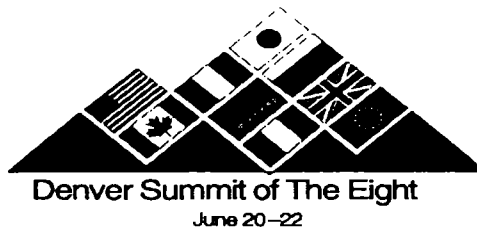


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COMMUNIQUE

DENVER, JUNE 22, 1997

INTRODUCTION

1. We, the participants in the Denver Summit of the Eight, as major industrialized democracies, have discussed the steps necessary, both internationally and domestically, to shape the forces of integration to ensure prosperity and peace for our citizens and the entire world as we approach the twenty-first century. We have agreed to work closely with all willing partners in fostering global partnership for peace, security, and sustainable development that includes strengthening democracy, and human rights, and helping prevent and resolve conflicts.
2. Continuing the important steps we have taken, the Denver Summit of the Eight marks a new and deeper participation by Russia in our efforts. Russia has taken bold measures to complete an historic transformation into a democratic state with a market economy. We are committed to continue the trend of increased Russian participation in the work of our officials between Summits and reiterate our shared commitment to the promotion of a fuller involvement of Russia in the Summit process. Cooperation to integrate Russia's economy into the global economic system represents one of our most important priorities. We welcome the understanding reached between Russia and the Chairman of the Paris Club on the basis for Russia's participation and look forward to the Paris Club and Russia finalizing an agreement in the near future. We support the goal of early Russian accession to the WTO on the basis of conditions generally applicable to newly acceding members. We also look forward to continued Russian progress toward accession to the OECD using the potential of the recently created Liaison Committee between Russia and the OECD.

ECONOMIC AND SOCIAL ISSUES

3. The process of globalization, a major factor underlying the growth of world prosperity in the last fifty years, is now advancing rapidly and broadly. Globalization encompasses the expansion of cross-border flows of ideas and information, goods and services, technology and capital. More openness and integration across the global economy create opportunities for increased prosperity as countries specialize in those economic activities which they do best, while also promoting increased competition and efficiency, and the rapid spread of technological innovations. Our task, as we enter the 21st Century, is to make the most of these opportunities.
4. At the same time, globalization may create new challenges. The increasing openness and interdependence of our economies, with deep trade linkages and ever greater flows of private capital, means that problems in one country can spill over more easily to affect the rest. We

must cooperate to promote global growth and prosperity. We must also ensure that all segments of society, and indeed all countries across the globe, have the opportunity to share in the prosperity made possible by global integration and technological innovations. It is particularly important that young adults see the path to a successful life, and be adequately prepared to follow that path.

5. Rapid technological change and demographic shifts are also having an important impact on the global economy. We must take advantage of the possibilities for growth to address unemployment and economic insecurity. Sound economic policies and the structural reforms necessary to allow markets to function properly are essential if we are to meet the many domestic and international challenges we all face. Measures that expand the availability of high quality education and training and increase the responsiveness of labor markets to economic conditions will aid the ability of our people to adjust to all types of structural changes. We look forward to the high-level conference on employment that takes place this fall in Japan, which is expected to contribute to the discussion on responses to structural changes. We also welcome the proposal by the United Kingdom to host a conference of ministers responsible for finance and social affairs early next year on growth, employability, and inclusion, to prepare for further discussion of these vital issues at our meeting next year.

THE OPPORTUNITIES AND CHALLENGES OF AGING POPULATIONS

6. Increased life expectancy and improved health among our elderly are two major achievements of this century. In the next century, these successes will present us with both opportunities and challenges, as longer life expectancies and lower birth rates significantly raise the proportion of seniors in our countries' populations. Prime Minister Hashimoto's "Initiative for a Caring World" has provided us the opportunity to focus on the implications of these developments.
7. We discussed the idea of "active aging" -- the desire and ability of many older people to continue work or other socially productive activities well into their later years, and agreed that old stereotypes of seniors as dependent should be abandoned. We considered new evidence suggesting that disability rates among seniors have declined in some countries while recognizing the wide variation in the health of older people. We discussed how our nations can promote active aging of our older citizens with due regard to their individual choices and circumstances, including removing disincentives to labor force participation and lowering barriers to flexible and part-time employment that exist in some countries. In addition, we discussed the transition from work to retirement, life-long learning and ways to encourage volunteerism and to support family care-giving.
8. We examined the differing implications of population aging for our nations' pension, health and long-term care systems in the next century. Active aging strategies can be a useful way to advance structural reforms in the areas of health and social welfare. Some of our countries face major challenges in sustaining their public pension systems and would benefit from early action to restore balance. Different ways were suggested to address this issue, including increasing the labor force participation of seniors and raising national savings rates. Investing in human capital, including maximizing opportunities for life-long learning, were

mentioned as ways to facilitate the continued work preparedness of mature adults. Some countries will be more affected by the demands of health care financing for seniors. We concluded that efficient and effective management of this challenge should help us to meet the needs of an aging society without overburdening younger generations.

9. We agreed that it is important to learn from one another how our policies and programs can promote active aging and advance structural reforms to preserve and strengthen our pension, health and long-term care systems. Our governments will work together, within the OECD and with other international organizations, to promote active aging through information exchanges and cross-national research. We encourage collaborative biomedical and behavioral research to improve active life expectancy and reduce disability, and have directed our officials to identify gaps in our knowledge and explore developing comparable data in our nations to improve our capacity to address the challenges of population aging into the 21st Century.

SMALL AND MEDIUM ENTERPRISES

10. The contributions of small and medium-sized enterprises to employment and economic dynamism in our societies are widely recognized. Fostering a business setting conducive to the growth of dynamic young enterprises is a key to job creation. In our discussion, we surveyed the obstacles to such growth, including the unavailability of debt or equity capital at critical stages of a firm's growth, unnecessary regulation, difficulties adopting existing innovative technologies, and the problems of smaller businesses in entering global markets. We stress the need to remove these obstacles. We also examined some exemplary practices within our countries to promote the growth of small and medium-sized companies, as well as vocational training and education within these companies, and considered how we might benefit from these successes. Best practices in our countries could also be useful examples for developing and transition-market economies, as development of small and medium-sized enterprises favors creation of jobs and social stability, disseminates entrepreneurial capacities and helps to promote and diversify exports. We will pursue our work in other areas.

GLOBAL ISSUES

11. Even as global integration and rapid advances in communications and transportation have spurred economic growth, these same trends have exposed us to complex problems that defy unilateral solutions. In recent years our Summits have devoted increasing attention to our cooperative efforts to confront these problems.

ENVIRONMENT

12. This is a pivotal year for efforts to promote sustainable development and protect the environment. We are determined to address the environmental challenges that will affect the quality of life of future generations and to enhance public awareness, especially among our youth, of the importance of advancing sustainable development goals.

