applied to traditional fermentation processes to improve understanding of these processes and improve product quality and consistency. However, potentially useful biotechnologies require adequate funds and education to be used effectively. There is a need for capacity building and to better integrate biotechnology in the food science and technology curricula of higher institutes of learning in developing countries. These were some of the main issues and outcomes of a moderated e-mail conference, entitled "Biotechnology applications in food processing: can developing countries benefit?" hosted by the FAO Biotechnology Forum from 14 June to 15 July 2004. Over 400 people subscribed to the conference and 68 messages were posted by 38 participants from 19 countries, with over 70 percent of the messages coming from people living in developing countries.

6.2.1 Introduction

Although the conference topic was relatively specialized, there was a surprisingly large number of subscribers (411). Over the course of the conference, 68 messages were received from 37 participants, numbered in the order of posting. Specific references to posted messages are included, with an indication of the participants' names and message number. The individual messages can be consulted at www.fao.org/biotech/logs/c11logs.htm.

The number of potential areas where biotechnology can be applied to food processing is quite large. This was highlighted in the Background Document and also by Krishna (12), who provided an extensive list of such areas, most of which were discussed in the conference, including food preservation; isolation, identification and improvement of strains of food fermenting micro-organisms; malolactic fermentation (for production of wines); lactic acid fermentation (milk products); preparation of food flavours; supply and maintenance of starter cultures; and exploitation of antioxidants, prebiotics and probiotics and production of single cell proteins.

The main themes of the discussions are given in Section 6.2.2 of this document under eight headings. Participation is summarized in Section 6.2.3, and Section 6.2.4 provides a list of the participants, with their country of work, who sent messages that are referenced here.

6.2.2 Main themes discussed

6.2.2.1 The importance and diversity of fermented products

The conference highlighted the important contribution of fermented products to diets throughout the world, but particularly to those in developing countries. A diversity of products was described and discussed. Oyewole (4) drew attention to the importance of fermented foodstuffs in African diets, providing extensive details on a range of fermented foods and beverages across the entire continent. Fall (36) indicated that in some parts of West Africa, a fermented cereal-based gruel might be the first solid food a child eats. Muralidharan (6) described some traditional fermented breakfast foods in India (idli, dosa and appam), all made with rice flour as the main ingredient, pointing out that many of the fermented, steam-cooked foods are nutritious and recommended as part of the diet of convalescents. Hofman (5) furnished some information on traditional fermentation in Europe and Mathooko (9) provided details on fermented milk produced in East Africa. Wacher (59) suggested that the traditional fermented foods of Mexico, mostly based on maize, have been less well studied in comparison with those of other countries. Nuñez (31) reported that Peru also had many tasty and nutritious, traditional fermented foods and drinks. Sharma (24) described the use of some traditional fermentation methods in Bangladesh and India, such as those used for fermenting fish (iromba) and bamboo shoots. One advantage of such methods, he suggested, was that they increased the amount of food, by reducing wastage, and secondly, by making it possible to eat products which, if unprocessed, would not normally be suitable for human consumption.

Some fermented food products of regional importance were described. There are differences in production methods using the same plant species within a region that reflect the importance of local requirements and tastes. Sasu (27) suggested that for agbelima, a cassava dough used in Ghana, every family of cassava processors uses a different method to enhance features such as texture, taste and acceptability and that these methods were passed down from generation to generation. The features of gari, a fermented cassava product, were reported by Sasu (54) to depend on cassava variety and length of fermentation. Uzochukwu (40) and Edema (52) also described some of the different procedures used to make different kinds of gari, to suit individual and regional preferences. Hounhouigan (18) explained that in West Africa the same food product could also have different names in different villages, regions or countries, and suggested that the passage of traditional knowledge through generations was no longer as sure as before. Muralidharan (6) indicated that some traditional Indian breakfast foods tasted differently now that modern housewives used baker's yeast for the pancake batter rather than allowing natural fermentation to take place overnight. These examples illustrate the very particular character of many traditional food production processes, and indicate the difficulties that might be involved in scaling-up processes for an expanded market while attempting to maintain key characteristics of the product. In short, the attraction of many fermented food products for the consumer is that they have organoleptic characteristics unique to a process and producer.

6.2.2.2 Control and variable quality of traditional fermentation

A range of opinions existed as to whether traditional fermentations were controlled or not and the importance of developing well selected starter cultures was emphasized. Wuerthele (2) noted that the Background Document reported that traditional fermentation processes are uncontrolled and are dependent on micro-organisms from the environment or the fermentation substrate for initiation of the fermentation processes and that such processes, therefore, result in products of low yield and variable quality. Edema (52) noted that what is sometimes referred to

as variability in quality is actually a consequence of using different processes to suit individual preferences. Ouoba (10) highlighted the problem of variability in stability and nutritional quality of traditional fermented food. She proposed that the use of well selected starter cultures could help to solve the problem, citing the successful example of *Bacillus subtilis* starter cultures in Burkina Faso for soumbala, a fermented product from the African locust bean tree. These starters differed in type according to the proteolytic, lipolytic, saccharolytic and antimicrobial properties of the component *Bacillus* isolates. Consequently, the soumbala produced differed in character, depending on the starter, but had quite a high stability and nutritional quality. Gendel (64) also argued that use of well designed starter cultures would improve the consistency of fermented products as it would reduce one of the major sources of variability.

Hounhouigan (3) reported that many local fermentation processes relied on locally produced, and at times, imported starters, noting that "small scale traditional food producers know the efficiency of the use of starters and where it is possible, know how to develop and keep their own starter". This indicated an element of control over the fermentation reactions, although as Edema (30) wrote, attempts at using starter cultures for locally fermented foods usually resulted in a product with different properties, particularly their sensory attributes. Bhushan (11) saw an element of control in traditional fermentations and this view was echoed by Hofman (5), who reported that traditional processes did not necessarily result in products of low yield and variable quality. He suggested that well-adapted starters were able to provide strong process control, be it in a low technology environment of developing countries or a more sophisticated environment of developed countries. To support his remarks, he cited some examples including Asian fermented foods, based on solid fermentation technology with little or no control strategies, and Belgian gueuze beer, where spontaneous fermentation has resulted in a successful product since the Middle Ages. Hounhouigan (3), supported by Hofman (8), underlined the need to investigate the characteristics of some starters commonly used for some widely produced foods in Africa. Participants also noted the importance of developing starter cultures for scaling up production of traditional fermented foods (e.g. Oguntoyinbo, 58).

6.2.2.3 Documenting information about traditional fermented food

Throughout the conference, the importance of documenting information about traditional fermentation food and processes was highlighted (e.g. Krishna, 51). The need for further research into traditional fermented foods was also mentioned several times. Many foods and processes, it was suggested, were not sufficiently well characterized and modern methods of analysis, including biotechnological tools, could assist in this. For example, Edema (32) argued that not enough studies on the traditional fermentation processes had been carried out and that "detailed studies on these foods, their fermentation processes, the organisms involved and proper identification of the nutritional, organoleptic and aroma characteristics of the products are needed to form a strong scientific database for these foods". Hofman (61), supported by Bhushan (62), suggested that globalization might displace much of the traditional foods and that there was an "urgent need for research, data collection and information distribution. The creation of regional data bases and culture collections has been proposed". Seth (66) saw an important role for international organizations, like FAO and the World Bank, to enable national, regional and international cooperation in areas such as this. Blanchfield (38) provided some details on a new food science and technology research project database created by FAO and the International Union of Food Science and Technology.

6.2.2.4 Scaling up production of traditional fermented foods

One of the main issues debated during the conference concerned the practicality and desirability of scaling up traditional processes of producing fermented foods. A distinction was made between commercialization of food production, whereby small-scale producers might supply their products to expanded markets, and industrialization of food production, representing a highly capital- and labour-intensive transformation of production processes. It was indicated that there could be many markets for fermented food products from several countries and that these markets could be national, regional or international.

Hofman (7, 49) questioned the desirability of industrialization of the African food industry, mentioned by Oyewole (4), and was of the opinion that improved commercialization of food production in the developing world represented a better option, as suggested by Olang'o (46). Hofman (49) pointed out that in the developed world, only 5 percent of the consumer price of food goes to the primary producer and suggested that industrialization would be a bad choice in areas where a large proportion of the population earns its living from primary food production. Olang'o (46) considered that development of small-scale rural-based processing industries would help in developing countries, especially given that fermented food production generally did not require substantial capital investment. Krishna (50) also believed that promotion of village industries would improve employment and income prospects. Otieno (56) agreed with Olang'o (46) and suggested that "by introduction of simple biotechnology techniques, skills, equipment and technologies into the rural areas, this could form the beginnings of agriculture-led industrial development in Africa". Punchihewa (23) was more cautious about the potential benefits of moving applications of biotechnology from a non-commercial village setting to a commercial one. Muralidharan (6) stressed the need to evaluate the effects and benefits of scaling up production of traditional food preparations on their nutritive value, on traditional cuisine and on the community of small restaurateurs.

Rolle (55) and Mayer (57) emphasized the importance of taking an integrated approach to development of traditional fermentation processes, including raw material preparation, fermentation monitoring/control and product recovery. Owusu-Biney (67) suggested that Africans living in America and Europe represented a potentially lucrative market for fermented African foods, concluding "I believe there are commercial opportunities and there is the need for fermentation scientists and biotechnologists to engage industry in developing starter cultures for specific fermented foods which can be upstreamed for mass production and export of dry starter cultures". Muralidharan (6) also suggested that there was a large market for ready-to-eat commercially produced traditionally fermented Indian foods in India and elsewhere in the world.

Nishio (20) pointed out that commercial producers e.g. bread makers, would want to preserve their starters in the interests of maintaining the particular properties of their products. Regarding palm wine, Edema (30) acknowledged that the bottled and pasteurized product had a longer shelf-life than the fresh product, but the taste was not as good as when the yeasts were alive and active. The same occurred, she suggested, when extending the shelf-life of uncooked fufu paste by drying it into powder. Edema (30, 52) proposed that biotechnology applications might be best focused on new products rather than traditional ones, as biotechnology might alter the accepted taste and flavour of traditional products. Edema (30) considered it difficult to upgrade existing fermentation technologies in countries where infrastructure and services were not optimal. Krishna (51) emphasized the importance of infrastructure, in particular the provision of regular and sufficient power and water supply, for exploiting the benefits of food processing technologies. Mathooko (9) also suggested that, although food biotechnology has been used for a long time in the East African region, it might require a change of image (as well as the

availability of funds) to make a commercial breakthrough in the region. This was supported by Krishna (51), who argued that the "documentation of the benefits of fermentation and fermented products are not well disseminated. Awareness creation, capacity building, training and establishment of food processing units might help in popularizing these technologies".

Oyewole (14) noted that in Burkina Faso, in addition to developing starter cultures for soumbala production, there had been improvements in traditional processing machineries and packaging of the product. These developments were aimed at small-scale producers and served to indicate how applied biotechnology could help such producers. Local knowledge of the fermentation processes is very important, but is not always taken into account when commercial production begins. In Kenya, the Maasai and Kalenjin have traditionally made sour milk, according to Mathooko (9), but Muchugi (16) noted that the fast growing Kenyan yogurt industry had not tapped into this indigenous knowledge, but instead had imported a lot of its starters.

