THE EU-U.S. BIOTECHNOLOGY CONSULTATIVE FORUM

FINAL REPORT

DECEMBER 2000

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FOREWORD

President Prodi of the European Commission and President Clinton of the United States agreed, in May 2000, on the launch of the EU-U.S. Biotechnology Consultative Forum, an independent group of experts representing diverse views on the two sides of the Atlantic. The Forum was asked to report to the next EU-U.S. Summit meeting in December 2000.

The EU-U.S. Biotechnology Consultative Forum was accordingly formed in late June 2000 as a group of 10 experts from the U.S. and 10 experts from the EU drawn from different areas related to biotechnology (including scientists, lawyers, consumer representatives, specialists on ethics, farmers, environmentalists and people in business). The list of participants is annexed to this report. The Forum met four times from September to December 2000.

The charge to the Forum was:

> "[to] consider the full range of issues of concern in biotechnology in the United States and the European Union, most of which relate to the use of modern biotechnology in food and agriculture. The forum will provide a consensus report reflecting their views and assessments of the benefits and risks. This should include factors such as health, safety, economic development, food security, and the environment. Cross-cutting issues such as the role of science, the ethical dimension, consumer information, public perceptions, risk analysis, including the use of precaution in the U.S.' regulatory process and the EU's precautionary principle, and, intellectual property rights, including patenting, should also be considered."

The group decided to focus on the use of biotechnology in the context of agriculture and in particular on biotechnology with respect to plants. The debate on animal biotechnology has, of course, many aspects in common with that on plant biotechnology but is much more complex and was not addressed by the Forum. In this report, the term biotechnology should be understood to be restricted to genetically modified crops or foods and not crops or foods produced by other biotechnology approaches.

The Forum decided to concentrate its report on two separate but interrelated aspects of the present and future uses of biotechnology: the regulatory process and potential uses of the technology as one important component of more general strategies for attaining global sustainable agriculture.

No person is an expert in all the various aspects of the potential use of biotechnology, certainly not the participants of the Forum. Accordingly every participant involved in the drafting of this report is, in some sections at least, straying outside his or her field of professional expertise. Each participant would have written the report somewhat differently, with different emphasis, had he or she written it as a personal statement. Thus this report is a collective effort and represents a consensus view.

1. INTRODUCTION: THE CONTEXT

Modern biotechnology holds the promise of dramatic and useful advances in some of the areas of greatest challenge for humankind during the 21st Century. Like all new technologies, it also holds risks, both known and unforeseen. In the absence of broadly acceptable and open consultation processes, discussion about the issues has become polarised.

The Consultative Forum has decided to concentrate its recommendations on the use of biotechnology in food and agriculture. Thus other potential applications of biotechnology, for example, in forestry or aquaculture or medicine, have not been covered in this report. The Consultative Forum also concluded that the challenges that this new technology presents could only be understood when set in a broader context. This context is defined by four elements.

1.1. The first element: Parallels from History

The societal debate on biotechnology parallels other social debates about the appropriate use of new technologies. Biotechnology, like many other technologies, offers both positive, intended, benefits and potential negative and often unforeseen consequences. Because these consequences may have both social and technical contexts, judgements about risk cannot be reduced to scientific assessment alone. There are legitimate concerns for which science, at least natural science, cannot provide answers. Such concerns may cover issues of distribution of power and influence, risks of concentration of knowledge and expertise to a few very large corporations, relations between different social groups and classes, between ethics and social values, between large corporations and small companies, between small-scale subsistence farmers and family farmers and the agro-industrial complex, between developed and developing countries. As is true of all technologies with the potential for far-reaching benefits, the societal consequences are far reaching as well.

Technological developments frequently require large-scale investments in research and development as well as in production technologies. When they also offer the possibility of considerable immediate benefits and revenues the tendency - or even temptation - to underestimate potential longer-term risks and dangers is there; in particular where materials are unfamiliar and appropriate assessment and consultation processes are lacking. Moreover, when the pressures to recover investment costs are present, they may be accompanied by the urge to rush to markets. However, the choice should never be full speed ahead and repairs afterwards. Surely, the best course is to set up processes and mechanisms for strong, effective and forward-looking governance in advance.

The scientific world has a responsibility for the public good. The role of science is to serve humankind. Scientists have the obligation to evaluate possible long-term consequences of new technologies and to inform policy makers honestly. Within the scientific community, opinions can differ significantly e.g. related to potential risks and benefits associated with new technologies. These differences in opinion frequently occur in areas where there is a lack of substantial scientific data and evidence, often more as personal interpretations disguised as scientifically validated statements. This information reaches the citizen through the media, which uses many different sources, for example industry and interest groups, as well as scientists, thus making interpretation more difficult. We must not forget that, in the end, it is the public that has to decide whether or not to accept a new technology.

1.2. The second element: Globalisation

The biotechnology debate is also affected by the coming of globalisation, produced by the spread of inter-linking economic and technological developments all around the globe. The power and the capacity of biotechnology to innovate are accelerated by the new information and communication technology. The marriage of biotechnology and information and communication technology speeds up everything, including the rate at which products are being brought onto the market. But it also could facilitate monitoring and communication and transparency in the risk/benefit discussions.