UN General Assembly Special Session

13. We discussed the progress that has been made since the 1992 Rio Earth Summit in defining and promoting sustainable development, and we commit ourselves to taking action in areas critical to advancing this agenda. Sustainable development demands the full integration of environment, economic and social policies; should be based upon democratic governance and respect for human rights; and should have poverty eradication as one of its ultimate objectives. In this connection, we reaffirm the vital contribution of civil society. We urge the United Nations General Assembly, at its Special Session to be held next week, to reaffirm and give impetus to the Rio commitments, to take stock of implementation since Rio, and, most importantly, to develop a manageable list of priority issues to address in future work on sustainable development.

Climate Change

14. Overwhelming scientific evidence links the build-up of greenhouse gasses in the atmosphere to changes in the global climate system. If current trends continue into the next century, unacceptable impacts on human health and the global environment are likely. Reversing these trends will require a sustained global effort over several decades, with the involvement of all our citizens, and changes in our patterns of consumption and production.
15. We are determined to take the lead and show seriousness of purpose in strengthening international efforts to confront climate change. Our ultimate goal must be to stabilize atmospheric concentrations of greenhouse gasses at an acceptable level. This will require efficient and cost-effective policies and measures sufficient to lead to a significant reduction in emissions.
16. International cooperation will be essential. At the Third Conference of Parties to the UN Framework Convention on Climate Change in Kyoto we must forge a strong agreement that is consistent with the Berlin Mandate and that contains quantified and legally-binding emission targets. We intend to commit to meaningful, realistic and equitable targets that will result in reductions of greenhouse gas emissions by 2010. The agreement must ensure transparency and accountability and allow Participants flexibility in the manner in which they meet their targets.
17. Action by developed countries alone will not be sufficient to meet this goal. Developing countries must also take measurable steps, recognizing that their obligations will increase as their economies grow. We agree to work in partnership with them to that effect by implementing technological development and diffusion and supporting environmental education and capacity building.
18. We stress the importance of setting up an appropriate mechanism for monitoring and ensuring compliance among Parties. We also agree to work together to enhance international efforts to further develop global systems for monitoring climate change and other environmental trends.

Forests

19. Forests continue to be destroyed and degraded at alarming rates in many parts of the world. To reverse this trend, we call upon all countries to make a long-term political commitment to achieve sustainable forest management practices worldwide and to join us in the immediate implementation of proposals put forward by the UNCSD Intergovernmental Panel on Forests. We have discussed in Denver and have agreed to support a practical Action Program that includes implementing national programs and building capacity for sustainable forest management; establishing networks of protected areas; assessing the state of each nation's forests using agreed criteria and indicators; promoting private sector management of forests; and eliminating illegal logging. We ask that our officials meet early next year to assess progress in implementing this Action Program and call for a report at our next meeting.
20. At the Special Session of the United Nations, we will work with the active involvement of environmental groups to build consensus on an international agreement with appropriately high international standards to achieve these goals. We welcome the progress made in implementing the Brazil Pilot Program initiated in Houston, and see it as an example of practical international cooperation.

Freshwater

21. Many people throughout the world do not have access to safe water. Increased human, industrial and agricultural wastes can diminish water quality, with adverse effects for ecosystems and human health and safety, particularly for children. The Special Session of the UN General Assembly should encourage the CSD to develop a practical plan of action to address freshwater-related issues, including promotion of efficient water use, improvement of water quality and sanitation, technological development and capacity building, public awareness and institutional improvements. To achieve these objectives, we have also agreed to promote bilateral and regional cooperation on freshwater concerns, and to enhance coordination of our efforts in this area.

Oceans

22. We must strengthen our efforts to protect the world's oceans. We will work to ensure an effective and integrated effort to deal with key issues, including sustainable fishing, shipping, marine pollution from land-based and off-shore activities, and oil spill prevention and emergency response. In this connection, we will also enhance cooperation in monitoring the ecology in the Northern Pacific, as well as in forecasting earthquakes and tsunamis in this region.

Desertification

23. We welcome the entry into force of the "Convention to Combat Desertification," and urge the parties to develop concrete steps to implement the convention at the First Conference of the Parties this Fall in Rome.

Environmental Standards for Export Credit Agencies

24. Private sector financial flows from industrial nations have a significant impact on sustainable development worldwide. Governments should help promote sustainable practices by taking

environmental factors into account when providing financing support for investment in infrastructure and equipment. We attach importance to the work on this in the OECD, and will review progress at our meeting next year.

Children's Environmental Health

25. Protecting the health of our children is a shared fundamental value. Children throughout the world face significant threats to their health from an array of environmental hazards, and we recognize particular vulnerabilities of children to environmental threats. Our governments will explicitly incorporate children into environmental risk assessments and standard setting and together will work to strengthen information exchange, provide for microbiologically safe drinking water, and reduce children's exposure to lead, environmental tobacco smoke and other air pollutants.

Institutions

26. Strong international institutions are essential to coordinating global efforts to protect the environment and to achieve sustainable development.
27. The UNGA Special Session should confirm the role of the UN Commission on Sustainable Development (CSD) as the strategic forum for integrating the social, environmental and economic aspects of sustainable development. The CSD should develop action plans with concrete objectives and timetables to guide its work in the four agreed priority areas: freshwater; oceans; land resources, including forests; and sustainable energy use.
28. To ensure an effective response to urgent global environmental problems, we have supported the refocused mandate for the United Nations Environment Program (UNEP), the leading global environmental authority, as affirmed by the UNEP Governing Council in Nairobi this year. UNEP should promote the coherent implementation of environmental protection within the UN system and serve as an authoritative advocate for the global environment. The newly formed High-level Committee of Environment Ministers and Officials should consider the international environmental agenda and elaborate upon and advance the reforms needed to ensure UNEP's effectiveness, with a particular emphasis on greater policy, program and financial accountability. We look forward to a revitalized UNEP being able to attract the resources needed for its tasks.
29. Further efforts are necessary to ensure the long-term coherence and efficiency of the UN's work on the environment. We encourage the Secretary General to review the handling of environmental matters within the UN system and to explore possible means and structures to improve further the coordination among, and effectiveness of, the concerned institutions.
30. We reaffirm the importance of the Global Environmental Facility as the leading multilateral funding mechanism for the global environment. We will work to strengthen its finances and enhance its effectiveness. In this regard, we will each do our part to contribute to a successful replenishment of the Facility.

INFECTIOUS DISEASES

31. Infectious diseases, including drug-resistant tuberculosis, malaria, and HIV/AIDS are responsible for a third of all deaths in the world. They pose significant challenges to the

health, security and financial resources of the global community. In many parts of the world, infectious diseases and deaths from infectious disease have risen sharply in the last decade for a variety of reasons, including the emergence of drug-resistant microbes and the increased movement of people and products.