6.2.2.5 Appropriateness of individual biotechnologies

The wide range of biotechnology tools that can be used in food processing was briefly summarized in the Background Document and some participants discussed the appropriateness of individual biotechnologies and their particular advantages and disadvantages when applied to food processing.

Early in the conference, Wuerthele (2) raised the issue of whether, and in which situations, genetically modified (GM) micro-organisms might be beneficial in food processing, suggesting it would be useful to discuss the potential environmental, human health and socio-economic effects of use of commercial GM strains. Oyewole (4) pointed out that to date there had been little effort made to apply GM micro-organisms for the production of African fermented foods, though their use was desirable. Uzochukwu (41), supported by Okoli (44), suggested that genetic modification of yeast could solve an important problem related to production of palm wine and that the current barriers to carrying out such work were lack of funding (for expensive reagents and equipment) and lack of adequate awareness by scientists of the potential of modern methods. Edema (32) felt, however, that at least as far as Nigeria was concerned, it was too early for GMOs as more studies on the traditional fermentation processes were needed.

Hofman (5) indicated that GMOs would extend the range of available micro-organisms for selection for particular processes but, because many successful fermentation processes involve mixed culture, he was unsure whether incorporating GMOs would increase efficiency. Nishio (19) envisaged a useful role for GMOs in fermentation processes, specifically to develop micro-organisms more adapted to different environmental conditions (temperature, pH, concentrations of inhibitory metabolites, etc.), while Gendel (64) argued that they could be introduced to improve performance and safety.

Ezeronye (13) felt that before thinking of genetic improvement and GMOs, the way to start improving the food fermentation industry in developing countries was "to be sure of the diversity of organisms involved and their individual roles in the process". He emphasized that, whereas in the past, physiological tools had been employed to study the biodiversity of micro-organisms involved in food fermentation, modern molecular tools could now be used. Oguntoyinbo (58), Gendel (64) and Owusu-Biney (67) advocated using molecular methods to identify useful and deleterious organisms in fermentation mixtures. Denaturing gradient gel electrophoresis (DGGE) was suggested by Oguntoyinbo (58) to be a useful molecular typing technique for identifying beneficial and deleterious organisms in fermentation, allowing pathogens and micro-organisms responsible for spoilage to be identified.

Wacher (59) agreed on the usefulness of the technique, reporting that it had been used for studying the microbiology of pozol, a fermented food from Mexico based on maize. DGGE allowed changes in the microbiota in a pozol ball to be monitored at different depths and over time. It allowed them to discover that *Streptococcus* was the dominant bacterial genus present throughout the fermentation and was the principal amylolytic lactic acid bacterium in the mixture. Unusual and unexpected micro-organisms were also found. Molecular typing, as shown in the case of pozol, allows detailed microbiological analysis of the fermentation process and has implications for food hygiene and safety, allowing the entire fermentation process to be improved, as recommended by Rolle (55). Another illustration example of what such research can uncover was provided by Mayer (57), who referred to characterization of micro-organisms involved in solid state fermentation of cassava in Colombia. As a result of the research, it was determined that this fermentation, thought to involve many different micro-organisms, could be achieved using a single strain of bacteria and that the time required for the process could be greatly reduced.

Single cell protein (SCP) refers to protein produced by micro-organisms, particularly yeast, and used as either a feed or a food additive. Lal (15) discussed production of SCP and its possible use to address protein deficiency in humans and domestic livestock. He had, however, some questions about the environmental effects of SCP, and the need for safety regulations, given that many of the micro-organisms had toxic cytoplasmic compounds. Krishna (21) suggested that there were standard procedures available to reduce toxic factors in SCP production and that extensive safety evaluation was carried out to ensure a high quality end product. Edema (32) suggested that waste materials themselves might be used to produce SCP for livestock feed, thereby releasing protein rich foods for human consumption and simultaneously reducing pollution. On a related issue, Lal (34) noted that rumen micro-organisms synthesized relatively large amounts of protein in the rumen and wondered, *inter alia*, whether they could be exploited by biotechnology to increase the protein supply from poor quality foods. Hofman (35) noted that the rumen environment could be created *in vitro* but (37) advised caution in conducting experiments in this area as rumen fluid contains many fungi and protozoa, some of which are not inoffensive when swallowed by humans.

6.2.2.6 Education and capacity building

Education in food processing and the application of biotechnology was thought by some participants to be a weak point, particularly in developing countries, and the importance of capacity building was highlighted in the conference. There was a call for improvements to be made to the curricula of universities to emphasize biotechnology and its application. Among others, this was highlighted by Olang'o (46), Kingamkono (48), Oyewole (53), Otieno (56) and Oguntoyinbo (58). Oyewole (53) specifically called for incorporation of food biotechnology oriented courses into undergraduate programmes of food scientists and for postgraduate programmes in food biotechnology. Otieno (56) agreed with Olang'o (46) that there should be more emphasis on biotechnology, especially molecular biology, in the food science and technology curricula in African universities. Oguntoyinbo (58) saw biotechnology as a "major key to food productivity and empowerment" and he thought there was limited awareness about its potential in most developing countries. Obstacles he saw were poor services and infrastructure, detailed earlier by Krishna (51), especially energy, and funding, where he suggested that a regional approach, covering, for example, similar West African fermented foods, could reduce costs and avoid unnecessary duplication. He proposed forming an international biotechnology and culture collection centre, that would also create strategy for science-based enterprises. Wacher (59) liked this regional approach.

Uzochukwu (41) emphasized the need for large scale re-training of scientists in DNA manipulation techniques so that developing countries would not be left behind in the biotechnology revolution. Similarly, Oguntoyinbo (58) advocated training and re-training of personnel in universities and research institutes as the key to teaching of biotechnology and advancement in biotechnology. Ezeronye (13), stressing the need for laboratory equipment, and Olutogun (42) noted that low capacity prevented effective use of beneficial biotechnology. Oguntoyinbo (58) similarly noted that "most techniques in biotech require good laboratory work with modern equipment to cope with. Most of these facilities are still absent in universities and research institutes in most developing countries".

6.2.2.7 Food safety and human health

Participants discussed the safety of traditional fermentation processes, in terms of hygiene and consequences for human health (e.g. Krishna, 12). Nuñez (31) pointed out that two traditional fermented Peruvian drinks, 'chicha de jora' and 'chicha de molle', respectively made from maize and a small fruit, could contain toxins, including furfural compounds and formaldehyde. Olusegun (39) indicated that food-borne diseases represented a major global health problem and that there was the need for "work and documentation on safety aspects of African fermented foods". Edema (30) felt that "the nutritional characteristics (and safety aspects) of most of the fermented foods in Africa are adequately documented and appreciated in developing countries although more can still be done". Bhushan (11) noted that when the fermentation is over, the downstream processing could affect the quality of the product and result in health hazards. Wacher (59) illustrated how application of molecular typing to a typical fermented product could be used to identify and monitor the presence of harmful micro-organisms. Gendel (64) also argued that well-designed starters could reduce the possibility of pathogen growth in the fermented product.

On the other hand, there was also discussion about the potential positive human health impacts of applying biotechnology to food processing. Kingamkono (48) reported results suggesting that consumption of specific fermented products could enhance protection against diarrhoeal diseases through reducing the levels of faecal enteropathogenic bacteria. Muralidharan (6) noted that many of the traditional fermented steam-cooked foods were recommended for convalescents in India. Olang'o (46) underlined the potential application of biotechnology to food processing in the food-medicine interface, specifically in production of functional foods and nutraceuticals that might, for instance, be developed for HIV/AIDS patients. Sharma (47) supported Olang'o (46), considering this to be "perhaps the most fertile area for development in food biotechnology" and went on to mention production of probiotics, prebiotics, synbiotics and food additives. He cited the potential value of high lutein eggs for prevention of cataracts but noted that, although nutraceuticals is potentially an important field for developing countries, they "have to take up a number of steps, including investment in research and development, development of educative programmes through the mass media and putting in place a good regulatory and monitoring systems before letting such products onto the markets".

6.2.2.8 Intellectual property rights (IPR) and traditional knowledge

Benhura (45) argued that operation of the patent system was heavily weighted against discoverers of a novel product or process because they were often unable to meet the financial requirements of registering and maintaining the validity of a patent and, as a result, "many academics in African institutions give up about applying for patents". He noted that many African universities did not have a policy on this issue and he highlighted the problem of ownership of

IPR for a discovery based on indigenous knowledge, but requiring intellectual input. Krishna (51) stated that in these cases the benefits accruing from IPR should be shared with the indigenous communities. The potential commercial benefits of exploiting indigenous knowledge/products, was highlighted by Muchugi (16), referring to traditional sour milk production of the Maasai community in Kenya. Wacher (59) indicated that Mexican law required authorization to use Mexican biological resources and that authorization could only be granted with the consent of the owner of the place where the biological resource was to be extracted. In addition, the owner should be informed how the biological resource was to be used and also had the right to an equitable share of the economic benefit that might result from the studies or use of the resource. She noted that, although procedures are well established for wild flora and fauna, the situation regarding traditional knowledge and resources such as fermented foods was less clear, the main problem being to decide who should give the consent and receive the economic share.

6.2.3 Participation

The conference ran for four weeks from 14 June to 15 July 2004, and 411 people subscribed. Sixty-eight messages were received in total from 37 participants from 19 countries. Twenty-seven of the participants were living in developing countries and ten in developed countries. Among the developing country participants, the majority was living in Africa, particularly West Africa. Of the 17 participants living in Africa, seven were in Nigeria. Asia was the second largest contributor, with six participants from India. Roughly two-thirds of the messages came from people working in universities (31 messages) or research centres, including CGIAR centres. The remainder came from people working as consultants, for farmer organizations, government agencies, NGOs, UN organizations or the private sector.

6.2.4 Name and country of participants with referenced messages

Benhura, Mudadi. Zimbabwe
Bhushan, Shashi. India
Blanchfield, Ralph. United Kingdom
Edema, Olayinka. Nigeria
Ezeronye, Obioha. Nigeria
Fall, Abdou. Senegal
Gendel, Steven. United States
Hofman, Marcel. Belgium
Hounhouigan, Joseph. Benin
Kingamkono, Rose Rita. United Republic of Tanzania
Krishna, Janaki. India
Lal, Nand. India
Mathooko, Francis. Japan
Mayer, Jorge. Germany
Muchugi, Alice. Kenya
Muralidharan, E.M. India
Nishio, John. United States
Nuñez, Jose. Peru
Oguntoyinbo, Folarin. United Kingdom.
Okoli, Charles Ifeanyi. Nigeria
Olang'o, Nelson Ojijo. Kenya
Olusegun, Obadina Adewale. Nigeria
Olutogun, Olusanya. Nigeria
Otieno, Wellington. Kenya

Ouoba, Irene. Burkina Faso
Owusu-Biney, Alex. Ghana
Oyewole, Olusola. Nigeria
Punchihewa, Asitha. Sri Lanka
Rolle, Rosa. Italy
Sasu, Lydia. Ghana
Seth, Ashok. United Kingdom
Sharma, Mrinal Kumar. India
Uzochukwu, Sylvia. Nigeria
Wacher, Carmen. Mexico
Wuerthele, Suzanne. United States

CHAPTER 7.
PUBLIC PARTICIPATION IN DECISION-MAKING REGARDING GMOS IN DEVELOPING COUNTRIES: HOW TO EFFECTIVELY INVOLVE RURAL PEOPLE

7.1 BACKGROUND DOCUMENT

7.1.1 Introduction

Very few issues have raised as much public discussion and controversy recently as the use of genetic modification in food and agriculture. According to Stone (2002): "It is rather remarkable that a process as esoteric as the genetic modification of crops would become the subject of a global war of rhetoric. Yet for the past few years Western audiences have been bombarded with deceptive rhetoric, spin, and soundbite science portraying the wonders - or horrors - of the new technology". For audiences in non-western countries the issue of genetically modified organisms (GMOs) has also been the object of much debate and in some cases individual African countries have refused to accept food aid derived from GM crops.