The impact of biotechnology and its applications and regulation is global, extending well beyond the frontiers of the European Union and the United States. However, globalisation does not automatically take care of equity or social justice. There is one global economic space, with impressive power to create global wealth, but there is not one single social space, and there is no mechanism to ensure global equity.

Peoples and nations, though connected more closely than ever before, are still in different stages of development. The generation of wealth across the world is heavily dependent upon the access to novel technologies and sharing of knowledge. Inequalities of capacity - lack of trained scientists for example or lawyers familiar with the intricacies of the international intellectual property system - perpetuate inequalities of societal wealth and well being.

Historically, meeting the challenge of combining wealth-creation with the equitable development and self-determination of people was a domestic challenge for individual nations; but now, it crosses national boundaries and is truly global - another reason for serious reflection on governance at all levels, national, supranational, inter-governmental and global.

We should not burden biotechnology with the full weight of these broader problems, but as the broader problems are the cumulative effect of many different forces, we should not make decisions about biotechnology out of context. How biotechnology helps or harms the world, contributes to equity or reduces it, should be part of decision making.

1.3. The third element: the Power of the Citizen

The biotechnology debate is also a debate over the role of the citizen. Modernity and the spread of information and communication technology empower the citizen. Citizens in the EU and the U.S. are increasingly well informed through the increased flow of information over the Internet and by the global media and want to make informed choices and participate in the decision-making process. This trend, in turn, strengthens the role of non-governmental organisations (NGOs), both within and between countries.

Democratic societies should be based on confidence in public institutions. So the transparency of decision-making processes and meaningful participation - involving all stakeholders - are matters of rapidly increasing importance. Lack of trust jumps across seemingly unrelated areas of regulation and policy.

The Consultative Forum has looked carefully at the role of the citizen in relation to both governance and regulatory processes. Pressures will increase for more inclusive agendas and for the communication of full and accurate information about the issues in plain language, understandable to lay people. The issues associated with labelling genetically

modified (GM) foods, for example, must be understood in relation to this fundamental aspiration in modern society.

1.4. The fourth element: Safeguarding the Future - sustainable development

The biotechnology debate is also a debate on globalisation and about sustainable development. Scientists have just begun to understand how immense the challenges that protecting the global environment in general and biodiversity in particular really are. The debate on the uses of modern biotechnology and its potential impact on sustainability and biodiversity should be seen against this growing awareness of the fragility of natural systems.

One of the greatest challenges facing today's world is achieving sustainable agriculture in developed and developing countries. Today the world is not food secure in terms of access to food. Eight hundred million people are undernourished and 200 million children under five years of age are underweight. The world's population will increase by another 1.5 billion within the next 20 years. Improvements in yield on a reliable and sustainable basis will be needed to meet the demands of the growing population. The place of biotechnology and other technologies and approaches in today's world should be seen in this context.

The Consultative Forum endorses public responsibility for global governance of biotechnology as one contribution to sustainable agriculture. All stakeholders should take their share of responsibility in being open with citizens and consumers, establishing transparent and accountable mechanisms for developing accurate information, sponsoring participatory debate, and striving for comprehensive and comprehensible regulatory systems.

2. THE REGULATORY PROCESS

2.1. The Role and Structure of Regulation

Regulation is a means by which governments seek to gain the benefits and ameliorate the potential negative consequences of a market economy. The U.S. and EU differ in the particulars of how they approach regulation for agricultural biotechnology products. Nevertheless, we share the same goals of ensuring human and environmental safety and we agree that regulatory processes on both sides of the Atlantic should meet basic, minimum standards. Regulatory processes should be about the exercise of caution. Current systems are largely designed to address concerns that can be dealt with through science. Of course, science, by its nature, is provisional, always evolving, and not always value-free. The dependence of regulatory processes on science makes them inherently provisional.

Regulation is also influenced directly and indirectly by economic and socio-cultural factors. One very common problem is to allow risk assessment - the prediction of likely hazard - to drift into risk management, where economic and socio-cultural factors may play a role in deciding whether to accept a particular level of risk. As far as possible, these two elements of risk analysis should be kept distinct, although they ultimately inform each other during the risk analysis process.

Comprehensive, rigorous, and credible regulation serves the purpose of minimising the possibility that unsafe products will be sold or that these products or their manufacture will harm the environment. Regulations should thereby increase public confidence in new products and technologies. Thus, regulatory processes must be sufficiently strong to ensure public confidence. This may necessitate strengthening existing regulatory systems for agricultural biotechnology products in some respects.

2.2. General Principles for Adequate Regulation of Agricultural Biotechnology.

An appropriate and effective regulatory system will embody three general principles. It will establish comprehensive and rigorous substantive requirements for ensuring the safety for human health and/or the environment of genetically modified crops, foods and animal feed. It will implement those requirements through a process that is open, transparent and inclusive, and it will provide the public with information to make informed choices or decisions.

This section of the report addresses the specific elements of a regulatory system that should realise these principles, and makes a series of specific recommendations.