32. In the coming year, our governments will promote more effective coordination of international responses to outbreaks; promote development of a global surveillance network, building upon existing national and regional surveillance systems; and help to build public health capacity to prevent, detect and control infectious diseases globally including efforts to explore the use of regional stocks of essential vaccines, therapeutics, diagnostics and other materials. Central to this work will be strengthening and linking existing activities in and among each of our countries, with developing countries, and in other fora, especially the World Health Organization. We support the efforts of the WHO and the recent World Health Assembly resolutions regarding the quality of biological and pharmaceutical products.
33. Preventing the transmission of HIV infection and the development of AIDS is an urgent global public health imperative. While other prevention and treatment methods must be pursued, in the long term the development of safe, accessible, and effective vaccines against AIDS holds the best chance of limiting, and eventually eliminating, the threat of this disease. We will work to provide the resources necessary to accelerate AIDS vaccine research, and together will enhance international scientific cooperation and collaboration. Cooperation among scientists and governments in the developed and developing world and international agencies will be critical. We call on other states to join us in this endeavor.
34. The Joint United Nations Program on HIV/AIDS (UNAIDS) must help expand the scale and quality of the response to HIV/AIDS. As a group and with others, we will work to assure that it has resources adequate to fulfill its mandate.

NUCLEAR SAFETY

35. We reaffirm our commitments from the 1996 Moscow Summit on Nuclear Safety and Security to give an absolute priority to safety in the use of nuclear energy. We note that further substantial progress is still required in the countries of Central and Eastern Europe and in the Newly Independent States, especially by strengthening regulatory authorities, enhancing reactor safety and improving safety culture. We consider further joint efforts to this end a major priority. In this regard, we attach the greatest importance to the full implementation of the Nuclear Safety Account agreements.
36. We note with satisfaction the entry into force by the Nuclear Safety Convention and the preparations now underway for the first review meeting to be held in April 1999. We applaud the rapid progress made in developing the Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management and encourage finalization. We welcome the forthcoming adoption of the Protocol to amend the Vienna Convention on civil liability for nuclear damage and of a new Supplementary Funding Convention. These conventions will facilitate international safety cooperation and provide for increased compensation for victims in the event of a nuclear accident.

GLOBAL ENERGY ISSUES

37. We decided to convene a ministerial on energy issues in Moscow next year, and request our officials to start preparations for such a meeting. Its results will be discussed at our next Summit.

TRANSNATIONAL ORGANIZED CRIME

38. Our efforts to combat transnational crime will be a priority of the group for the foreseeable future. Transnational criminal groups can often adapt to global change more swiftly and efficiently than our governments. International crime not only threatens our citizens, but also undermines young democracies and nations in transition.
39. Last year, we adopted the Lyon forty recommendations to combat transnational organized crime. We have substantially implemented those recommendations, taking action within our own borders and with one another. Together, we have strengthened cooperation bilaterally, multilaterally, and with other nations and groups to bring criminals to justice through mutual legal assistance and extradition, to promote cooperation among our law enforcement agencies, to strengthen document security and improve strategies to combat alien smuggling, and to prevent illegal trafficking in firearms.
40. We must intensify our efforts to implement the Lyon recommendations. In the coming year we will focus on two areas of critical concern: First, the investigation, prosecution, and punishment of high-tech criminals, such as those tampering with computer and telecommunications technology, across national borders; Second, a system to provide all governments the technical and legal capabilities to respond to high-tech crimes, regardless of where the criminals may be located.
41. We also will develop additional methods to secure our borders. Border security is central to all efforts to fight transnational crime, drug-trafficking and terrorism. To this end, we will combat illegal firearms trafficking, by considering a new international instrument. We will seek to adopt standard systems for firearms identification and a stronger international regime for import and export licensing of firearms. We will continue our work to strengthen document security, and improve strategies to combat alien smuggling, attacking the problem at the source and transit the destination countries. Our governments will also move further ahead with efforts to strengthen international legal regimes for extradition and mutual legal assistance, to ensure that no criminal receives safe haven anywhere in the world.

ILLICIT DRUGS

42. We are determined to intensify our efforts to combat the production, trafficking and use of illicit drugs, which represent a global threat to the safety of our citizens, and the well-being of our societies and institutions. Reaffirming the common responsibility of all concerned States, we recognize that a successful strategy to combat illicit drugs requires effective action against both the supply and the demand for such drugs. We stress the importance of demand reduction. Together with strict enforcement of drug-related laws, programs aimed at

treatment and rehabilitation, education and prevention are of major importance in our fight against drugs.

43. We have asked our appropriate government agencies to build on their established patterns of cooperation to address this common threat. In particular, we will study mechanisms that would assist in the development of healthy, drug-free economies in all States; support further efforts to share relevant information on money-laundering, chemical precursors, new synthetic drugs, trafficking patterns and methods, and other data; and will work together to strengthen the capabilities of law enforcement institutions to combat illicit drugs. Our governments will work together to develop the agenda for the UN General Assembly Special Session on Drugs in June 1998.

TERRORISM

44. We reaffirm our determination to combat terrorism in all forms, irrespective of motive. We oppose concessions to terrorist demands and are determined to deny hostage-takers any benefits from their acts. We welcome the growing consensus on adopting effective and legitimate means of countering terrorism.
45. Last year, our Ministers adopted twenty-five recommendations to combat terrorism. We have received a positive response worldwide, in particular in the UN General Assembly. Together we have made substantial progress on many of these recommendations, including: drafting and negotiating a UN convention on terrorist bombing; promoting improved international standards for airport security, explosives detection, and vehicle identification; promoting stronger laws and export controls on the manufacture, trade and transport of explosives; initiating a directory of counter-terrorism competencies; inviting all States to promote the use of encryption which may allow, consistent with OECD guidelines, lawful government access to combat terrorism.
46. We have asked our Ministers to intensify diplomatic efforts to ensure that by the year 2000 all States join the international counterterrorism conventions specified in the 1996 UN resolution on measures to counter terrorism. We have instructed our officials to take additional steps: to strengthen the capability of hostage negotiation experts and counterterrorism response units; to exchange information on technologies to detect and deter the use of materials of mass destruction in terrorist attacks; to develop means to deter terrorist attacks on electronic and computer infrastructure; to strengthen maritime security; to exchange information on security practices for international special events; and to strengthen and expand international cooperation and consultation.

HUMAN CLONING

47. We agree on the need for appropriate domestic measures and close international cooperation to prohibit the use of somatic cell nuclear transfer to create a child.

SPACE STATION

48. We look forward to the signing of the Agreement to establishing an international space station. This is an excellent example of international cooperation in carrying out large and promising projects in the field of exploration and peaceful uses of outer space.