Whereas there is no or little public concern about other biotechnologies used in food and agriculture, such as fermentation, use of molecular DNA markers, vegetative reproduction of crops and forest trees, embryo transfer and embryo/semen freezing in livestock or triploidization and sex-reversal in fish, public acceptance of genetic modification and of GM food products is a major issue that cannot be ignored. For example, Marris (2004) concluded that one of the lessons to be learnt from studies of public attitudes to GM crops and foods was that "Public concerns need to be taken into account by all the operators of the industry, including R&D, marketing, commerce and distribution. Governments and international bodies also need to take these concerns into account when elaborating risk-related regulations and dealing with trade disputes".

Of the different food and agricultural sectors, GMOs are currently being commercially used in the crop, forestry and agro-industry sectors and are not commercially used in livestock or aquaculture. Their use is most substantial in the crop sector, where the GM crop species involved are ones that are extensively traded internationally. Although most developing countries are currently not involved in developing GMOs, their governments may nevertheless be required to regulate and develop policies about them because of the possibility of releasing imported GM varieties or importing "GM food" (food from GMOs [e.g. GM corn] or food that contains ingredients from GMOs [e.g. chocolate containing GM soybean]).

The conference focuses on the rural people in developing countries. Agricultural activities take place, by and large, in rural areas. Production of GMOs therefore directly impacts the people living in rural areas and their environment. In addition, people in rural areas have often more limited access to information than their counterparts in urban areas, due for example to remoteness, higher illiteracy rates and poorer infrastructure. These kinds of factors similarly have a negative impact on the ability of rural people to access and influence policy-makers and the decision-making process. Awareness about GMOs and involvement in decision-making regarding GMOs may therefore differ for rural and urban people.

Note, discussions in the conference will not consider the issues of whether GMOs (or GM food or labelling of GM food, etc.) should or should not be used or the attributes, positive or negative, of GMOs themselves but instead how the rural people in developing countries can be

effectively involved in the decision-making process regarding production, release or import of GMOs.

This Background Document aims to provide information that participants in the conference will find useful for the debate. Firstly, a brief overview of the current status regarding GMOs in food and agriculture is provided (Section 7.1.2), followed by discussion of the decision-making areas where the public could be involved (Section 7.1.3). A brief overview of international agreements that are relevant to the topic is then given (Section 7.1.4). Some of the specificities regarding information access and participation for people in rural areas in developing countries are then discussed (Section 7.1.5). The questions that should be addressed in the conference are listed in Section 7.1.6 and, finally, references to articles mentioned in the document are provided in Section 7.1.7.

7.1.2 Background and current status regarding GMOs in food and agriculture

A GMO is an organism into which one or more genes (called transgenes) have been introduced into its genetic material from another organism. The genes may be from a different kingdom (e.g. a bacterial gene introduced into plant genetic material), a different species within the same kingdom or even from the same species. The current status of GMOs in the crop, forestry, livestock, fisheries and agro-industry sectors is looked at briefly.

7.1.2.1 GM crops

Estimates indicate that the global area planted with transgenic (GM) crops increased from 2 to 68 million hectares from 1996 to 2003, respectively (James, 2003). A small number of countries and crops has dominated the transgenic acreage statistics each year. Estimates for 2003 indicate that the United States, Argentina, Canada, Brazil and China accounted for 63, 21, 6, 4 and 4 percent, respectively of the global transgenic acreage, and that GM soybean, maize, cotton and canola comprised 61, 23, 11 and 5 percent, respectively of the 68 million hectares. As in other years, the vast majority (73 percent) of GM crops cultivated in 2003 was modified for herbicide tolerance, while 18 percent was modified for insect resistance and 8 percent was modified for both traits. Although few developing countries have released GM crop varieties to date, a preliminary analysis (FAO, 2005) from FAO-BioDeC, an FAO database providing information on crop biotechnology products/techniques in use or in the pipeline in developing and transition countries, reveals that more than 20 countries are involved in GM crop research and application activities (covering experimentation [including laboratory or glasshouse research], field testing or commercialization), including over 200 experimentation activities (where research on one trait in one crop in a single country is counted as one activity). The traits receiving most experimental attention, based on the number of activities, are pathogen resistance, quality traits, pest resistance, stress resistance, herbicide resistance and multiple resistance, respectively.

7.1.2.2 GM forest trees

FAO is in the process of publishing a preliminary study reviewing the global status and trends in forest biotechnology, including genetic modification (FAO, 2004a). It indicates that forest GMO activities (mainly in the laboratory or in contained field tests) occur in at least 36 countries, with most activities occurring in North America (48 percent) and Europe (32 percent), followed by Asia (14 percent), Oceania (5 percent), South America (1 percent) and Africa (<1 percent). They are restricted largely to three genera (Populus, 47 percent; Pinus,

19 percent; Eucalyptus, 7 percent). Field trials of GM trees take place in 21 countries, the large majority in the United States. Approximately half of all reported GMO activities are related to methods development (e.g. gene stability, gene expression) or basic biological questions (e.g. functional genomics, tissue culture). Of the remaining activities, herbicide tolerance (13 percent), biotic resistance (12 percent), wood chemistry (9 percent) and fertility issues (6 percent) dominate the traits that groups studied most. The commercial release of GM trees has been reported only in China (ca. 1.4 million poplar trees in 2002). These releases followed two stages of field trials and required government agencies regulatory approval.

7.1.2.3 GM livestock

Although transgenic animals (especially mice) are used routinely for research purposes (particularly in the medical field), no GM animals have yet been released on the farm. Research has, however, been carried out on a wide range of traits of potential interest for farm animal populations, involving for example, the growth hormone gene (to increase growth rates), the phytase gene (to reduce phosphorous emissions from pigs) or keratin genes (to improve the properties of wool in sheep). Compared with crops, genetic modification of livestock has proceeded at a much slower pace for a variety of reasons such as poor efficiency of the gene transfer techniques, high costs and low animal reproductive rates.

7.1.2.4 GM fish

There is much research and commercial interest in the production of GM fish. The trait of major interest is increased growth rate, although disease resistance and improved environmental tolerance are also being researched. GM fish from about 20 species, including carp, catfish, salmon and tilapia, have been produced for experimental purposes. Although applications have been made for the regulatory approval of GM fish for food purposes, none has yet been approved. In 2003, the first GM fish was released commercially, a fluorescent zebrafish (*Danio rerio*) sold as a pet.

7.1.2.5 GM micro-organisms

Recombinant DNA approaches have been used for genetic modification of bacterial, yeast and mould strains to promote expression of desirable genes, to hinder the expression of others, to alter specific genes or to inactivate genes so as to block specific pathways. For example, the first application of genetic modification for food was the approval in the United States in 1990 of a chymosin preparation, a solution containing chymosin, an enzyme used to curdle milk in the preliminary steps of cheese manufacture, derived from a GM bacteria (Escherichia coli K-12 containing the bovine prochymosin gene). It is estimated that at least 30 enzymes produced by GM micro-organisms are currently commercially available worldwide, many of which are used in the food industry. GM yeasts appropriate for brewing and baking applications have been approved for use (e.g. approval was granted in the United Kingdom for use of a GM yeast [*Saccharomyces cerevisiae*] in beer production, containing a transferred gene from the closely related *Saccharomyces diastaticus*, allowing it to better utilize the carbohydrate present in conventional feedstocks). None of these GM yeasts is, however, used commercially.

7.1.3 At which points could the public be involved in the decision-making processes?

The overview of GMOs in Section 7.1.2 shows that they are being commercially produced in developing countries, albeit in a small number of countries. In addition, it is expected that more GM products will be produced in a larger number of developing countries in the future. In this section, the main places in the decision-making process where the public could be involved will be considered.

7.1.3.1 National policy dialogues

In the light of the controversy about GMOs, some governments have engaged in national dialogues to assist them in their national policy-making. A small number of countries has specifically developed national biotechnology policy documents (see for example, www.fao.org/biotech/country.asp), and in some of these cases the public has been actively encouraged to participate in the process. For example, the Royal Commission on Genetic Modification was established by the Government of New Zealand in May 2000 to look into and report on the issues surrounding genetic modification in New Zealand. In producing its report, the Commission undertook an extensive series of public consultations (including 15 public meetings held throughout the country, a public submission process resulting in more than 10 000 written submissions and formal hearings lasting 13 weeks). The report was submitted by the Commission in July 2001 and one of its recommendations was that the Ministry of Research, Science and Technology should develop a biotechnology strategy for New Zealand. The draft strategy document was made available by the Ministry on the World Wide Web and comments were invited from interested individuals. The final strategy document was then released in May 2003.

In the United States, a statement of policy on foods derived from new plant varieties was issued in 1992 by the Food and Drug Administration (FDA, www.cfsan.fda.gov/~acrobat/fr920529.pdf) and other statements on specific biotechnology matters have been issued periodically by the White House, the United States Department of Agriculture, FDA and the Environmental Protection Agency. By law, these agencies are required to solicit public comments on guidelines, regulations, etc. This information is provided on the World Wide Web.

In other cases, no specific biotechnology policy document is being produced and the major impact of the national dialogue has been to inform policy-makers about the positions, opinions and concerns of different stakeholders and the extent of agreement and disagreement in their positions. Birner and Alcaraz (2004) reviewed five recent initiatives, organized in France, Germany, Switzerland, the United Kingdom and by the European Commission, and showed that a wide range of methods have been used for such policy dialogues. For example, the German dialogue involved experts, government officials and representatives of 30 stakeholder organizations, whereas the Swiss initiative involved limited participation of interest groups and focused on a citizen panel of 28 people. The United Kingdom initiative instead involved a much wider audience, with an estimated 20 000 people attending several hundred workshops and with inputs also provided via 1 200 letters or e-mails and over 36 000 feedback forms. Based on insights from these dialogues, Birner and Alcaraz (2004) made a series of nine recommendations regarding a policy dialogue for Africa, such as focusing on stakeholder organizations in the dialogue process and ensuring that all relevant stakeholder interests are represented in the dialogue.