2.3. Elements of a Comprehensive and Rigorous System for ensuring Safety of Biotechnology

To ensure that genetically modified food and animal feed are safe, we recommend that all products be subject to a mandatory pre-market examination by the appropriate regulatory authorities and approved for sale only after they are found to meet the standard of presenting a reasonable certainty of no harm. (*Recommendation 1)*

Genes code for proteins, and when a new gene is added to a crop plant, that gene could be adding a new protein to foods derived from that genetic addition. In some cases, other types of substances may also be added to foods, because added proteins (enzymes) result in the alteration of biochemical pathways and the synthesis of new carbohydrates, fats, or other types of compounds. New substances intentionally added to foods, and which are not already consumed safely in food, whether proteins or other compounds, should have to meet the same safety standards that are required for other new substances added deliberately to foods. Regulatory authorities should require that industry submit data or otherwise provide evidence demonstrating that these substances do, in fact, meet the established safety threshold.

The addition of new genetic material might also result in inadvertent changes in the composition of foods derived from biotechnology. As a result, such foods have the potential to differ in composition from their untransformed counterparts. Compositional differences in nutrient levels or natural plant toxins could be of concern, and, genetically modified foods should be monitored for any changes in composition. In general, the standard for the composition of genetically modified foods should be that these foods be comparable in composition to other foods of the same type, and thus are as safe as and not significantly less nutritious than other foods of the same type. Regulatory authorities should require that industry submit appropriately comprehensive data to demonstrate that genetically modified foods are comparable in composition to other foods of the same type.

2.3.1 Risk Assessment.

Competent risk assessment as a regulatory tool in judging the safety of genetically modified foods should be further enhanced. The EU and U.S. assign risk assessment to different groups. The EU generally relies on independent committees of scientists while the U.S. assigns this function to civil servants. We believe that it is less important "who" does the work than that the function be specifically delineated, and competently executed.

The individuals charged with risk assessment should be well qualified to make decisions in the area under review, be individuals of the highest integrity, and meet stringent requirements for public disclosure of actual and potential conflicts of interest. (*Recommendation 2*)

2.3.2 Improving Hazard Identification.

The present regulatory process would be strengthened by additional scientific information and testing methodologies on which to base regulatory reviews.

More public funds should be invested in basic research that addresses safety concerns. (*Recommendation 3*)

The identification of any gaps in scientific understanding should be defined as far as possible, made a mandatory part of regulatory reviews, and addressed.

Specialists and stakeholders (e.g., social scientists, ethicists, representatives of civil society, in addition to those usually included such as toxicologists, nutritionists, molecular biologists and plant breeders) who are responsible for the regulatory process

should have the authority to make recommendations for funding relevant research to fill gaps uncovered in regulatory reviews.

2.3.3 Ensuring independent and adequate academic scientific research

In considering the role of publicly funded scientific research in supporting the development and evaluation of biotechnology, the Forum expressed concern that scientists in academic research institutions are increasingly seen to be serving the goals of industry rather than the public at large. Public policies that oblige academic scientists to collaborate with industry in order to secure public funding for research may mean that the independence of scientists who are employed by academic institutions comes into question. Shortage of public research funds encourages academic scientists to accept research funding from private sources, resulting in increased private influence. In addition, legislation that encourages public institutions to seek intellectual property protection on the results of basic biological research, may stimulate undesirable changes in the kind of publicly supported research being done, how the results of such research are made available to the research community and used in the public interest.

We recommend that consideration be given to changes in public policy regarding public funding for basic research that would ensure the existence of a vigorous and independent public scientific research enterprise. (*Recommendation 4*)

2.3.4 Substantial Equivalence

Applying the concept of substantial equivalence entails comparing the biotechnology food with its closest traditional counterpart in order to identify any intended and unintended differences that then become the focus of the safety assessment**.** This comparative approach should take into account all potentially relevant data, including agronomic, genetic and chemical aspects. Unfortunately, the concept of substantial equivalence is often misunderstood as being a safety assessment in itself or as a means for characterising hazard**.** It is neither of these things.

The concept of substantial equivalence should only be used to structure a safety assessment. The fact that a biotechnology food is held to be substantially equivalent to a conventional food should not be taken automatically to mean that it needs less testing or less regulatory oversight than "non-substantially" equivalent biotechnology foods. The concept of substantial equivalence should be improved by the development and application of new techniques, which can help to identify unintended and potentially harmful changes. (*Recommendation 5*)

Forum participants agree that proteomics and metabalomics, are novel and promising new technologies that could upgrade the concept of substantial equivalence. This is because of their potential ability to identify any harmful changes in metabolites and other constituents of genetically modified food products. Further development, evaluation and use of these technologies could provide valuable tools for assessing differences between new transformants and their non-modified counterparts.

2.3.5 Regulatory Actions to Assess Environmental Impact.

The regulatory process should address environmental effects of GMOs both at the field test stage and before products are commercialised.

Risk/benefit considerations should not be introduced until the basic threshold of reasonable certainty of no harm to human health has been reached. (*Recommendation 6)*

Human health concerns will not usually be relevant at the field test stage. However, before commercialisation, a genetically modified organism (GMO) must be determined to be safe for human consumption and the regulatory process should address its possible environmental effects. Because of the possibility that a GMO cannot be contained once it is released, the potential environmental effects of a GMO release should be considered permanent. Although most crops could not persist without human assistance, the genes present in those crops may persist indefinitely through outcrossing with wild relatives of the crop species. However, many advocates of agricultural biotechnology believe that the majority of potential applications do not entail significant outcrossing risks because the likelihood of outcrossing is very low, or because the spread of modified traits will not be favoured by natural selection.