UNITED NATIONS REFORM

49. We reaffirm the crucial role of the United Nations in maintaining international peace and security and in fostering global partnership and sustainable development. We support thorough-going reform, with the goal of strengthening the UN. We welcome progress that has occurred in the economic and social fields since our meetings in Halifax and Lyon. In this regard, we welcome Secretary General Kofi Annan's recent reform proposals and support their rapid implementation; we also look forward to the Secretary General's more extensive proposals next month. We remain committed to working with all UN members to realize these reforms.
50. In order for the UN to cope with the challenges of the 21st century, financial reform should proceed together with necessary reform measures in other areas. The UN system must be placed on a firm financial footing through full and timely payment of obligations, and development of a more logical and equitable scale of assessments. Budgets throughout the UN system should be scrutinized with emphasis on prioritization and maximum operating efficiency. We look forward to the Secretary General's specific proposals for reinvesting savings from improved cost-effectiveness in high priority development programs. Robust oversight mechanisms and sound personnel policies are essential for success.
51. The urgent challenges of economic and social development require the UN to coordinate more effectively the policies and activities of its various bodies including the specialized agencies. To this end, the UN's Economic and Social Council (ECOSOC), supported by the Under Secretary General for economic and social issues, should strengthen its policy and coordination role, in particular through streamlining its subsidiary bodies and improving its working relationship with international financial institutions and the WTO. We welcome the recent reforms in the governance of the funds and programs as well as in the various UN bodies, in particular at UNCTAD and in the regional commissions; these efforts should be sustained and expanded.
52. We call for a thorough and urgent review of the UN's funds and programs, as well as a system-wide review of the roles and mandates of specialized agencies and commissions. We welcome the Secretary General's recommendations for strengthened integration at the country level and better coordination at headquarters. In this context, we recommend the UN undertake performance evaluations of the coordination of its development activities in a range of representative countries. We expect the least developed countries to be the principal beneficiaries of improved efficiency in the UN's development work.
53. We reaffirm that the UN must further improve its ability to act quickly and effectively to address threats to international peace and security. We will continue to help develop the capacities of the UN in preventing and resolving conflicts. We support steps taken recently by the UN to strengthen its capacity for rapid reaction from the early warning stage to the

stage of rapid deployment of new, approved, peacekeeping operations and urge continued improvements in these areas.

AFRICA: PARTNERSHIP FOR DEVELOPMENT

54. At Lyon, we initiated a New Global Partnership for Development, noting both that developing countries have a fundamental responsibility for promoting their own development, and that developed countries must support these efforts. We paid particular attention to the problems of Sub-Saharan African countries, many of which continue to face unusually severe challenges. This year, we aim to translate the principles of that Partnership into new concrete action to support the efforts of African countries to participate fully in the expansion of global prosperity and to spread the benefits throughout their societies. Our objective is not only to facilitate the progressive integration of African countries into the world economy, but also to foster the integration of poor populations into economic, social and political life of their countries.
55. We are encouraged by positive developments, including the adoption of democratic and economic reforms in many Sub-Saharan African countries. Since 1990, more than twenty African nations have held free and fair elections. Democratic governance and the rule of law, in Africa as elsewhere, lay the foundation for human rights, including the rights of women, and sustainable development. We commend those African countries that have set an example by undertaking democratic reforms, improving rule of law and administration of justice, avoiding unproductive expenditures (including excessive military expenditures), and strengthening public institutions and civil society. We will support African efforts to promote democracy and good governance, improve the integrity of public institutions, enhance the transparency of government spending, in particular of procurement, and develop national anti-bribery regulations.
56. Increased prosperity ultimately depends upon creating an environment for domestic capital formation, private sector-led growth and successful integration into global markets. We are encouraged by the increasing number of Sub-Saharan countries that have made progress toward financial sustainability through fiscal and financial practices and have adopted growth and market oriented economic policies, including trade liberalization and investment climate improvement. These initiatives have produced a welcome acceleration of growth since 1994. We expect the international financial institutions to play an important role in supporting reform in Sub-Saharan African countries. Their support should help to promote productive foreign direct investment and domestic capital formation. We look forward to the IFIs reporting on their efforts by the time of the Hong Kong World Bank/IMF meetings.
57. Access to our markets is a crucial tool for fostering economic growth in Sub-Saharan Africa. We each will continue to improve, through various means, access to our markets for African exports. We support the further integration of the least developed countries into the world trading system. In this regard, African countries will be major beneficiaries of efforts in the WTO on a plan of action to promote capacity building and to provide predictable and favorable market access conditions for least developed countries. We are committed to the effective implementation of this plan and intend to participate actively in the high-level WTO/UNCTAD/International Trade Center meeting later this year. Furthermore, trade

liberalization by African countries will promote more efficient utilization of resources. We also welcome African initiatives for regional trade liberalization and economic cooperation.

58. We will consider ways to enhance opportunities for the Sub-Saharan African countries that need them most and are undertaking effective reform measures. We will review our own bilateral aid and trade promotion programs to ensure that they support climates conducive to economic growth and private investment, including by strengthening capacity.
59. Substantial flows of official development assistance will continue to play an essential role in building the capacity of Sub-Saharan African countries to achieve their sustainable development objectives. We are committed to a results-oriented approach to development policy, with the particular goal of combating extreme poverty. But development assistance alone cannot overcome inappropriate policies. We will work with African countries to ensure adequate and well-targeted assistance for those countries which have the greatest need and carry out the necessary broad-based reforms. This assistance will include support for democratic governance, respect for human rights, sound public administration, efficient legal and judicial systems, infrastructure development, rural development, food security, environmental protection and human resource development, including health and education of their people. In this regard, we will work to strengthen cooperation among concerned institutes to facilitate and coordinate capacity building efforts.
60. To maximize the effectiveness of our efforts, we will deepen the dialogue with African partners, work for greater local ownership of development strategies and encourage the participation of non-governmental actors. We will also strengthen donor coordination, including with emerging donors. We welcome and fully support the emerging trend of intra-regional and inter-regional cooperation to further African development.
61. The United Nations plays a major role in development in Africa, and African countries will be major beneficiaries of reform of the UN economic and social development activities. We encourage the UN's development funds and programs and specialized agencies, to emphasize work in the field in Africa and to fully integrate and coordinate their efforts, both at the headquarters and at the country level. We are encouraged by the Economic Commission on Africa's efforts to energize and focus its activities. The UN Development Program's decision to allocate a portion of its resources based on program quality is a useful approach to assuring effectiveness, and we urge that it be adopted more broadly in the UN's work.
62. A number of African countries are making impressive efforts to harness the information revolution in support of democracy and sustainable development. We welcome the Africa Information Society Initiative. We support their efforts to establish information networks to link African countries with each other and to the rest of the world. In this regard, we welcome the Toronto Global Knowledge '97 Conference.
63. We applaud African leadership in developing effective local capacities in conflict prevention, peacekeeping and post-conflict reconciliation and recovery. We will support African peace-building initiatives at the regional, sub-regional and national levels, in particular by the Organization of African Unity (OAU), taking into account the recent OECD Guidelines on Conflict, Peace, and Development Cooperation, and we will help to forge active partnerships with the United Nations and other donors. We encourage the UN Secretary General, as part

of his reform efforts, to identify ways the international community can further strengthen Africa's initiatives. We also call for the expanded utilization of the existing UN Trust Fund for African peacekeeping and conflict prevention, as well as other relevant UN funds; and broader and substantial donor commitments to the OAU and to subregional bodies with specialized mechanisms for conflict mediation, as well as to the UN/OAU Special Envoy to the Great Lakes.