7.1.3.2 Developing a regulatory framework for GMOs

As pointed out in Chapter 4.1, the majority of developing countries does not currently have a regulatory system for GMOs in place, although many are now being established with technical assistance and policy advice provided by a number of UN and non-UN organizations. Many of these activities, e.g. a UNEP-GEF project assisting 123 countries to develop a draft national biosafety framework (NBF), are related to the Cartagena Protocol on Biosafety (discussed in Section 7.1.4), an important international agreement concerning viable GMOs (the term living modified organisms [LMOs] is used in the Protocol).

One of the key elements governments have to consider when developing a regulatory framework, concerns public involvement in the decision-making processes e.g. whether there should be public participation in the development of the regulatory framework. As part of the UNEP-GEF project, a series of six regional workshops were held between November 2002 and May 2003 which considered, *inter alia*, these issues. The synthesis report, summarizing the deliberations and conclusions of these workshops, is a strong endorsement for public participation, as participants considered that public awareness, public education and public participation were needed in the establishment of a NBF, for the following nine reasons: "To provide for public feedback, comments and advice into the decision-making process; for transparency and accountability of the decision-making process; to protect the public interest and adequately reflect the interests of different groups; to enable involved parties to share the responsibility for, and have a sense of ownership of, the final decision; because it is part of the democratic process and of an ongoing global trend towards public involvement in decision-making; because there is an obligation under Article 23 of the Cartagena Protocol; to enable socio-economic and other non-scientific issues to also be taken into account; to inspire public trust and make the NBF workable and sustainable; to permit a pooling of resources" (UNEP-GEF, 2003). FAO has assisted a number of its member countries through biosafety capacity building projects, some of which (e.g. Bolivia, Grenada and Paraguay) have adopted, or are adopting, a participatory approach to the drafting and revision of national biosafety regulations (www.fao.org/sd/sdrr/bio_en.asp).

IDS (2003) considered some of the choices regarding public participation that governments might face when developing regulatory frameworks for GMOs, such as who should participate in the development and whether people are enabled to participate. The kinds of processes that then might be used include: a) identifying key stakeholders; b) ensuring adequate legal frameworks (rights to information, access to decision-making) are in place; and c) ensuring people are sufficiently informed about the issues to engage meaningfully in the process. The kinds of tools that might be used here include: a) local and regional consultations to discuss issues and solicit views; b) laws and resources to enable public participation and access to information; and c) decision trails showing how views will be carried forward, with follow-up explanations about how and why inputs have or have not been used.

7.1.3.3 Approval of individual GM products

Once a regulatory framework for GMOs is in place, requests for commercial approval of individual GMOs can be processed. The public can also be involved at this step. The regulatory framework may require that assessment of the potential human health and environmental risks be carried out prior to eventual approval, so these data might be made publicly available allowing the public to provide its comments. Concerning approval of individual cases, participants in the UNEP-GEF workshops (UNEP-GEF, 2003), in the context of individual applications for importation of LMOs, "pointed to the vital need to provide the public with access to the

maximum amount of information, both the raw data received and a 'translation' of the information in an understandable format. In that context, it was necessary to explain and justify why any information in an application was being withheld or labelled confidential. The decision-making process needed to provide an entry point for consultation with the public, and provisions for taking into account feedback from groups of the public. That entry point could take a number of forms: e.g. a committee containing representatives of the public, feedback through a focal point, a formal process of submission of a decision to the public, etc. In addition, there had to be a recourse procedure for appeal of a decision, as well as access to justice".

IDS (2003) considered some of the choices regarding public participation that governments might face when implementing a regulatory framework for GMOs, such as how far people should be included in decisions on: a) the roles, duties and powers of responsible agencies; b) mechanisms of reporting, public scrutiny and accountability; and c) the location and design of biosafety trials. The kinds of processes that then might be used include ensuring: a) openness about applications for biosafety review and commercialization; b) openness about the purpose, location and design of biosafety trials; and c) opportunities for public comment. The kind of tools that might be used include public registers of GMO applications under review, with opportunities for public comment and obligations to respond to public comments.

Whether or not individual GM products should be approved falls under the broad umbrella of risk analysis, a discipline of key importance for regulating health and environmental risks. Risk analysis follows a structured approach comprising three distinct but closely linked components, risk assessment, risk management and risk communication, where the last component is relevant to public participation and public access to information. Following Codex Alimentarius, and as given in the FAO biotechnology glossary (www.fao.org/biotech/index_glossary.asp), risk assessment is defined as "a scientifically based process consisting of the following steps: (i) hazard identification; (ii) hazard characterization; (iii) exposure assessment; and (iv) risk characterization"; risk management as "the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and if needed, selecting appropriate prevention and control options"; and risk communication as "the interactive exchange of information and opinions throughout the risk analysis process concerning risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions".

In February 1998, a joint FAO/WHO expert consultation was held on the application of risk communication to food standards and safety matters, which identified the elements and guiding principles of risk communication, barriers to effective risk communication and strategies for effective risk communication (FAO, 1999). The consultation identified the following principles for effective risk communication:

- know the audience: Understanding the motivation, opinions, concerns and feelings of the individuals and groups that make up the audience and designing risk communication messages to address these issues improve communications. Listening to all interested parties is an important aspect of risk communication;
- involve the scientific experts: These experts should be involved to the extent that they can provide information on the risk assessment process and the results, including the assumptions and subjective judgement, so that risk managers have complete information and understanding of the risk;

- establish expertise in communication: Communication expertise is important to the conveyance of the appropriate risk message in a manner that is clear, understandable and informative. Experts in this field should be involved in the process of communication from the very start;
- be a credible source of information: Information from a credible source is more likely to be accepted by the public. Consistent messages received from multiple sources lend credibility to the risk message. To be credible the public must recognize competence, trustworthiness, fairness and lack of bias. In addition, the communications specialist must be factual, knowledgeable, expert, aware of the public welfare, responsible, and truthful and have a good track record. Effective communications acknowledge current issues and problems, are open in their content and approach, and are timely;
- share responsibility: There are multiple players in the communication process, including regulatory officials, industry, consumers and the media. Each has a specific role to play and by sharing this responsibility, each can do its part to assure effective communications;
- differentiate between science and value judgement: It is essential to separate fact from values in considering development of a risk communication message;
- assure transparency: To ensure public acceptance of risk messages, the process must be open and available for scrutiny by interested parties;
- put the risk in perspective: By examining the risk in terms of the benefits and by comparing with other more familiar risks the risk can be put into perspective. However this must not be done in a manner that may be construed by the public as using a comparison to diminish the importance of the risk issue at hand.

7.1.3.4 Post-release monitoring

After individual GM products have been approved, the regulatory framework may include provisions for post-release monitoring of the impacts of GMOs, where feedback from the public, especially those in rural areas where they are produced, would be of particular importance.

7.1.4 International agreements/guidelines concerning public participation in decision-making and GMOs

In recent years, the importance of public participation in decision-making has been increasingly recognized by policy-makers. For example, Principle 10 of the Rio Declaration on Environment and Development, adopted by over 170 countries in 1992, states "Environmental issues are best handled with the participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided" (www.un.org/documents/ga/conf151/aconf15126-1annex1.htm).

According to a recent study published by the FAO Legal Office (Glowka, 2003), "One of the most useful legal tools for realizing the potential and avoiding the risks of modern biotechnology may be legally requiring public participation in the policy-making and regulatory decision-making processes. Opening decision-making processes up to the public may help to

ensure that decision makers have the best information at their disposal in order to evaluate the benefits and risks that modern biotechnology could present. Public participation could also help to ensure better transparency and accountability in decision-making". The study reviewed international, regional and a selection of national laws related to GMOs, also considering the topic of public participation. Here, the study suggests that many international legal instruments address the public's access to information in relation to GMOs while few specifically address public participation in decision-making on GMOs.

Three recently adopted international instruments of special relevance to public participation in decision-making on GMOs are discussed below.

7.1.4.1 Aarhus Convention

The Aarhus Convention (i.e. the United Nations Economic Commission for Europe [UNECE] Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters) was adopted in June 1998 in Aarhus, Denmark and entered into force in October 2001. It contains three broad themes: public access to information (covering the obligation on public authorities to respond to public requests for information and other obligations relating to providing environmental information, such as collection, updating, public dissemination, etc.), public participation (setting out minimum requirements for public participation in various categories of environmental decision-making) and public access to justice on environmental matters.

The Convention gives special treatment to decisions and to information pertaining to GMOs, which are specifically mentioned in the preamble to the Convention. In addition, Article 6 (concerning public participation in decision-making by public authorities on whether to permit or license specific activities) specifically includes a paragraph (number 11) stating that "Each Party shall, within the framework of its national law, apply, to the extent feasible and appropriate, provisions of this article to decisions on whether to permit the deliberate release of genetically modified organisms into the environment".

Much effort has been devoted to applying the Convention to the topic of the deliberate release of GMOs. After the Convention was adopted, a task force and then a working group on GMOs was established, their work resulting in the first meeting of the Parties to the Convention adopting in October 2002 the "Guidelines on access to information, public participation and access to justice with respect to genetically modified organisms", recommending their use by all Parties as a non-binding, voluntary instrument. At the meeting, a new working group on GMOs was also established, which held four meetings in 2003-2004 (www.unece.org/env/pp/gmo.htm). Its task has been to explore the options for a legally binding approach to further developing the application of the Convention in the field of GMOs, including through possible instruments, and to develop selected options for consideration and possible decision or adoption by the Parties at their second ordinary meeting (to be held from 25 to 27 May 2005 in Kazakhstan).

To date, 30 countries have ratified the Convention, many of which are countries with economies in transition. The UNECE is one of five regional commissions of the UN and has 55 member countries from North America, Western, Central and Eastern Europe and Central Asia. Although a UNECE convention, it has a global significance as it is also open to all non-UNECE states which are members of the UN.

7.1.4.2 Cartagena Protocol on Biosafety to the Convention on Biological Diversity

The Cartagena Protocol (www.biodiv.org/biosafety/default2.aspx) was adopted in January 2000, entered into force in September 2003 and has been ratified by 111 countries to date (16 December 2004). Its objective is "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements". Article 23 of the Protocol specifically addresses the issue of public awareness and participation, stating "The Parties shall: (a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other states and international bodies; (b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House". Public awareness and participation will be among the main issues to be addressed at the second meeting of the Conference of the Parties (to be held from 30 May to 3 June 2005 in Canada).

7.1.4.3 Codex principles on risk analysis

The Joint FAO/WHO Codex Alimentarius Commission is an intergovernmental body with 169 member countries that sets food safety and agricultural trade standards. It has devoted considerable attention to the safety evaluation of GM foods. For example, in 1999 the Commission established the ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology to consider the health and nutritional implications of such foods. It completed its work and the Commission established a new biotechnology task force in 2004, which should submit its final report to the Commission in 2009.