The environmental effects of the use of GM crops in agriculture should also be factored into regulatory decisions. Many people believe that biotechnology offers potential environmental benefits that should be weighed against possible risks. For instance, the ability to engineer herbicide resistant plants may allow the use of relatively environmentally benign agrochemicals and facilitate the implementation of no-till agriculture. Pest and pathogen resistant crops may decrease the application of indiscriminately toxic chemicals that kill beneficial insects and harm other non-target organisms. On the other hand, many other people believe that current GM crops will not generally ease environmental problems caused by modern agriculture. For example, herbicide-resistance crops entrench farmers' reliance on chemical weed control, rather than encouraging more diverse weed control tactics. Pests may quickly evolve resistance to GM pest-resistant crops, making them ineffective. The evolution of resistant pests to GM Bt crops may even cause traditional Bt insecticide sprays, relatively safe pesticides used by both conventional and organic farmers, to lose their efficacy against certain pests.

Because of the complexities of environmental issues and the many hundreds or thousands of potential applications of the technology, this issue should be decided on a case by case basis. As experience grows, more generic principles can be formulated. An application that may be beneficial in one region may be potentially deleterious in another.

2.3.6 Risk-Benefit equations

We recommend that once the basic threshold of human safety has been met it is also appropriate to consider, on a case-by-case basis, the potential risks and benefits of each new product given the health and nutritional status of the people and the ecological and agricultural systems in a particular region of use. (*Recommendation 7)*

When weighing risks and benefits, the effects of introducing genetically modified products should not be compared solely to the status quo (e.g. present pesticide use), but also to other potential alternatives (e.g. bio-intensive pest management systems).

Risk assessors should not have the responsibility of balancing risk against benefit. This is the responsibility of risk managers together with other interested parties. Both risk assessment and risk management should take account of circumstances in which the risk of non-compliance with regulatory restrictions is high.

2.3.7 Traceability and Monitoring

Mandatory monitoring should be considered carefully whenever unanswered questions regarding specific health, environmental and/or safety concerns are raised about a new product approved for marketing. It may also be required when companies wish to make claims for benefits from the use of genetically modified crops or foods.

Effective monitoring requires the ability to trace the presence of genetically modified products. At the present time, no obvious health effects have yet been identified with crops or foods that have been approved. Anticipated effects are likely to be of low-level, evident only after long periods of use among especially at risk population groups, difficult to detect with certainty and thus, monitoring for such effects is likely to be costly to implement. However, the capacity to trace these products is essential to ensuring consumer choice, understanding the causes and establishing liability in cases of unanticipated negative effects, ensuring effective product recall should a safety problem arise, and, in some cases, validating benefit claims.

Governments should undertake to develop and implement processes and mechanisms that will make it possible to trace all foods, derived from GMOs, containing novel ingredients or claiming novel benefits. Before such new products are approved for marketing or when there are significant environmental questions, a detailed plan for mandatory monitoring should be established on a case-by-case basis. (*Recommendation 8*)

Monitoring for environmental effects should occur when there is the possibility of outcrossing, evolution of resistant pests, or other potentially harmful environmental impacts that could not be ruled out during the approval process. Monitoring also may be required to substantiate claims of benefits (e.g., decreases in pesticide use) that are weighed in the approval process.

Test sites planted with GM crops should be monitored closely. When there are questions about the health or environmental effects of large-scale commercial uses of GM crops, these crops should be monitored for these effects. Whether or not monitoring is occurring, licensees should be legally obligated to report to the regulatory authorities any observed adverse effects of GM crops.

2.3.8 Time Limited Licenses.

In the U.S., licenses for Bt maize have expiration dates. During the term of the licenses, licensees have substantial monitoring and other requirements, and individual farmers are limited in the percentage of their acreage that they may plant with Bt maize. In some

areas, total Bt maize acreage among farms is also limited. These limits were instituted primarily as tools to slow the evolution of Bt resistant pests. In the EU, the proposed revised directive regulating approval for deliberate release of GMOs into the environment includes a general ten-year expiration date for licenses.

As noted above, effects on ecosystems are generally poorly understood and may also vary from one location to another. Further aspects that may call for time and acreage limited licenses include uncertain or contentious ethical or social aspects or reasoned doubts about compliance.

There is a need for instruments to enforce effectively the obligation to monitor. For this purpose the limitation of the duration of marketing approvals may be an appropriate instrument. For these marketing approvals, continued approval would be based upon the results of the monitoring. (*Recommendation 9*)

2.3.9 Periodic Review

We believe that much can be learned from the cumulative experience of risk analyses and monitoring activities.

A periodic review of the field should be undertaken every 18-24 months by specialists and stakeholders who are responsible for the regulatory process. Mechanisms should also be developed for a way of debating future applications and the issues that they might raise for interested parties at the earliest opportunity in the process. This will help frame the questions that should be addressed by the risk assessors and risk managers. (*Recommendation 10*)

2.3.10 Liability

Although risk assessment, risk management, and finally monitoring aim at preventing damage to the environment and human health, damage may occur even though all precautionary measures have been taken. Any biosafety framework might therefore be incomplete without addressing potential cases of damage at international level.