64. We express our support for long-term efforts to promote rapidly deployable African peacekeeping capacities. We welcome closer coordination among African troop-contributing countries, regional and subregional organizations, donors, and the UN in the development of training, joint exercises, common peacekeeping doctrine, and other efforts to ensure interoperability. We also welcome recent progress towards the establishment of an African Peacekeeping Support Group at the UN, and we urge interested countries to actively explore mechanisms for coordination of practical activities.
65. We express our grave concern at the recent attacks against refugees as well as against personnel of refugee and humanitarian organizations. We emphasize that host States must prevent such acts and prosecute the perpetrators.
66. We have requested that our officials report to us prior to next year's Summit about the efforts they have undertaken together to implement all aspects of this partnership.

POLITICAL ISSUES

67. Together, we are pursuing a strategy of global integration to create a more secure and stable international community. Already, we have used our political cooperation to broaden and deepen the community of open markets and open societies, and in the next year we will work together to build on these efforts. Our Partnership for Development is designed explicitly to support the economic and political development of nations which run the risk of being marginalized from the process of integration. We will focus our energies on strengthening adherence to the norms and principles of international cooperation, and will work together to take effective measures against those who threaten those objectives. We recognize our common interest and responsibility in helping bring an end to conflicts that threaten to disturb international peace and to undermine our deepened cooperation.

DEMOCRACY AND HUMAN RIGHTS

68. Recent years have seen an unprecedented growth of democracy worldwide. Yet young democratic states can be fragile and short-lived. We have a responsibility and opportunity to further strengthen democratic values and fundamental freedoms where they have taken hold and extend their reach where they have not.
69. Human rights are at the heart of our concerns. Ensuring accountability for violations of human rights and international humanitarian law is essential to promote conflict resolution and peace. The new UN High Commissioner for Human Rights will have a crucial role to play. We will continue to give full support to the International Tribunals for the former

Yugoslavia and Rwanda, and work to ensure that the international community and States concerned bring to justice through due process persons responsible for violations of human rights and international humanitarian law.

70. Recognizing that strengthening democracy is essential to strengthening peace and human rights, and looking to the 50th anniversary of the Universal Declaration of Human Rights in 1998, we will work together in the coming year to build on our governments' most effective democratic development, peacebuilding and human rights programs. Our efforts will focus on promoting good governance and the rule of law, strengthening civil society, expanding women's political participation, and boosting business and labor support for democracy, particularly in young democracies and societies in conflict. The protection of the most underrepresented or vulnerable is critical to broaden participation in the democratic process and prevent societal conflict. We will work to ensure adoption and ratification of international instruments designed to provide protection to these groups, in particular the speedy adoption of an International Labor Organization Convention on the eradication of intolerable forms of child labor. We will work through multilateral and regional organizations, particularly with the Development Assistance Committee of the OECD as well as in partnership with non-governmental organizations and young democracies. We also will consider common efforts to promote democracy where it is not now established.
71. We have asked our Ministers to pursue these efforts and to make recommendations for consideration at our next Summit.
72. Democracy, economic growth and development cannot reach their full potential without good governance, in particular the accountability of political leaders and public servants, especially for corruption. We will actively work to eliminate corruption in aid-funded procurement. We will take prompt steps to criminalize, in an effective and coordinated manner, bribery of foreign public officials, and to implement previous undertakings on the tax-deductibility of such bribes. We call upon all other countries to do the same.

NON-PROLIFERATION, ARMS CONTROL AND DISARMAMENT

73. Since the Moscow Summit on Nuclear Safety and Security, we have taken important steps to implement the agreed "Programme for Preventing and Combating Illicit Trafficking in Nuclear Materials." We will expand participation in this program to include countries in Central and Eastern Europe, and in Central Asia and the Caucasus.
74. Further regarding the safe and effective management of fissile material, with respect to such materials no longer required for defense purposes, we will continue our cooperation through concrete initiatives, in particular the French-German-Russian project to build a pilot plant in Russia to produce MOX fuel from weapons plutonium, which is open to additional states, and the related U.S.-Russian cooperation on the conversion of weapons plutonium.
75. We have worked together to advance our common non-proliferation, arms control, and disarmament goals. The Comprehensive Test Ban Treaty is an historic milestone, and we call upon all States to sign and ratify it rapidly to ensure its early entry into force. We

welcome the entry into force of the Chemical Weapons Convention. We advocate its full, effective and universal implementation, and look forward to the early ratification of the Convention by the States that have not yet done so. Recognizing that enhancing confidence in compliance would reinforce the Biological and Toxin Weapons Convention, we reaffirm our determination to complete as soon as possible through negotiation a legally-binding and effective verification mechanism.

76. We reaffirm our unwavering commitment to full implementation of the objectives set forth in the Non-Proliferation Treaty. To that end, we welcome the IAEA's recent adoption of a program on strengthening the effectiveness and improving the efficiency of the safeguards system. We urge all States to conclude additional protocols with the IAEA at the earliest possible date. We reaffirm our commitment to the immediate commencement and early conclusion of a convention banning the production of fissile material for nuclear weapons or other nuclear explosive devices.
77. We welcome the progress on strategic arms control made at Helsinki in March, and look forward to the early entry-into-force of the START II agreement and the initiation of START III negotiations. We reaffirm the key role of the Conventional Forces in Europe Treaty in strengthening European security, and welcome the decision to conclude its adaptation as expeditiously as possible. We welcome the recent agreement among Russia, Kazakstan, Kyrgystan, Tajikistan, and China on reduction of military forces along their borders and consider it an important contribution to the region's security.
78. We endorse unequivocally efforts by the UN Special Commission and the IAEA to eliminate weapons of mass destruction capabilities in Iraq and to monitor compliance. We reaffirm the importance of implementing the U.S.-DPRK Agreed Framework and full compliance by North Korea with its non-proliferation obligations. We therefore place great value on the continuing role of the IAEA in monitoring the freeze on North Korea's nuclear program, implementing safeguards, and helping preserve all information relating to the DPRK's past activity. We welcome the conclusion of negotiations for the EU to participate in the Korean Peninsula Energy Development Organization (KEDO) and call for further international support for KEDO, including the provision of funds. We stress the importance of Four Party talks and the necessity of North-South dialogue. We call on North Korea to halt its development, deployment and export of ballistic missiles.
79. We welcome the emerging high-level dialogue between India and Pakistan. We encourage both countries to bring their activities into conformity with international non-proliferation norms. Consistent with our support for the CTBT's early entry into force, we encourage both countries to adhere to that treaty.
80. We recognize that global security and stability are strengthened by promoting international responsibility in the transfer of arms and sensitive technologies, and to that end reaffirm our support for the Wassenaar Arrangement. We welcome the steady achievements under the UN Register of Conventional Arms in promoting transparency in armaments. We encourage the work of the UN Panel of Governmental Experts on Small Arms to identify the ways and

means to prevent and reduce the excessive and destabilizing transfer of small arms and light weapons and we will continue to work together to curb illegal trafficking in firearms.