At its 26th session, held in Rome in the summer of 2003, the Commission adopted guidelines that lay out broad general principles intended to make the analysis and management of risks related to GM foods uniform across Codex members. Considering risk communication, the "Principles for the risk analysis of foods derived from modern biotechnology" state: "Effective risk communication is essential at all phases of risk assessment and risk management. It is an interactive process involving all interested parties, including government, industry, academia, media and consumers. Risk communication should include transparent safety assessment and risk management decision-making processes. These processes should be fully documented at all stages and open to public scrutiny, whilst respecting legitimate concerns to safeguard the confidentiality of commercial and industrial information. In particular, reports prepared on the safety assessments and other aspects of the decision-making process should be made available to all interested parties. Effective risk communication should include responsive consultation processes. Consultation processes should be interactive. The views of all interested parties should be sought and relevant food safety and nutritional issues that are raised during consultation should be addressed during the risk analysis process" (www.fao.org/ag/AGN/food/risk_biotech_taskforce_en.stm).

7.1.5 Information, communication and participation of the rural people in developing countries

This e-mail conference focuses on the people living in rural areas of developing countries, the farmers, their families, their neighbours, the landless labourers, etc. and how to effectively involve them in the decision-making processes regarding GMOs. In order to participate, they need, however, to be able to access information about GMOs. They also need to be able to provide input into the decision-making process, if allowed to do so, through appropriate communication channels. As described in Section 7.1.3, their input could potentially be sought at a number of different stages, during national policy dialogues, in development of a regulatory framework for GMOs, in considering applications for approval of individual GMOs and in monitoring the impacts of GMOs after their release. Some topics (literacy, access to ICTs [information and communication technologies]) as well as communication approaches relevant to this issue, will be briefly considered.

The annual Human Development Report (UNDP, 2004) shows that the adult literacy rate (defined as "the percentage of people aged 15 and above who can, with understanding, both read and write a short, simple statement related to their everyday life") is 77 percent in developing countries (and just 53 percent in the 49 least developed countries). Classified by developing country region, literacy rates are 90, 89, 63, 63 and 58 percent in East Asia and the Pacific, Latin America and the Caribbean, the Arab States, sub-Saharan Africa and South Asia, respectively. There are also gender differences regarding adult literacy rates. For females they are 88 percent of those of males in developing countries (and this ratio is 70 percent in the least developed countries). Again, by the five regions given above, the ratios of female to male literacy are 91, 98, 70, 79 and 67 percent, respectively. Literacy is obviously closely linked to school attendance and UNDP (2004) shows that the combined gross enrolment ratio for primary, secondary and tertiary schools (i.e. the number of students enrolled in primary, secondary and tertiary levels of education, regardless of age, as a percentage of the population of official school age for the three levels) is 60 percent in developing countries (and 43 percent in the least developed countries), compared with 87 percent in OECD countries.

In recent years, ICTs (i.e. the telephone, radio, video and Internet) have become increasingly important for accessing and exchanging information. However, there are tremendous global inequalities in the use of ICTs. UNDP (2004) shows that whereas over half the people in OECD countries has a mainline telephone, nearly 60 percent has a cellular telephone and nearly 40 percent has access to the Internet, the corresponding figures for developing countries are 10, 10 and 4 percent. Furthermore, among 1 000 people in the 49 least developed countries, an average of only seven has a mainline telephone, ten has a cellular telephone and three has access to the Internet. By developing country region, there are again substantial differences in these three parameters, ranging from 166, 191 and 81, respectively in Latin America and the Caribbean down to 15, 39 and 10 in sub-Saharan Africa. Reflecting on the subject of this e-mail conference, these figures mean that whereas a country like New Zealand, where almost half of the population has access to the Internet, can theoretically solicit and receive inputs from a large proportion of the country's population concerning GMOs using the World Wide Web, this is not a realistic option in countries like Burkina Faso, Chad, Ethiopia, Mali and the Niger where only 0.1-0.2 percent of the population has access to the Internet.

This conference focuses on the rural people in developing countries, the people who make up the large majority of the world's hungry (FAO, 2004b). Within developing countries, there is a wealth gap between urban and rural areas, which persists and seems even to be

widening, and the rural-urban divide tends also to be reflected in education and health indicators. The incidence of illiteracy is higher (often far higher) in rural than in urban areas. This large rural-urban gap in illiteracy rates applies both to men and women. In addition, women in rural (but also in urban) areas have higher illiteracy rates than men (IFAD, 2001). Recent results from a survey of 21 African countries also highlight the substantial disparities in primary schooling between urban and rural areas, in favour of urban dwellers (Mingat, 2003).

The term "digital divide" has been used to describe the discrepancy amongst people who have access to, and the resources to use, ICTs and those who do not. This may be due to factors such as lack of infrastructure, resources and investment, high costs of connectivity and low levels of technological skills, education and literacy. Within individual countries, Internet users tend to be young, male, better educated and wealthier and are predominantly urban and located in certain regions (UNDP, 2001). Some specific examples of rural-urban differences are also highlighted in the same report, where "In China the 15 least connected provinces, with 600 million people, have only four million Internet users - while Shanghai and Beijing, with 27 million people, have five million users. In the Dominican Republic 80 percent of Internet users live in the capital, Santo Domingo. In Thailand 90 percent live in urban areas, which contain only 21 percent of the country's population". Most of the estimated one billion people who have not benefited from the transformation of global information systems are the rural poor, a reality which has given rise to the term "rural digital divide". The advent of ICTs has served only to widen the gap amongst the rural poor and others who do have access to such technologies. FAO and its partners are working on an integrated set of activities to bridge the rural digital divide by strengthening human and institutional capacities to harness information and knowledge more effectively (www.fao.org/rdd/index_en.asp).

While lack of literacy or access to ICTs may be obstacles to participation, appropriate communication strategies should be used to ensure that people that are illiterate or unable to access ICTs can be provided with good information about GMOs as well as be represented in the decision-making process.

Special attention has to be given to the relevant knowledge and information needs of rural people related to GMOs (e.g. whether related to production, marketing or transport, etc. of GMOs). Appropriate communication approaches and methods should then be selected to properly reflect the specificities and characteristics (language, etc.) of the rural audience involved. For example, the Communication for Development approach, integrating local and modern media, can help in planning and implementing appropriate communication strategies and activities based on the knowledge and information needs of the rural stakeholders (www.fao.org/sd/KN1_en.htm).

7.1.6 Questions to be addressed in this e-mail conference

This conference is devoted to the subject of public participation in decision-making regarding GMOs for food and agriculture in developing countries, considering in particular how rural people can be effectively involved in the decision-making process. The questions that participants should address in the conference are:

- what priority should governments give to involving the rural people in decision-making regarding GMOs in developing countries?
- in which situations is it most important to include the rural people in decision-making regarding GMOs in developing countries?

- how can public participation opportunities be extended to groups in rural communities which are more difficult to reach or which have less access to communication channels (e.g. women, subsistence farmers)?
- should specific considerations be given to involving indigenous communities in decision-making regarding GMOs? If so, how can this best be achieved?
- what is the best medium (e.g. newspaper, radio, Internet, etc.) for rural people in developing countries to access quality information about GMOs, that will allow them to participate effectively in the decision-making process?
- which mechanisms can be used to ensure that relevant and reliable information/content is provided by the above-mentioned media?
- what are the main information and communication needs of the rural people related to GMOs? How can local capacity be built to respond to these needs? What are the most appropriate approaches to respond to these needs?
- what is the best medium for rural people in developing countries to provide their inputs, if requested, to the decision-making processes regarding GMOs?
- how should local languages of the rural people be dealt with in a public participation exercise?
- who can best represent the interests of the rural people in stakeholder discussions?
- involving the public in decision-making processes can be costly. Who should pay?
- how important, implementable and relevant are the currently available international instruments relating to public participation and GMOs (see Section 7.1.4)?
- concerning requests for approval of individual GM products, what kind of information should it be possible to withhold from public disclosure?
- can certain public participation activities be organized on a regional basis in developing countries instead of at the national level?
- is public participation regarding GMOs in developing countries more important for some food and agriculture sectors (crop, forestry, livestock, aquaculture and agro-industry) than others?

7.1.7 References

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7.2 SUMMARY DOCUMENT

Executive summary

The rural people in developing countries are often far removed from many important decision-making processes. Production and consumption of genetically modified organisms (GMOs) is a topical issue and could impact on sociocultural systems of rural populations in developing countries. Involving the rural people in decision-making on GMOs was discussed during this moderated e-mail conference hosted by the FAO Biotechnology Forum from 17 January to 13 February 2005. Over 500 people subscribed to the conference and 116 messages were posted, from 70 people living in 35 different countries. Half of the messages were from people in developing countries.

There was broad agreement that citizens, including rural people, should be involved in decision-making when it is likely to impact on them, but opinions on the degree and nature of the suggested participation differed. It was proposed that participation of the rural people could usually be indirect, through representatives they had chosen. It was felt that effective participation depended on access to unbiased and comprehensive information on the nature and consequences of GMOs. This information would have to be adapted to the needs and capacities of the various groups of rural people and their representatives in order for it to be helpful. Once available, the information would have to be communicated effectively. Numerous channels of communication were suggested and the importance of extension services, radio and use of local languages was particularly emphasized. Many participants complained that misinformation abounded (both for and against GMOs) and some were quite sceptical that a real public participation exercise might take place on this issue and, if it did, that its outcomes would have any impact. It was suggested that the costs of involving the rural populations in decision-making might be shared between the government and other relevant stakeholders. International agreements were regarded as being useful, but concern was expressed that commitments to these agreements might compromise the outcomes of an eventual national debate on GMOs.

7.2.1 Introduction

The conference generated interesting and valuable discussion, with 116 e-mail messages posted, numbered in chronological order of posting, from 70 people living in 35 different countries. Protz (103) in the last week of the conference wrote “I’ve been very impressed with the geographical range of the comments and the diversity of experience represented - farmers, scientists, lawyers, academics, anthropologists, activists, communicators, bioethics specialists, consumer affairs specialists...”. This Summary Document represents a synopsis of the principal issues and discussions from the conference. Specific messages are referred to in the document using participants’ surnames and message numbers. All the messages can be read at www.fao.org/biotech/logs/c12logs.htm.

The Background Document suggested that the relative importance of public participation regarding GMOs in the different food and agriculture sectors, namely crops, forestry, livestock, aquaculture and agro-industry, might be discussed. GMOs were frequently discussed in the conference without reference to a particular sector, but GMOs and food were of primary concern and particularly food derived from genetically modified (GM) crops.

In Section 7.2.2 of this document the main issues discussed during the conference are summarized under seven main themes. Section 7.2.3 provides information on participation and

Section 7.2.4 provides a list of names and countries of the people who sent messages that are referenced in the document.

7.2.2 Main themes discussed

7.2.2.1 The degree and nature of public participation of rural people in decision-making regarding GMOs

A major topic of discussion during the e-mail conference was, if and to what degree, the public, particularly the rural populations of developing countries, should participate in decision-making regarding GMOs. There was a certain polarization seen in the views expressed, no doubt reflecting polarization of views held on the production and release of GMOs *per se*.

While most people agreed that participation of rural populations, including women (Keter, 34; Huyer, 104) and indigenous populations (Krishna, 1; Vallings, 26; Lin, 89; Protz, 108), was a good and necessary development (e.g. Krishna, 1; Okello, 62), there was considerable discussion about the optimal level of participation and the form it should take. Midway through the conference, Torres (60) noted that the prevailing opinion in the conference was in favour of public involvement, although the question of "how" had only been touched on by some messages. Shantharam (48) suggested that no one seemed to know how to go about involving the rural public in such a complex issue.