The EU and the U.S. should, as a priority, help to elaborate international rules and procedures in the field of liability and redress. (*Recommendation 11*)

2.3.11 The Role of Precaution

Citizens of both the EU and the U.S. have insisted that governments act effectively to reduce the risk of any serious negative unintended consequences resulting from genetic manipulation of plants. Although it is unattainable to prove in advance that each and every action is risk free, preventing mistakes in the future and ensuring public trust in the integrity of decision-making demands precaution.

Precautionary decision-making requires:

- Taking action proportionate to the nature of the potential risk, imposing more stringent restrictions on risks that could have irreversible, catastrophic consequences for future generations than against risks with modest repercussions.

- Applying consistent precautionary limits on activities that incur similar risks.

- Applying more stringent limits on risks that cannot be reversed easily. As the risk of irreversibility rises, mandatory monitoring for specific outcomes should be more easily imposed. Conversely, controls may be relaxed when those concerns prove unfounded.

- Applying comparative analysis, examining the extent to which alternative precautionary requirements advance or detract from relevant societal goals.

- Consideration of the costs that caution imposes. Conserving scarce resources and making the benefits of new technologies available are important societal goals. Therefore the cost that caution imposes on the regulated industry is a relevant, but never the dominant, consideration.

Where there are threats of serious or irreversible damage to the environment or human health, or of potential adverse effects of a genetically modified organism on the conservation and sustainable use of biological diversity, it is particularly important to exercise caution in order to minimise such damage or adverse effects.

When substantive uncertainties prevent accurate risk assessment, governments should act protectively on the side of safety. (*Recommendation 12)*

The open, transparent and inclusive process we describe below is an integral part of precautionary decision-making,

2.4. Elements of an Open, Transparent and Inclusive Regulatory System

Regulatory processes should be and be understood to be, open, transparent and inclusive. These characteristics are inherently appropriate in democratic societies. Moreover, not insignificantly, the inclusion of a wider range of views throughout the process may raise substantive issues that might otherwise have been overlooked.

All regulatory processes governing the approval of products of agricultural biotechnology should be open, transparent and inclusive. (*Recommendation 13*)

Elements associated with openness and transparency include requirements that the regulatory authority:

- Notify the public that a new application for product approval has been received.
- Place all relevant non-confidential scientific information about application in the public record and on the Internet immediately upon receipt.

- Discourage the maintenance of information as confidential, unless confidentiality serves an essential business purpose.

- Accept comments in writing

- Hold formal public meetings and use other mechanisms of public participation to provide the opportunity to offer comments and address regulators and scientists performing risk assessments

- Publish a final decision, the reasons for it and the supporting data

- Accept written comments and consider holding a public meeting before the decision becomes effective.

- Provide an opportunity for the public to note concerns that may arise after the product is on the market.

The regulatory procedure should ensure the opportunity for participation of a wide range of experts and consideration of the broadest possible array of views. The way the public assesses or perceives risk can also involve many complex factors that need to be considered. Examples include whether the risk is voluntary or involuntary, perceived benefits, or whether the risk could cause hidden or irreversible damage. An inclusive regulatory system will also enable decisions to be made in a way that respects societies' judgements of appropriate societal goals, ethical boundaries, and value concerns. Finally, an appropriate regulatory system will recognise and consider the special concerns attending applications that break new ground.

The regulatory procedure, including risk assessment and risk management, should include, apart from those usually included (e.g., toxicologists, nutritionists, molecular biologists and plant breeders), a broad range of specialists and stakeholders (e.g., social scientists, ethicists, representatives of civil society). (*Recommendation 14*)

We recognise that the concerns we raise and recommendations we make in this chapter may delay approvals and incur expense, but a rush to judgement will be self-defeating to both the public and industry. We believe experienced and resourceful regulators can implement these steps in ways that minimise delay while serving the public interest.

2.5 Ensuring the Opportunity for Consumer Choice: Labelling Genetically Modified foods

The Consultative Forum considers it of importance that consumers are informed truthfully and adequately about genetically modified food products. Labelling of genetically modified food products is an important tool in providing consumers with relevant information. The Consultative Forum is aware of various labelling protocols that are either in discussion or already applied. Since there is a flow of food products across the world, standardisation and harmonisation in this area are desirable, but flexibility should be maintained to enable higher standards to be introduced where necessary to meet consumer requirements.

Consumers should have the right of informed choice regarding the selection of what they want to consume. Therefore, at the very least, the EU and U.S. should establish content-based mandatory labelling requirements for finished products containing novel genetic material. (*Recommendation 15)*

Regulatory authorities charged with developing labelling protocols should consider the reliability of detection systems in identifying modified/novel ingredients, and the need to define appropriate minimum levels which would trigger mandatory labelling requirements.

3. BIOTECHNOLOGY IN RELATION TO GLOBAL FOOD SUPPLY AND SUSTAINABLE AGRICULTURE

3.1. Introduction

One of the concerns voiced about agricultural biotechnology is that the marketed crops will have negative social or environmental effects in developing countries. The environmental concerns are largely focused on several risks, e.g., that genetically modified crops could threaten biodiversity by interbreeding with indigenous species and in some way altering the competitive abilities of those species. This, in turn might lead to unforeseen and undesirable changes in species composition. Environmental concerns also stem from concerns that most genetically modified crops are now designed for use in industrial agricultural systems that are viewed by many as unsustainable, and may spread and entrench such systems. The concerns about social effects are largely centred around the possibility that biotechnology will be used to induce farmers to use farming practices that are not sustainable without high inputs and/or a continuing dependence on the multinational corporations. The spectre of modified plants that produce nonviable seeds due to genetic use restriction technology (e.g. "terminator" technology) is an example of possible scenarios that generate considerable concern.