EXPORT CONTROL REGIMES

81. We underline our support for the arrangements that make up the international export control regimes. The Zangger Committee and the Nuclear Suppliers Group, the Missile Technology Control Regime, and, for those who are members, the Australia Group export control regime, all contribute critically to the global application and enforcement of international export control norms.

ANTI-PERSONNEL LANDMINES

82. Last year we committed ourselves to spare no effort in securing a global ban on anti-personnel landmines. To this end, we note the useful and complementary efforts in a variety of fora, including at the Conference on Disarmament and in formal negotiations to take place in Oslo in September through the Ottawa Process which has set the goal of achieving such a ban before the end of the year. We welcome the restrictions on anti-personnel landmines unilaterally declared by States, including by the members of the EU. We reaffirm the UN General Assembly resolution, approved overwhelmingly, calling for concluding an effective, legally-binding international agreement to ban anti-personnel landmines as soon as possible. All States should adhere to the strengthened Protocol on Mines, Booby Traps and Other Devices. We encourage the international community to develop technological solutions to mine detection and clearance, and to strengthen its support for humanitarian demining and assistance to mine victims.

POLITICAL SITUATIONS

Hong Kong

83. We recognize the historic nature of China's imminent resumption of sovereignty over Hong Kong. Considering our durable interests in this financial and economic center, we welcome and place weight on China's commitments, contained in the 1984 UK-PRC Joint Declaration and in the 1990 PRC Basic Law. These include ensuring Hong Kong's continued stability and prosperity and preserving its way of life, its high degree of autonomy -- including an independent monetary and economic system -- its fundamental freedoms and the rule of law. These will provide the essential underpinnings for Hong Kong's future economic success. We look forward to democratic elections in Hong Kong for a new legislature as soon as possible. We take serious note of China's assurances in the Joint Declaration and Basic Law that the provisions of the International Covenant of Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights will continue to apply in Hong Kong.

Middle East

84. The Peace Process faces a crisis, and we are determined to reinject momentum into it. Restoring the sense of security and confidence among Israelis and Palestinians is essential.

We shall do our utmost to reinvigorate implementation of the Oslo Accords and to uphold the principles of Madrid, including the exchange of land for peace. All the problems need to be addressed peacefully through serious and credible negotiations. Both sides must refrain from actions that impede the peace process by preempting permanent status negotiations. We believe strongly in the importance of working with Israel, Syria and Lebanon to resume direct talks in order to achieve a comprehensive settlement in the region. We welcome the important role the Monitoring Group has played in strengthening the Understanding of April 26, 1996 and in reducing risks to civilians in southern Lebanon and in Israel. We affirm the importance of the activities within the multilateral framework of the peace process.

85. Economic growth and prosperity are critical to peace. We urge regional parties to pursue economic cooperation among themselves and integration into the global economy. We welcome all efforts to promote the region's development of viable and sustainable economies, including assistance to the Palestinians, and urge donors to fulfill pledges made.
86. We have noted with interest the results of the recent elections in Iran and renew our call upon the Government of Iran to play a constructive role in regional and world affairs. In this regard, while noting the role Iran played in inter-Tajik talks in conjunction with the United Nations and other regional parties, we call upon the Government of Iran to desist from material and political support for extremist groups that are seeking to destroy the Middle East peace process and to destabilize the region. We further call upon the Iranian Government to respect the human rights of all Iranian citizens and to renounce the use of terrorism, including against Iranian citizens living abroad, and, in that connection, to desist from endorsing the continued threat to the life of Mr. Salman Rushdie and other people associated with his work. We call on all States to avoid cooperation with Iran that might contribute to efforts to acquire nuclear weapons capabilities, or to enhance chemical, biological, or missile capabilities in violation of international conventions or arrangements.
87. We confirm our determination to obtain full compliance with all UN Security Council resolutions related to Iraq and Libya. Only full compliance with these resolutions could result in the lifting of sanctions. We are pleased to note that the distribution of food and medicine under UNSCR 986 is providing some humanitarian relief to the Iraqi people.

Cyprus

88. The Cyprus dispute has remained unresolved for far too long. We fully support the mission of good offices of the United Nations Secretary General on Cyprus aimed at engaging the two Cypriot communities in negotiations to achieve a comprehensive settlement in accordance with relevant UN Resolutions and high-level agreements. We strongly endorse the Secretary General's recent invitation to the leaders of both communities and call on them to approach negotiations constructively and in good faith. We call upon the governments of Turkey and Greece to do everything possible to contribute to a solution of the Cyprus problem and to work towards solving their bilateral disputes with regard to the Aegean through early meetings of "Wise Men."

Albania

89. Noting the situation in Albania and its implications for regional stability, we express our appreciation to those organizations and institutions, acting within the coordinating framework of the OSCE under the strong leadership of Franz Vranitzky -- especially the EU as well as the WEU, UNHCR and Red Cross -- that are working with the Government of National Reconciliation to restore normalcy in the country. We applaud the deployment of the Multinational Protection Force under Italian leadership and the authority of the UN Security Council. We underscore the need for the Albanian parties to work together to ensure that the elections reinforce democracy and thereafter work to reestablish order and public safety, pursue economic reform, and create a sound financial system.

NEXT SUMMIT

90. We have accepted the invitation of the Prime Minister of the United Kingdom to meet in Birmingham on 15-17 May next year.

Cloning 68

Inf. disease group 5/27

UNCLASSIFIED FAX FROM
THE NATIONAL ECONOMIC COUNCIL
AND
THE NATIONAL SECURITY COUNCIL OF
THE WHITE HOUSE

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DATE: 6/17/97

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SUBJECT: Rachel Lewinson	6-6027	6-6137

Please review attached draft fact sheet on cloning. Please forward your comments/clearance/redrafts by 10am tomorrow morning (Wed 6/18/97). Thanks.

UNCLASSIFIED

MAY 1

Cloning Human Beings Fact Sheet

The Summit Leaders agreed that a new animal cloning technology, known as somatic cell nuclear transfer, should not be used to create children, but affirmed the positive uses of cloning technology for basic science and medical and agricultural research and product development.

Various forms of cloning technology have been used for decades resulting in important biomedical and agricultural advances. Genes, cells, tissues, and even whole plants and animals have been cloned to develop new therapies for treating such disorders as cancer, diabetes, and cystic fibrosis. Cloning technology also holds promise for producing replacement skin, cartilage, or bone tissue for burn or accident victims, and nerve tissue to treat spinal cord injury. While agreeing that such beneficial applications should not be impeded, member nations concluded that it would be unacceptable to create a child using somatic cell nuclear transfer technology.

This is consistent with the view recently expressed by several domestic and international advisory bodies. Last month, the European Commission's Group of Advisers on the Ethical Implications of Biotechnology issued its opinion condemning "Reproductive Human Cloning." On June 9, President Clinton accepted the National Bioethics Advisory Commission's report on the profound ethical issues raised by the possible cloning of human beings: the Commission unanimously agreed that it is morally unacceptable for anyone to attempt to create a child at this time with the technology used to create Dolly the sheep.