Some of the discussion hinged on the use and meaning of words, including "involve" and "consult" and the extent to which "involvement" and "consultation" needed to be implemented. For example, Infante (40) regarded "involved" and "consulted" as being quite different and argued that the public should be consulted in the decision-making process, but that decision-making on GMOs had to be carried out by people "with the right expertise". Shantharam (28) felt that "public participation, public input, public comment and public right to know" could be reasonably accommodated, but not public decision-making, because unless decision-making was left to a small group of decision-makers, chaos would reign. He (15) suggested that seeking general public input would not really serve any purpose, but that stratifying the public into focus groups and surveying them for their perceptions and opinions on a continuous basis would be useful.

Infante (4) and Kambikambi (29), among others, questioned why the public would be involved in decision-making on GMOs, given the technical nature of the subject and the fact that the public was not involved in many other analogous decision-making processes (e.g. approval of new chemicals for agriculture or of new human drugs). Djoulde (21) felt that if GMOs had been authorized by scientists and international or national authorities, there was no need to involve the public. For Izquierdo (86), decision-making should remain in government hands, and they should receive the most accurate expert advice. Infante (105) suggested, however, that in some cases, decision-makers in government ministries lacked the necessary knowledge on GMOs. Mayer (66) stressed the need for technically versed staff in administrative/regulatory posts in developing countries rather than purely political administrators.

Others argued that decision-making should not be left to scientific experts. For example, Hodges (49) maintained that the experts do not agree on the risks and benefits of GMOs, so leaving them with the responsibility for decisions on GMOs was not an acceptable solution. Harris (83) also suggested that there was not a single scientifically correct answer on GMOs as "at all levels of scientific quality, the literature is still replete with widely divergent estimates of

the impacts of various biotechnologies, their costs and benefits, and their probabilities". Dunn (53) noted that change is a social process and that biotechnologies cannot be judged to be desirable (or not) by scientists alone, but that local knowledge needs also to be sought and blended with outside knowledge. Although pointing out that they are not problem-free, he (53, 64, 70), supported by Protz (107), advocated participatory approaches, noting that each situation required a tailored methodology. Lin (10) indicated that several case studies already existed on applying participatory approaches to biotechnology. Nasar (47) argued that public participation in this issue should be allowed for at the different levels of a democratic system and that an "informed decision is essential". For Torres (60), the bottom line was that "participation and access to information affecting one's life is a basic human right".

Chibisa (9) believed that rural people should be given the first priority in decision-making on GMOs and Obura (41) suggested that involving the farmers in policy-making at the pre-release GM crop stage was necessary and valid. Others raised the difficult question of who exactly from the rural populations might be expected to participate in decision-making on GMOs. Nishio (43) noted that it was unrealistic to expect the involvement of huge numbers of people in decision-making of the sort being discussed here. Communication with the rural poor may be difficult. For example, Krishna (1) commented that in many parts of rural India, people are "not part of the formal communication networks that keep them up to date and in poor communities, newspapers, radios and television are scarce". Nevertheless, Soleri (30) suggested, with examples from Cuba, Guatemala and Mexico, that it was possible to quickly and inexpensively include smallholders in discussions and policies on GMOs.

Benedito (2) pointed out that rural populations are quite heterogeneous, with different education, economic and political profiles. For Brazil, he noted that they could be sorted into several categories, including big farmers (with access to finance, good organization and the ability to influence politics, even at the national level); medium farmers (with a wide range of education and technology uptake, usually with political influence at the local level); and small/subsistence farmers (who are mostly lowly educated, poor, unorganized and with no political influence). For Africa's rural poor, Mbassa (98) wondered how they could be expected to decide on GMOs when they are "powerless, information-less, starving, and in abject poverty". Instead, for Seth (45), "the fact that farmers in many countries are uneducated or illiterate is no excuse for not consulting them and taking them into full confidence before introducing new technologies. Farmers are very good judges of the value of a new technology. In fact, they should also be directly involved in helping to target research to their priority needs". Indeed, Krishna (1, 18) gave an example of a biotechnology project in India in which rural people were involved in all stages. These messages highlighted the fact that there is great diversity among rural peoples regarding their capacity to participate in decision-making processes and that this would influence the structure of any debate involving the public in developing countries.

For the practical reasons mentioned previously, participants supporting public participation generally favoured indirect participation of the rural people through their representatives. Khouma (8) suggested that democracy and good governance required participation of all stakeholders, and that public participation must be organized to be representative, otherwise "we will have as many opinions as individuals". For Torres (60), regardless of the communities or sectors involved, "participation by representation still remains as the basic workable management tool for large scale involvement". Farnese (11) argued that true democracy requires all citizens being involved in the democratic process and that elected representatives have therefore a duty to ensure that their actions are representative of all voices. She concluded that without the voice of the rural population on GMOs, government regulation in

this area would be illegitimate. Mayer (66) believed that democracy in practice was not about involving the people in every decision but about letting them choose their representatives.

Who should the representatives be? Obura (35) with an example from Kenya, highlighted the difficulties of choosing suitable representatives for the people and Muchugi (19) indicated that representatives did not always represent the views of the people they were elected to represent. Krishna (18) thought local representatives, with credibility in the villages and nominated by people in the villages, as well as credible civil society organizations could represent the interests of the rural people. For Vallings (26) they could be democratically elected representatives of farming groups, foresters and local communities. Hogg (54) noted that every society had some form of social structure, including leadership functions. Protz (108) also noted that most organized indigenous groups have clearly identified leaders that could represent them and that they also have their own processes for discussion and decision-making. Huyer (104) emphasized that particular efforts were needed to ensure women were involved as, in many cases, despite being the ones with practical environmental/agricultural knowledge, they were not included in community decision-making sessions.

Birner (116) felt that stakeholder consultation was essential on an issue as controversial as GMOs, even if elected policy-makers usually were the legitimate body to make final decisions on GMOs or to delegate the decisions to regulatory bodies: people therefore are given a "voice" but not a "vote". In a similar vein, Shantharam (48) suggested that democracy can guarantee an opportunity to contribute, but cannot guarantee that everyone's input will be included in decision-making. Cuming (71) emphasized the importance of the fundamental rights of consumers, arguing that even if rural communities were not aware of them, their governments should take them into account when making important decisions on GM agriculture and food aid.

Although the conference title specified decision-making in developing countries, some examples were provided from developed countries of public participation exercises in this sensitive area. These examples could be usefully taken into account in planning similar endeavours in other countries. Burke (78) provided details of some initiatives of the Government of the United Kingdom for consulting with the public and building consensus regarding GM food, concluding "we in the UK have been unable to find a mechanism which leads to conclusions satisfactory to companies, scientists and NGOs. The public has become confused and I think rather bored by the whole debate..." Regarding decision-making at committee (representative) level, he said the major stumbling block had been groups holding non-negotiable positions that were effectively able to veto decisions. Lin (56) later supplemented by Birner (116) provided brief information on public debates on GMOs in Germany, Switzerland and the United Kingdom. The structure of the three debates differed considerably, but the main questions addressed were similar. He suggested that the debates represented efforts to bring different stakeholders together, sometimes for the first time, but did not actually represent efforts towards public decision-making and that the process of public consultation and decision-making could vary from country to country and might reflect the political environment and level of openness in a given society. Shantharam (15) said that his experience in the United States from allowing public input on regulatory decision-making had been that the inputs were not very useful and that the public was not really interested in the topic.

7.2.2.2 What type of information do the rural people require?

There was considerable agreement that the information needed to assist the rural people to participate in decision-making processes associated with GMOs should be adapted to the needs

and capacities of the various groups of rural people and their representatives. Overly technical information/language should be avoided.

Mayer (88) suggested that with appropriate representation at all levels and with good control mechanisms in place, there would be no need for the general public to be involved in the scientific details. Similarly, Protz (103) argued that while rural people should be involved in decision-making regarding biosafety legislation, policy and regulatory frameworks, it would probably not be necessary to involve them in understanding detailed scientific information. Krishna (58) suggested that when obtaining views from the public, they should be provided with a simple understandable abstract of the scientific dossier. The practical aspects and implications of the technology were important for the rural people and not the complex scientific details, said Mesghenna (82). Bhatia (92) asked how anyone, including professional science communicators, could explain genetic modification to illiterate farmers when not even the literate public of developed countries was fully familiar with the relevant information or other standard information on less technical issues. Blanchfield (110) said it was important to distinguish amongst the three components of risk analysis i.e. risk assessment, risk management and risk communication, where participation of the rural people was valuable and essential for this final component. He emphasized that it was two-way and not one-way communication and that the rural people provided crucial input on their "on the ground" needs and problems and, in this context, they did not need detailed scientific knowledge on genetic modification.

Newman (50) argued that bombarding farmers with information not relevant to farming was a waste of time and money; information relevant to their farming practice was, on the other hand, crucial, including for example, details of costs involved with GM crops. Many lectures that she had attended, which had focused only on the scientific issues, had left most farmers "feeling understandably confused and numb to the debate", she suggested. Similarly, Moghaddam (63) noted that scientists are poor at communicating with non-scientists. Since scientific information on GMOs could be difficult to understand, Farnese (22) suggested it was the duty of scientists to make their research findings accessible to the general public. Infante (40) supported this, although noting that it is sometimes difficult to explain research to a non-technical audience. In a similar vein, Olutogun (37) advocated delivering messages "in simple language that the layman can understand", although Torres (38) noted that popularizing technical jargon was itself a science and an art that must be learnt.

Kosky (6) stressed the need for rural people to know the advantages of GMOs, while Keter (34) said the general population felt that the scientific world had failed to fully explain the disadvantages of GMOs. Information on opportunities, costs and risks of GMOs was considered essential for the rural people by Mesghenna (55), while information regarding liability for adverse impacts caused by the introduction of GM crops was emphasized by Newman (31, 95). She believed that aspects of liability would have to be explained to potential users of the technology and that no information should be withheld from public disclosure. Stone (90), supported by Dunn (96) pointed out, however, that farmers do not necessarily use economic or agronomic criteria in decision-making. Social processes, he suggested, are important and farmers may adopt new practices or varieties for cultural reasons, citing the case of adoption of cotton types in Andhra Pradesh, where strong local preferences for cotton cultivars had little or no agronomic basis.

7.2.2.3 Misinformation and the quality of information required by the rural people

Participants stressed the need for the public to have access to unbiased information but many complained that misinformation (either for or against GMOs) was a problem.

The importance of education and access to good quality information was emphasized in several messages. For example, Kosalko (16) considered education to be an essential first step in any new proposed change, but said it was important to first ask why it was desired to educate the rural people on this particular issue, echoing the sentiments of Ferry (3). Sitengu (39) and Bridges (72) thought that education of rural people needed to be prioritized: without education, they "will go with the wind and follow the opinions of their informants rather than making their own decisions" (Sitengu, 39). Nishio (43) felt that "educating the masses" was currently unrealistic and that educating political representatives and their staff seemed a good strategy.