On the other hand, advocates of agricultural biotechnology believe that biotechnology could have a very positive effect on the maintenance of biodiversity and on promoting sustainable agriculture by subsistence farmers. The basic argument is that by improving productivity without increasing inputs, the widespread application of the technology may decrease intrusion of agriculture onto land that currently supports natural ecosystems. Unlike the technology of the green revolution, which encouraged increased use of pesticides and fertilisers, there is nothing intrinsic to agricultural biotechnology that requires increased inputs by subsistence farmers. A good example is plants that are engineered for disease resistance. The effective yield of these plants is increased without any increase in inputs.

In considering both the potential benefits and possible risks associated with biotechnology in the developing world, the Consultative Forum was of the opinion that the application of biotechnology to the problems of the developing world cannot be considered in isolation but must be considered as just one element in a broad programme of measures necessary to address hunger and its underlying causes. The following recommendations were designed to reflect this conviction.

3.2. Global Sustainable Agriculture

Today the world is not food secure in terms of access to food. However, most populations in the developing world are increasingly rapidly. By the year 2020 there will be an additional 1.5 billion people to feed. Improvements in yield on a sustainable basis will be needed to meet the demands of this growing population.

Today, over 800 million people, equivalent to 15% of the world's population, get less than 2000 calories per day, live a life of permanent or intermittent hunger and are chronically undernourished. Most of the hungry are women and young children. 180 million under-5 year olds are severely underweight for their age.

Lack of proteins, vitamins, minerals and other micronutrients in the diet is widespread. Over 100 million children suffer from vitamin A deficiency. They are more likely to develop infections and the severity of the infection is likely to be greater. Each year half a million go blind and some 2 million die as a result. Iron deficiency is also common. About 400 million women of childbearing age (15-49 years old) are afflicted by anaemia caused by iron deficiency and are therefore more likely to die in childbirth.

Agriculture is an elemental engine of economic growth in the developing world. Local gains in productivity will not only increase food security for the poor, they will also increase farmer incomes and allow them greater opportunity to break the cycle of poverty. A new system of sustainable agriculture is needed which is ecologically sound and meets the food needs of the poor.

Sustainable agriculture uses ecological principles in combination with traditional and modern technologies so as to combine higher productivity with environmental friendliness and social and cultural sensitivity. Implementing sustainable agriculture means working with natural systems to prevent pest outbreaks and other problems, rather than waiting to treat them, once they occur. Sustainable agriculture relies on diverse cropping patterns, integrated crop-livestock systems, new and appropriate crop varieties, organic and inorganic inputs, the use of biological controls and where appropriate; comparatively safe, selective pesticides.

Modern biotechnology holds the potential to provide new tools for farmers in developing countries to increase yields, produce crops resistant to drought, salinity, pests and diseases, and produce new crop products of greater nutritional value. It also has the potential to reduce unfavourable impacts on the environment by reducing the use of pesticides, and reduce the use and costs of inputs and, hence, increase farmer income.

However, while biotechnology has the potential to help, it can only be part of the solution. As with some conventional plant varieties and chemical pesticides, pests are likely to evolve resistance to GM crops used in pest control, and many of these crops will only remain effective if their use is properly managed. Many of the food security problems facing developing countries require political and infrastructure-related solutions. While control of the technology remains predominantly in the hands of developed countries, and mainly with the private sector, its application will inevitably be focused on a business agenda, and its potential benefit to developing countries is unlikely to be realised. It is therefore essential that all stakeholders within developing countries participate in the debate about its potential application including where public research priorities lie.

The United States and the European Union should commit themselves to stimulating the development of global sustainable agriculture that will provide both adequate amounts and variety of nutrients in a manner that is accessible to all, equitably distributed and culturally acceptable. ***(Recommendation 16)***

3.3. Research and Infrastructure

Sustainable agriculture is a priority for developed countries and developing countries. Present practices in developed countries have many characteristics that are unsustainable, i.e. they pose threats to groundwater, top soils, fresh and marine waters and to biodiversity. It is important that the developing world not reproduce our mistakes.

The increase in agricultural productivity over the past 50 years has been the result of significant research efforts in such areas as:

- the development of new plant varieties better adapted to the environment, with higher yield and/or better nutritional quality;

- novel crop culturing practices such as crop rotations, efficient irrigation and integrated pest management;

- increased use of fertilisers and agro-chemicals;

- conservation and preservation technologies that enable the distribution of agricultural products and decrease post-harvest losses.

In both the United States and the Europe Union, the relative amount of public funding for agricultural research has decreased over the past ten years as compared to the level of private research funding.

Given the size of the challenge on a global level to produce adequate levels of nutrients to feed mankind, it is of critical importance to enhance the efforts in agricultural research and to understand how to best meet the nutritional needs of the population. This will also ensure that novel techniques, processes and crop varieties will be available to the public domain and can be used and applied by nations and institutions worldwide for enhanced productivity and well being.