The President's Commission found that attempting to create a child using so-called somatic cell nuclear transfer cloning would pose great risks to the child and raises ethical issues needing further discussion, and the Commission called for a legislative moratorium on the use of the technique in humans. The Commission also found that the new technology may have many agricultural and medical benefits. It also concluded that the cloning of DNA, cells, tissues, and animals -- using somatic cell nuclear transfer and other cloning techniques -- is not ethically problematic when conducted in compliance with existing regulations and guidelines.

Acting on the Commission's key recommendation, President Clinton announced legislation banning the use of the new technology to clone human beings. The "Cloning Prohibition Act of 1997" would prohibit any attempt to create a human being using somatic cell nuclear transfer technology. In addition, the President:

- Reaffirmed that no Federal funds will be used to clone human beings; the prohibition he put in place in March will remain in effect while the proposed legislation is pending.
- Urged privately funded scientists and clinicians to adhere to the voluntary moratorium he called in March pending legislation.
- Pledged to work with other countries to enforce common aspects of our policies. Several countries, including [France?], Great Britain and Germany, have banned human cloning. The Denver Summit agreement is consistent with this pledge.



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MEMORANDUM

**To: Elizabeth Drye
Rachel Levinson**

From: Chuck Ludlam

Subject: Briefing Materials

Date: June 18, 1997

One of the biotech issues which may arise at the G-7 Summit -- if the AIDS vaccine and human cloning come up -- is the current fight over genetically modified crops -- a huge fight between the U.S. and the Europeans.

Attached are materials we ask that you give to Dan Tarullo as background. We don't want the issue to be raised in any plenary, public session, but we would be happy if Clinton raised in his bilateral, private discussions with the other heads of state.

BIO will be asking Dan for a few minutes to discuss this issue.

We are reviewing your draft bill and will have our comments ready early next week.

Thanks very much.



BIOTECHNOLOGY
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G-7 SUMMIT BRIEFING PAPER

RE LABELING OF GENETICALLY MODIFIED CROPS:

- It will not be in the best interests of the U.S. biotechnology industry, seed companies, farmers, grain shippers or processors to have the potential trade problems over labeling, that we face with this year's harvest of corn and soybeans elevated to the G-7 level.
- USTR and USDA are leading a coordinated effort to stave off imposition by the E.U. of mandatory requirements that all genetically modified crops be segregated and labeled.
- The National Academy of Sciences long ago established there is no higher degree or different risk posed by genetically modified crops as compared with conventional crops. Japan and Canada have joined the U.S. and the European Union in approving genetically modified soybeans and corn for import.
- The agreement over labeling in Europe is politically motivated, with anti-biotechnology groups like Greenpeace leading the opposition.
- The U.S. needs to be directly and constantly involved in working out an acceptable solution which protects agricultural exports from this country, now in excess of \$50 billion annually, from unreasonable requirements concerning segregation and labeling.
- The Biotechnology industry feels strongly this can best be accomplished through coordinated government/industry efforts headed by USTR and USDA. G7 involvement would be lengthy and uncertain and ought to be avoided at all cost, should it be proposed.

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Biotechnology Works: In Agriculture

Take a walk through the produce section of a supermarket today and you may see some interesting new products. Even if your visit is in the dead of winter, you might find red, vine-ripened tomatoes that rival the taste of a home-grown garden variety. Unlike the home-grown fruit, however, these tomatoes will stay fresh up to two weeks after they're harvested.

A little farther down the produce aisle you may see baby whole carrots, sweet red mini-peppers, nearly seedless green peppers and tastier cherry tomatoes, all just right for healthy, delicious snacks.

All of these nutritious, high-quality foods are products of a new approach to farming called biotechnology. Biotechnology is the next step in techniques, gained over centuries of experience, in improving plants and animals to produce better nutrition, flavor and yield.

But that's only the beginning. Let's look ahead to what we'll find in our produce aisle in a few short years. In addition to several different brands of tomatoes that stay fresh longer, you may find longer-lasting strawberries and raspberries, broccoli and cauliflower. You could also see seedless mini-melons, sweeter snap peas and potatoes that absorb less oil when cooked. Potatoes, sugarbeets, melons, corn, bananas, pineapples and strawberries will also be naturally resistant to insects and plant viruses, all thanks to biotechnology.

Elsewhere in both today's and tomorrow's supermarkets, many processed foods have been, or will be, improved through the use of biotechnology. Most of today's hard cheese products, for example, are made with a biotech enzyme called chymosin. This is produced by genetically engineered bacteria to be purer and more plentiful than its naturally occurring counterpart, rennet.

Feeding the World Through Biotechnology

While the United States and other developed nations produce surpluses of staples like rice, corn and other grains, many countries are not self-sufficient. Often, this is because of climate or other environmental limitations that make it difficult to grow conventional crop plants. Biotechnology may make it possible to "customize" the genetic makeup of crop plants so they can grow in exceptionally dry or wet, hot or cold climates. This could make self-sustaining agriculture a reality for people in areas of the world that aren't currently able to feed their population.

Increased crop yield, greater flexibility in growing environments, less use of chemical pesticides and improved nutritional content make agricultural biotechnology, quite literally, the future of the world's food supply.

Environmental Benefits of Agricultural Biotechnology

Beyond biotechnology's agricultural and economic benefits, the industry offers great promise in increasing crop yields without greater reliance on traditional chemical pesticides. For example, proteins that are toxic only to certain insects, and harmless to all other animals and people, are

produced by the *Bacillus thuringiensis*, or B.t., bacterium, organism that occurs naturally in soil. By transplanting the genes that produce those proteins into crop plants, we can make the plant toxic to pests that normally feed on it. This makes it possible to reduce our reliance on chemical pesticides.

Other agricultural biotechnology products, like modified pulp trees for use in paper production, will allow manufacturers to use less water and other natural resources, and to produce less waste from the production stream, while producing higher-quality materials.

Agricultural Biotechnology: Building on Centuries of Science

Traditional agriculture has relied for centuries on crossbreeding and hybridization to improve the quality and yield of crops and to overcome natural obstacles such as plant viruses and pest infestations. Crossbreeding and hybridization involve the controlled breeding of plants and animals with desirable traits (or that lack undesirable characteristics) to produce offspring that have the best traits of the parent organisms.

In today's world, virtually every plant and animal grown commercially for food or other applications is a product of crossbreeding and/or hybridization.⁸ Unfortunately, these processes are often costly, time-consuming, inefficient and subject to significant practical limitations. For example, producing corn with natural resistance to certain insects could take dozens of generations of traditional crossbreeding, if it is possible at all.

In addition, some of the other methods for controlling challenges to a plant's survival (i.e., insects, plant diseases and viruses, weeds) can currently be addressed only through the use of chemical pesticides that may harm the environment.

But there is another way. We can, for example, take the gene responsible for creating the chemical that makes the bacteria toxic specifically to the insect and transfer it to a plant. The plant's cells take up the new genetic information as their own and produce the protein, which protects it from the insect without the help of chemically based pesticides.