The standard of the information required by rural populations was defined by participants in a variety of ways: it should be quality, unbiased, factual and objective (e.g. Mkula, 12; Newman, 5, 24; Nasar, 14), although Stone (33) argued that the definition of "correct" or "objective" information was a complex problem that merited more study. Hogg (87) suggested that the media should be provided with data that is "unbiased, consistent and relevant", through fact sheets prepared by national/regional bodies. McNeely (76) said that the key factor was provision of objective information from a credible source (or sources), in languages relevant to local people, although Shantharam (48) was not convinced that "anyone can provide so-called objective and impartial information on biotechnology today". Ferry (27) also argued that unbiased and rigorous information on the consequences or relative advantage of GMOs was not yet available. According to McNeely (76), developing countries often seemed to be under considerable pressure from parties with an interest for or against GMOs. He argued, supported by Steane (79), that a government agency would probably be the most appropriate intermediary for information provision and would be likely to be trusted by the local people, when its credibility had been proven over time. Ramirez (57), however, believed that governments and universities in many countries had yielded to the influence of the biotechnology industry and had lost their independent public service role. Mayer (66) felt that, although there was danger of a conflict of interest, companies could provide good information and training opportunities to farmers, proposing also the establishment of alliances between governments and companies in extension services. Both Newman (84) and Ashton (100) had concerns about such alliances.

Soleri (30) commented that proponents and opponents of GM crops often speak on behalf of farmers whose own voices are seldom heard. Zidana (17) suggested that, in Malawi extension agents engendered considerable trust among the rural people and that more investment in them was merited. He emphasized that they needed to be well informed on the scientific and ethical issues of GMOs. Farnese (22) agreed with him that extension agents had a critical role to play in providing balanced, unbiased information on GMOs. Huyer (104) also advocated including women in extension teams to facilitate discussions with women farmers. Seth (45) suggested that increasing privatization of science meant that developing countries were not always able to obtain unbiased information. In a similar vein, Farnese (22) wondered what the implications of the shift of extension services from the public to the private sphere might be.

Several messages dealt with the consequences of providing poor quality or inappropriate information, illustrating also the perception of many participants that misleading information on GMOs abounds. For Nasar (14), pressure groups take opposite and, at times, fundamentally extreme views and "the casualties are the real issues and facts about GMOs. Public participation,

unless based on informed decision-making, will only complicate the process". Vallings (26) complained that farmers are targeted by those with vested interests and that the unbiased information that farmers and policy-makers need for decision-making is not freely available. Hogg (87) noted that "it is easy to 'scare' the public or lull them into a 'sense of security'. It is so much more difficult to 'inform and educate'". Olutogun (37) urged that scare-mongers should not be allowed to provide spurious information about GMOs to the public without being challenged, while Kambikambi (29) bemoaned the "misinformation" provided at a national GMO consultation in Zambia. Infante (4) claimed there is a demagogic campaign against GMOs, especially in Venezuela, while Jarrín (32) criticized the lack of proper objective information in Ecuador. Djoulde (21) described a case in Cameroon where negative information about a new sorghum variety was prematurely released to the public and which caused panic and prejudice against new technologies, illustrating the importance of appropriate dialogue with the public. Paz (74) wrote that the rural people in Brazil had been provided with misleading information about the advantages of GMOs and that rural people there were unaware of the consequences of adopting GMOs. Claparols (77) maintained that developing countries were in the grips of interest groups who wished only to sell GMOs. Conflicting information about spraying Bt cotton in India had, according to Stone (33), exacerbated breakdown of the social process of skilling (i.e. farmers learning how a technology works and integrating it into farm management strategy). Nasar (14) suggested that the public's suspicion of being exploited when Bt cotton was introduced to India had led to persistent suspicion about GMOs in general, something which had made meaningful participation of the public in decision-making difficult.

7.2.2.4 Scepticism about the public participation process

Some people were sceptical about the whole subject. For example, Blaney (46) was sceptical about the eventuality of public participation in decision-making on GMOs in developing countries, asking "how can we implement a public participation in this decision making process when it was never or scarcely done in the developed and 'officially' democratic countries?", arguing also that there was insufficient public participation generally in health and nutrition projects being implemented in developing countries. In a similar vein, McNeely (76) suggested that the 800 million hungry people in the world have generally little influence on formulation of agricultural policy and would therefore be unlikely to be involved in decisions on GMOs, noting that "the rural poor most in need of better agricultural support are usually the last to be consulted", echoing the comments of Benedito (2).

Even if such a process was to take place, some people were sceptical about the outcomes. For example, Mbassa (98) was pessimistic, arguing that the rural people might be involved in the process and make decisions on GMOs, but their decisions might not be honoured, so the process would be just pretence or hypocrisy. Hogg (42) also highlighted that if the people are involved then they must be listened to as, too often, "communities are asked to share opinions but they are not really paid attention to, and their concerns may even be totally ignored". Beitel (69) also emphasized that any well-intentioned dialogue must be accompanied by choice, with the existence of a meaningful alternative, and that farmers should be able to exercise their choice in a meaningful manner. Goven (59) supported by Ferry (67), warned that a public participation exercise could become a sham if the organizers assumed that the right answer was already known and that "public persuasion" rather than "public participation" was sought. For Ramirez (57), the key was having a legitimate convenor at the country level that was not seen to have a vested interest. Given the complexity of the GMO debate and the difficulties in communicating with the rural poor, Ferry (3) suggested that involving the rural people might be just a hypocritical exercise or one with a hidden objective.

7.2.2.5 Appropriate channels for communicating with the rural people in developing countries

Numerous suggestions were made by participants as to how to obtain information to and from the rural populations in developing countries (e.g. Krishna, 1). It became apparent from the suggestions that facilities differ enormously within and amongst countries. Interestingly, a self-described peasant farmer from Bangladesh, Zakir Hossain (23), contributed an e-mail to this conference. His contribution must, however, be regarded as an exception because the vast majority of the rural poor in developing countries currently does not have access to e-mail or other modern ICTs (information and communication technologies) and does not write fluent English. Müller (115) noted that this conference had been very interesting for the very select public with access to the internet. Even standard communication technologies such as telephones, mentioned by Protz (113) in the context of hot-lines for communicating information, would only be feasible in a relatively few circumstances. The cyber centres mentioned by Huyer (104) as a means of communicating with rural populations would likewise not be broadly applicable today. Some of the barriers to communication are more basic than restricted access to modern media. Literacy, as pointed out by Khouma (8) for Africa, is often weak in many rural societies (e.g. Ahmed, 109). This being so, many written means of communication, including newspapers and fact-sheets, suggested by Hogg (87), and pamphlets (Krishna, 18), have reduced impact. Apart from the question of access, Nasar (14) also noted that deprived rural communities have little time for the library, television, radio and printed media and likewise, "computer, internet, video and cinema are yet to be used by the majority in the remote countryside".

Although Torres (38) pointed out that it was a basic communication principle that "there is no single best medium", many contributors thought that modern mass media, including television and radio, could be used to great effect to communicate information to rural populations. Ahmed (109) advocated their use when illiteracy rates are high. The importance of radio, in particular, was highlighted by many participants (e.g. Krishna, 1; Chibisa, 9; Keter, 34; Zidana, 51). For example, Dakunimata (73) and Deo (91) suggested it was a particularly suitable medium for communicating information to the rural populations of the scattered islands of Fiji, where door-to-door contact (mentioned by Krishna, 1; Kosalko, 16; Mbassa, 101; Edema, 106, among others) would not be practicable.

There was considerable support in the conference for the idea of communicating with rural populations through existing structures such as the extension services. Zidana (17) favoured this means for Malawi where extension planning areas, each with staff of sector-specific expertise housed in the villages and thus part of the rural communities, represented platforms for providing information on new technologies in agriculture. Farnese (22) pointed out that in Canada, although extension agents played a key role in communicating unbiased, balanced information, their numbers had been significantly reduced. Zidana (51) supported by Brown (52), proposed that extension service staff could deliver information materials to radio stations for dissemination by radio at a given time. Dunn (64) suggested that extension, instead of being an add-on discipline to hard science, should be included in the biotechnology research from the beginning. In a similar vein, Harris (83) suggested that "science should itself be produced through a discursive or dialogic process involving public social decision makers". Ezeronye (111) argued that communication of information to the rural people would benefit greatly from the involvement of representatives from many disciplines, including biotechnology experts, researchers, environmental scientists and lawyers, and that an international body like FAO could help in this endeavour.

Torres (60) saw a role for development communicators, who could provide guidance on what information should be shared, "with whom, with what expected behavior outcome, through what channels, and at what cost". She said that, in this context, it was essential to "know the stakeholders" as they cannot all be lumped together into a "faceless public". One way of knowing the stakeholders, proposed by Torres (38) and Protz (112), was to use KAP (knowledge, attitude and practice) surveys, the results of which allow "an understanding of the differences among rural people so that effective communication strategies and participation approaches can be designed".

The need to use local languages to communicate information effectively was stressed by many contributors (e.g. Chibisa, 9; Krishna, 18; Vallings, 26; Zidana, 51; Mesghenna, 55). Khouma (8) said they had translated some GMO booklets into local languages in Senegal, while Deo (91) promoted the use of local languages through the radio for information dissemination.

Protz (107) drew attention to the circumstances in the Caribbean, where she said that a range of factors, including race, class, gender, age and religion, needed to be considered in communicating with rural communities. She suggested that civil servants, NGOs, extension officers, teachers, health workers and staff of farm supply stores could play a useful role in communicating information. She also pointed out that, in the Caribbean, rural men and youths might be contacted through rum shops, while women gather more at churches, clinics, schools and markets. Women's groups and teachers were also mentioned as being important in Kenya (Keter, 34) and New Zealand (Vallings, 26), among other countries. In some circumstances, religious leaders could play useful roles in providing and communicating credible information to rural communities according to Mesghenna (55) and Protz (107, 112). Other means of communication, in harmony with local traditions, included staging drama (Ahmed, 109; Protz, 113) and making use of model farmers (Mesghenna, 82), train-the-trainers programmes and imbizos (Ashton, 100), community elders (Mesghenna, 55) and farmer organizations (Rakotonjanahary, 97) to promote farmer-to-farmer communication. In summary, as Steane (81) noted, methods of communication of information will depend on the country and its culture.

7.2.2.6 Costs of public participation

Involving the rural people in decision-making on GMOs can be difficult and expensive (e.g. Obura, 35). Even for developed countries, getting information to and from the public can be costly, as indicated by Müller (115), who gave an example from the Canadian debate on GM wheat. She pointed out that Canada has good communication systems, is democratic and does not have a problem of illiteracy and yet considerable time and money was needed for farmer organizations and environmental groups to influence the debate. Sitengu (39) suggested that the costs of involving rural people might be too large in the presence of limited resources in a developing country and might not be prioritized when pressing issues of debt repayment, health and education had to be considered. Kambikambi (29) pointed out that if the public needed to be educated to allow them to participate effectively, it would increase the costs of the GM product to be put on the market. Krishna (36) suggested, however, that the costs were not high when compared with the expense of developing GM products. Chibisa (65) argued there might also be a cost to not including rural people in the decision-making process (e.g. lack of public confidence in regulatory mechanisms).