The United States and the European Union should increase public funding in the area of sustainable agriculture and nutrition research in the public interest. (*Recommendation 17)*

This funding may be directed in various ways, including research into the characteristics of sustainable agriculture in the EU and the U.S., and research into the agricultural and nutritional needs of the developing world. Publicly funded research should focus on areas that are unlikely to be of interest to the private sector. The results of publicly funded research should be made available at no cost to assist public agricultural programs serving developing countries.

The research and technical infrastructure for sustainable agriculture and sound nutrition on each continent and within each country should be strengthened. International efforts such as the Consultative Group on International Agricultural Research (CGIAR) should be supported.

The research and technical infrastructures necessary to implement systems of sustainable agriculture in the developing countries should be developed.

The EU and the U.S. should help set up an independently administered fund for the training of developing country nationals in sustainable agriculture, biosafety controls, molecular biology, nutrition and other related fields needed to implement sustainable food production systems, including the effective use of modern agricultural technology. (*Recommendation 18*)

3.4. Biosafety

Developed and developing countries should have access to the same body of evolving scientific and technical knowledge that is necessary for making informed decisions. They should also have the human infrastructure in place with the necessary technical and scientific capacity for implementing regulatory procedures.

This knowledge is very unevenly distributed. Skills in biosafety techniques are in short supply in many developing countries. Much greater emphasis needs to be placed on the training of developing country nationals in biosafety and biotechnology. Regardless of the current differences, the private and public sectors should apply the same level of scrutiny when dealing with potential uses and users in countries with different levels of skills in biosafety.

The EU and the U.S. should pursue the implementation of the biosafety principles outlined in the Cartagena Protocol on Biosafety. (*Recommendation 19*)

The Cartagena Protocol on Biosafety was adopted under the Convention on Biological Diversity. The Protocol seeks to establish a global framework for managing the safe introduction and use of biotechnology. Since the biosafety infrastructures in many developing countries are lacking, the agreement calls for a number of steps. New and additional financial support from the EU and the U.S. will be necessary in order to establish the capacity of developing countries to make regulatory decisions based on the same level of information that are or should be the norm in the developed countries. The same aspects of local and regional concerns in regulation that we have discussed in the previous section apply to developing countries only, perhaps, more so. Individual developing countries must therefore also be able to call for financial and technical resources as well as scientific support and advice necessary for implementing the biosafety standards envisaged in the Protocol and which are, or should be, taken for granted in the developed countries.

3.5. Intellectual Property Rights

Intellectual property right schemes are intended to provide a system that ensures a fair return on investments made in novel inventions. In the agricultural area, two systems have been developed, Plant Variety Protection and patent rights. The former has a long history in agriculture. The latter is relatively new to this field. The use of patents in licensing practices has major implications for the uses of genetically modified organisms in developed and developing countries. The Forum recognised ongoing controversies regarding the implications of the present systems. In developed countries, controversy centres on the potential for patents to foster monopolies on plant genetic material or germplasm. In developing countries, controversies include the implications of patents for food security and meeting the basic food needs of the poor.

The EU and U.S. should promote and participate in a global dialogue on an intellectual property rights regime (or some alternate method) that would both provide a fair return on research investment and support sustainable agriculture for the developing world. The aim should be to ensure fair and equitable access for developing countries to new biotechnologies and products. More specifically, developing countries should not be forced to grant intellectual property rights which could prevent farmers from freely replanting saved seeds or public breeders from freely using varieties as initial sources of variation. (*Recommendation 20*)

We thus see a role for new co-operative mechanisms in the public and/or private sectors that would bring to bear the benefits of information, technology, techniques, and material currently held as private intellectual property to increase food security especially for poor farmers in the poorest countries of the world.

The EU and the U.S. should explore the possibility of establishing an independently administered holding organisation that would receive donations of intellectual property from governments, universities and the private sector which would then be available for developing country public plant breeders at no cost.

The Forum also considers that new instruments or mechanisms might be needed to make technologies and products that are essential for food security available to the poor notwithstanding their protection by intellectual property rights.

The EU and the U.S. should call for respect of the traditional or indigenous agricultural and medical knowledge in any country of the world and for the fair distribution of the royalties and other rewards from inventions based on this knowledge. (*Recommendation 21)*

The EU and the U.S. should examine the development of incentive mechanisms to encourage private companies to engage in research of particular importance for developing countries, and to make available research results including proprietary technologies to those countries. *(Recommendation 22)*

Any undertaking related to intellectual property rights should continue to encourage innovation through the private and public sectors while meeting challenging needs related to food security in developing countries. These efforts should also result in greater indigenous capacity to evaluate and pursue, where determined desirable or necessary, modern biotechnology and locally appropriate intellectual property regimes.

It is important that the present trends towards increasing concentration of the commercial power of biotechnology to a few very large corporations are reversed. We see great problems ahead for biotechnology if its potential is not widely shared. An open attitude towards partnerships and an awareness of the potential risks of monopoly power is crucial for the worldwide public acceptance of agricultural biotechnology.

4. NEXT STEPS

We believe that the Consultative Forum on Biotechnology has been a useful exercise in promoting understanding of, and consensus on some of the difficult and contentious issues that underlie the different points of view on biotechnology within the EU and the US and between the governments. The dynamic created by the Forum's broad range of stakeholders resulted in a constructive dialogue that permitted addressing the most immediate issues related to agricultural biotechnology that were included in the Forum's mandate. Nonetheless the background and causes of the controversies surrounding the uses of biotechnology merit further analyses. The Forum also recognised that biotechnology is evolving, and new issues are likely to be raised by its development and applications. Issues of animal biotechnology and the use of plants for the production of non-edible products of industrial interest come to mind in this regard. The Consultative Forum represented an innovative approach to meeting the need for new public policies on contentious issues that merit further deliberation, thus

We urge the EU and the U.S. to promote a transatlantic process for engaging a broad range of stakeholders to examine ongoing issues of biotechnology. ***(Recommendation 23)***

Two areas are particularly important: firstly, the role of biotechnology in global agriculture; and, secondly the consideration of socio-cultural and other factors of importance to current and future applications of biotechnology that are not addressed readily by natural science. This process could also serve to anticipate second and third order beneficial and harmful effects of policies with respect to biotechnology and a consideration of additional issues related to biosafety, biodiversity, and food security.

Future differences in approach and interpretation may lead to disagreements on biotechnology within and between the EU and US related to risk assessment and risk management. These differences are likely to result in part from fine judgements on scientific factors, but more often from non-scientific considerations. They will be related only rarely to risk assessment and more often to risk management.

In the introduction of this report biotechnology was set in the context of parallels from history, globalisation, the power of the citizen and sustainable development. We suggest that the process we recommend build upon this. Participation should be broadly based and include policy makers, environmentalists, scientists, economists, lawyers, ethicists, consumers, farmers, and other representatives of civil society. Because of the global ramifications of these issues, the EU and the US should ensure, to the degree possible, the participation of individuals with direct knowledge of the needs of and conditions in the developing world. Among the process's principal aims should be to further the mutual understanding of and respect for the different perspectives of biotechnology and its application, thus diminishing the tensions between and within the EU and US. We suggest that this recommendation be promoted for a limited period before its utility is evaluated.

December 2000

5. Annex: LIST OF MEMBERS OF THE EU-US BIOTECHNOLOGY CONSULTATIVE FORUM

Norman Borlaug, Ph.D., Distinguished Professor of International Agriculture at Texas A&M University, winner of the Nobel Peace Prize in 1970 for his work on the "Green Revolution."

Derek Burke, Ph D., Professor, former Vice-Chancellor of the University of East Anglia, former Professor of Biological Sciences at the University of Warwick, former Chair of the Advisory Committee on Novel Foods and Processes, Specialist Adviser to the House of Commons Science and Technology Select Committee.

Gordon Conway, Ph.D., President of the Rockefeller Foundation and an agricultural ecologist.

Susan Davies, is Principal Policy Adviser with responsibility for food issues of the United Kingdom Consumers'Association.

Rebecca J. Goldburg, Ph.D., Senior Scientist at Environmental Defense (USA).

Cutberto Garza MD, PhD. (Co-chair); Professor, Division of Nutritional Sciences, Cornell Univesity, Ithaca NY.

Jennie Hunter-Cevera, Ph.D., President of the University of Maryland Biotechnology Institute.

Noëlle Lenoir, Chair of the European Group on Ethics in science and new Technology, European Union, Justice of the French Constitutional Court.

Dan Leskien, advisor to 'Gesellschaft für Technische Zusammenarbeit' (Germany) on intellectual property rights and plant genetic resources in developing countries and permanent biotechnology advisor to Friends of the Earth.

Måns Lönnroth, Ph.D., Managing Director of MISTRA, the Swedish Foundation for Strategic Environmental Research.

Ruud Lubbers, Prof., (co-chair), Professor for Globalisation and Sustainable Development at the Catholic University Brabant (Tilburg University), former Prime Minister of the Netherlands.

Terry L. Medley, J.D., Vice President, Biotechnology, Regulatory and External Affairs, Dupont Nutrition and Health (USA).

Pedro Puigdoménech Rosell, Prof., research Professor at the department of molecular genetics, Instituto de Biologia Molecular de Barcelona. CSIC.

Leonardo Santi, Prof., President of the Advanced Biotechnology Center, Genoa (Italy) and Chairman of the National Committee for Biosafety and Biotechnology Presidency of Cabinet of Ministers Rome.

Christopher Roland Somerville, Ph.D., Director of The Carnegie Institution of Washington, Department of Plant Biology and professor of Biological sciences at Stanford University.

Carol Tucker Foreman, Director, The Food Policy Institute of the Consumer Federation of America, former Assistant Secretary for Food and Consumer Services, US Department of Agriculture.

Ryland Frederick Utlaut farmer of corn, soybeans and wheat near Grand Pass, Missouri, past President of the National Corn Growers Association (USA).

Luis Vasconcelos e Souza, is President of the Portuguese Associations of Maize Producers and Vice-President of the European Association of Maize Producers.

Eduard Veltkamp, Prof., Senior Vice President, Research Unilever (the Netherlands).

LeRoy B. Walters, Ph.D., Senior Research Scholar, Kennedy Institute of Ethics, and Professor of Philosophy, Georgetown University.