Hogg (54) suggested that if countries were prepared to work as regional units, then money and other scarce resources could be saved. Citing the case of the Caribbean countries, she suggested that they lack economies of scale and could also speak with a greater voice as an economic, strategic planning and policy-making regional block. Lin (68) mentioned a regional initiative called the African Policy Dialogues on Biotechnology that, although not addressing the

rural population directly, aims at national and regional consensus. Ramirez (57) said there was a need for national and regional fora on a global scale to continue what FAO had begun through this e-mail conference.

Many contributors supported a shared responsibility for the costs. Zidana (51) considered that as a developing country government is responsible for its citizens, it is up to the government to seek funds for such initiatives, which would usually come from development projects funded by developed countries. Birner (116) thought that the government or international donors should bear the costs. Steane (81) felt that costs should be borne by the government, the companies involved and "whoever else is directly involved in the planning, operating and scientific evaluation and reporting of results". Hogg (42, 87) thought that the financial burden should be shared amongst GMO producers, local and national governments and non-governmental agencies. Chibisa (65) suggested the government should contribute, together with NGOs and farmer organizations. Torres (38), however, advocated that those selling an innovation should bear the costs associated with public participation and Ahmed (109) also believed that the GMO producer should pay.

7.2.2.7 International agreements/guidelines and public participation

Several contributors raised issues of public participation in connection with international agreements/guidelines on decision-making and GMOs. Lin (10, 13, 85) pointed out that many developing countries have signed international agreements (such as the Convention on Biological Diversity, the Cartagena Protocol on Biosafety and various World Trade Organization agreements) that are relevant to GMOs. He (10, 13) argued, supported by Muchugi (19) and Krishna (36), that national autonomy has been limited by signing these agreements and this might compromise the outcomes of an eventual national debate and public decision-making process on GMOs, leading to disillusionment with the consultation process. He emphasized that, before developing regulatory frameworks and approving GM products, development of a national biotechnology policy, based on public consensus and decision-making, should be the priority. Krishna (36) highlighted the importance of three international instruments relevant to public participation and GMOs that were mentioned in the Background Document (i.e. the Aarhus Convention, the Cartagena Protocol on Biosafety and Codex principles on risk analysis), but noted that some countries had not made provisions for these public participation issues in their national legislation. Paz (74) suggested that the Government of Brazil had shown little interest in applying the Codex principles on risk analysis. Krishna (1) also noted the relevance of the Rio Declaration to this area.

Oliva (20) provided details on the Aarhus Convention, stating that decisions on GMOs were currently excluded from the binding requirements on public participation, but that discussion of various options for a legally-binding approach in the field of GMOs was ongoing. (Note, after the e-mail conference was finished, at the 2nd meeting of the Parties to the Aarhus Convention in May 2005, an amendment to the Convention was adopted, extending the rights of the public to participate in decision-making on GMOs). She also discussed the Cartagena Protocol on Biosafety, writing that, although of more limited application than the Aarhus Convention, it does contain important public participation provisions.

7.2.3 Participation

The conference ran for four weeks, from 17 January to 13 February 2005. There were 508 subscribers to the conference, of which 70 (i.e. 14 percent) submitted at least a single message. There were 116 messages in total. Contribution to the conference was global, with

24 messages (21 percent) coming from Europe, 23 (20 percent) from Africa, 20 (17 percent) from North America, 17 (15 percent) from Latin America and the Caribbean and 16 each (14 percent) from Asia and Oceania. Contributors were living in 35 countries, the largest numbers of messages coming from people in the United States, Australia, India, France, Canada, Jamaica, Spain, Kenya, the Philippines and the United Kingdom, respectively. Participants living in developing and developed countries contributed equally to the conference in terms of the numbers of messages submitted. The majority of messages came from people working in universities (37 percent), as independent consultants (22 percent), in research centres (20 percent), for non-governmental organizations (11 percent), farmers' organizations (6 percent), in government ministries (3 percent) and the UN (1 percent).

7.2.4 Name and country of participants with referenced messages

Ahmed, Kasem Zaki. Egypt
Ashton, Glenn. South Africa
Beitel, Karl. United States
Benedito, Vagner Augusto. Brazil
Bhatia, C.R. India
Birner, Regina. United States
Blanchfield, Ralph. United Kingdom
Blaney, Sonia. Canada
Bridges, Anne. United States
Brown, J. Lynne. United States
Burke, Derek. United Kingdom
Chibisa, Gwinyai. Zimbabwe
Claparols, Javier. The Philippines
Cuming, David. United Kingdom
Dakunimata, Ruci. Fiji
Deo, Permal. Fiji
Djoulde, Darman Roger. Cameroon
Dunn, Anthony. Australia
Edema, Olayinka. Nigeria
Ezeronye, O.U. Nigeria
Farnese, Patricia. Canada
Ferry, Michel. Spain
Goven, Joanna. New Zealand
Harris, Craig. United States
Hodges, John. Austria
Hogg, Bridget. Bahamas
Hossain, Zakir. Bangladesh
Huyer, Sophia. Canada
Infante, Diógenes. Venezuela
Izquierdo, Luis Plácido Ortega. Cuba
Jarrín, Galo. Ecuador
Kambikambi, Tamala Tonga. Zambia
Keter, Carol. Kenya
Khouma, Mamadou. Senegal
Kosalko, Sylvia. United States
Kosky, Rafael Gómez. Cuba
Krishna, Janaki. India
Lin, Edo. France

Mayer, Jorge. Germany
Mbassa, Gabriel. United Republic of Tanzania
McNeely, Jeffrey. Switzerland
Mesghenna, Yoel. Eritrea
Mkula, Charles. Malawi
Moghaddam, Atefeh Fooladi. Iran
Muchugi, Alice. Kenya
Müller, Birgit. France
Nasar, S.K.T. India
Newman, Julie. Australia
Nishio, John. United States
Obura, Mallowa Sally. Kenya
Okello, Paul. Italy
Oliva, Maria Julia. Switzerland
Olutogun, Olusanya. Nigeria
Paz, Sezifredo. Brazil
Protz, Maria. Jamaica
Rakotonjanahary, Xavier. Madagascar
Ramirez, Ricardo. Canada
Seth, Ashok. United Kingdom
Shantharam, Shanthu. United States
Sitengu, Jackson. Zambia
Soleri, Daniela. United States
Steane, David. Thailand
Stone, Glenn Davis. United States
Torres, Cleofe. The Philippines
Vallings, Zelka. New Zealand
Zidana, Hastings. Malawi

CHAPTER 8.
FINAL CONSIDERATIONS

The main subjects of the six conferences reported in this book were quite distinct and the people who sent messages were, as a consequence, generally different in each conference. The conferences covered issues as diverse as marker-assisted selection in livestock; use of traditional fermented foods in West Africa and India; the ecological impacts of GMO gene flow; the appropriate channels to use for communicating GMO information with rural populations, etc. Nevertheless, a number of important observations can be made from a global consideration of the six conferences.

Firstly, there is a large demand for good quality, science-based, unbiased information regarding agricultural biotechnology in developing countries. Between 350 and 630 people subscribed for each of the conferences and very few of them unsubscribed once the conferences began. All the materials from the conferences (background and summary documents, e-mail messages) were also made available on the web (www.fao.org/biotech/forum.asp) and this has consistently been one of the most popular areas of the entire FAO Biotechnology web site. While the impact of the Forum material cannot be easily gauged, searches on Google indicate that they have been widely disseminated and used as reference material for numerous publications. It is also known that on at least a couple of occasions, the reports have been used as background information for development of national biotechnology policy in specific developing countries. The need for reliable good quality information was also highlighted during the conference on public participation in decision-making regarding GMOs (Chapter 7), where many participants complained that misinformation (both for and against GMOs) abounded and where the need for access to unbiased information to enable effective participation was emphasized. These observations from the Forum are in line with FAO's experiences in implementing a range of technical assistance projects in biotechnology and biosafety in developing countries, where participants in dozens of workshops, training courses and other meetings worldwide have consistently called for more and better information on all aspects of biotechnology. Note, this demand for information is valid for GMOs, but also for non-GMO biotechnologies, as shown by the large number of people (630) who subscribed for the marker-assisted selection (MAS) conference (Chapter 5).

Secondly, people in developing countries have a great interest and willingness to participate in dialogues on this subject. Despite the fact that there are tremendous global inequalities in access to the Internet, over half of the 608 messages posted in the conferences came from people living in developing countries. Messages were received from all of the world's major geographical areas, with 24, 21, 21 and 18 percent coming from Asia, Europe, North America and Africa respectively and the remaining 16 percent from Latin America and the Caribbean and Oceania. They came from people living in 61 different countries who were working in a wide range of different areas (e.g. as researchers, students, university professors, independent consultants and government, UN or NGO employees). Again, this interest in participation that was observed in the Forum is consistent with FAO's experiences in the field.

Regarding GMOs, there was no evidence of the intensity and polarization of the debate declining. This was shown by the degree of active participation in the three GMO-specific conferences and the considerable attention given to GMOs in the two conferences covering all

agricultural biotechnologies. Primary focus of the GMO debate continues to be on crops and there was much less debate about GM animals, fish or forest trees. This is likely to change in the future if there is significant commercial release of GMOs in these other sectors. One of the key unresolved points of conflict in the debate, which emerged in two conferences (on gene flow and on regulation of GMOs), is whether GMOs are fundamentally different from conventionally bred organisms, a point which has implications, *inter alia*, for the risk assessment and regulation of GMOs.

Regarding non-GMO biotechnologies, on the other hand, there was general agreement about the positive role that they can play in developing countries. In addition, they should complement other more conventional technologies. These points emerged clearly in the conference on research (Chapter 3) and were illustrated with specific examples in two later conferences, where there was a call for MAS to be used in conjunction with conventional plant and animal breeding programmes (Chapter 5) and where it was recognized that advanced biotechnologies, such as use of molecular typing to characterize micro-organisms, could be successfully applied to traditional fermentation processes in developing countries (Chapter 6).

For both GMOs and non-GMO biotechnologies, intellectual property rights were perceived as an important issue, one that was raised in four different conferences. Their consequences were generally seen as negative, with concerns expressed that they might for example, act as a constraint to biotechnology research in developing countries.

Finally, the conferences indicated that many developing countries currently lack the resources and capacity to minimize the risks and maximize the benefits of agricultural biotechnology. The specific needs expressed in the different conferences for capacity building activities in regulation of GMOs, in applying biotechnology in food processing and in the use of molecular markers for genetic improvement, convey a more general need for a comprehensive programme of capacity building activities in agricultural biotechnology for developing countries.

BACK COVER TEXT

This book presents the background and summary document from a series of six moderated e-mail conferences hosted by the FAO Biotechnology Forum from 2002 to 2005, relating to agricultural biotechnology for the crop, forestry, animal, fisheries and agro-industry sectors in developing countries. Three of the six conferences focused on genetically modified organisms (GMOs), dealing with gene flow from GM to non-GM populations; regulation of GMOs; and participation of the rural people in decision-making regarding GMOs. Two conferences covered the entire range of biotechnology tools (including GMOs), dealing with the role and focus of biotechnology in the agricultural research agenda and, secondly, applications of biotechnology in food processing. The remaining conference dealt with molecular marker-assisted selection.