⁸ Many of our most common plants -- including corn, potatoes, tomatoes and strawberries -- bear little resemblance to their ancestor plants that developed in nature, prior to improvement by humans.

Biotechnology Agricultural Products

on the Market

- **Liberty Link™ Corn (Produced by AgrEvo®)**- Introduced in 1997, Liberty Link™ Corn allows growers to apply Liberty™ herbicide over the top during the growing season. This results in weed control with no effect on crop performance or yield. Liberty Link™ Corn hybrids are offered by seed company partners; Liberty™ herbicide is offered by AgrEvo®.
- **Liberty Link™ Canola (Produced by AgrEvo®)**- Introduced in 1995, Liberty Link™ Canola allows growers to apply Liberty™ herbicide over the top during the growing season. This results in weed control with no effect on crop performance or yield.
- **IMI-CORN® (Produced by American Cyanamid)**- Introduced in 1992, imidazolinone tolerant and resistant corn allows growers to apply the flexible and environmentally friendly imidazolinone herbicides to corn. Registration of LIGHTNING™ herbicide, a new imidazolinone specifically for use on IMI-CORN®, was approved by the EPA on March 31, 1997. One postemergence application of LIGHTNING™ herbicide provides both contact and residual control of broadleaf and grassy weeds resulting in maximum yield potential.
- **IMI™ Canola Seed (Produced by American Cyanamid)**- Introduced in 1995, imidazolinone tolerant canola allows growers to apply environmentally friendly imidazolinone herbicides to canola. In Canada, registration of ODYSSEY™ herbicide, a new imidazolinone for use on imidazolinone tolerant canola, was approved on April 4, 1997. One postemergence application of ODYSSEY™ herbicide provides both contact and residual control of hard-to-control broadleaf and grassy weeds resulting in maximum yield potential.
- **Freedom II™ Squash (Produced by Asgrow)** - Squash with a natural resistance to plant viruses.
- **BXN® Cotton (Produced by Calgene, Inc.)** - BXN® cotton plants that require less chemical herbicides.
- **FLAVR SAVR™ Tomato (Produced by Calgene, Inc.)** - The Flavr Savr™ is a high-quality, fresh market tomato that has been modified using antisense technology⁹ to ripen on the vine.
- **Laurical® (Produced by Calgene, Inc.)** - A less-expensive source of high-quality raw materials for soaps, detergents and cocoa butter replacement fats. Rapeseed plants with more than 35 percent laurate in oil have been produced.
- **CIBA Maximizer™ Hybrid Corn (Produced by Ciba Seeds)** - This corn is modified to have natural protection against the European corn borer, one of the most devastating insect pests in modern U. S. agriculture.

⁹Antisense technology involves taking the gene in the tomato that is responsible for softening, creating a duplicate of that genetic sequence in reverse and inserting it in the tomato. The new genetic information effectively "turns off" the softening process, which allows the tomato to ripen longer on the plant.

• **DEKALB[®] Insect-Protected Hybrid Corn (Produced by DEKALB Genetics Corporation)**- Approved in 1997, select DEKALB leader hybrids are now available with built-in protection against the European corn borer.

• **DEKALB GR Hybrid Corn (Produced by DEKALB Genetics Corporation)**: Approved in 1996, DEKALB GR hybrids provide growers the added weed control benefits of over the top glufosinate herbicide application during the growing season.

• **FreshWorld Farms[®] Tomato (Produced by DNAP Holding Corporation)** - The FreshWorld Farms[®] tomato is a premium, fresh market tomato developed through somaclonal variation¹⁰ to have superior color, taste and texture and a 10- to 14-day shelf life.

• **FreshWorld Farms Endless Summer[®] Tomato (Produced by DNAP Holding Corporation)** - The Endless Summer[™] tomato is a genetically engineered version of the FreshWorld Farms[®] tomato on the market since April 1993, and shares its superior color, taste and texture. What's new is its greatly extended shelf life of more than 30 to 40 days after harvest. Company scientists used Transwitch[®] technology to suppress production of ethylene, the hormone that causes tomatoes and other fruits to ripen. It is the company's first whole-food product developed through recombinant DNA technology.

• **FreshWorld Farms[®] Carrot Bites (Produced by DNAP Holding Corporation)** - FreshWorld Farms[®] carrot bites are crisp, juicy baby whole carrots that are peeled and washed, ready-to-eat, in one-pound bags.

• **FreshWorld Farms[®] Sweet Mini-Peppers (Produced by DNAP Holding Corporation)** - The FreshWorld Farms[®] sweet mini-pepper has a novel sweet taste, deep red color and is nearly seedless. It was developed through anther culture, an advanced breeding technique that captures and stabilizes preferred characteristics such as taste, texture and low seed count.

• **FreshWorld Farms[®] Cherry Tomatoes (Produced by DNAP Holding Corporation)** - The FreshWorld Farms[®] cherry tomato is specially bred for superior taste, color and texture. It is sold through distributors and supermarket chains in the mid-Atlantic, Northwest and Midwest regions.

• **High Oleic Acid Soybeans (Produced by DuPont Agricultural Products)** These soybeans produce an oil containing higher levels of oleic acid (82-85%) than found in currently available soybean oil (24%) and also containing lower levels of saturated fat. The oil will fit applications that require stability without the need of chemical hydrogenation."

• **High pH Tolerant Corn Hybrids (Produced by Garst Seed Company)**-These corn hybrids are capable of growing successfully on the severely alkaline soils which characterize the Western US corn belt.

• **Gray Leaf Spot Resistant Corn Hybrids (Produced by Garst Seed Company)**- Corn hybrids tolerant to the disease *Cercospora* spp., which attacks corn hybrids in the central and south eastern corn belt.

Somaclonal variation is a biotechnology process that involves breaking a plant sample down to its individual cells, putting the cells in a growth medium and regenerating new plant "clones" from the cells. The new plants will have a broad diversity of characteristics. The new plants with the desired characteristics are then used to create new plant lines through traditional breeding techniques.

• **"G-Stac"[™] Corn Hybrids (Produced by Garst Seed Company)** - Corn hybrids featuring "stacked" genes providing multitask capability. For example, hybrids which contain genes for the control of European Corn borer (Bt), genes for resistance to Liberty herbicide and genes for resistance to Imidazolone herbicide all in the same corn hybrid.

• **Chymogen[®] (Produced by Genencor International and Marketed by Chr. Hansen's)** - Chymogen is the biotechnology-produced version of an enzyme (chymosin) found in calves that makes milk curdle to produce cheese. Because it is produced through biotechnology, it is purer, more plentiful and eliminates variability in the quality and availability of calves' stomachs. It is used in approximately 60 percent of all hard cheese products made today.

• **Bollgard[®] Insect-Protected Cotton (Produced by Monsanto)** - Introduced in 1996, cotton with Monsanto's Bollgard gene is protected against cotton bollworms, pink bollworms and tobacco budworms.

• **NewLeaf[®] Insect-Protected Potato (Produced by Monsanto)** - Introduced in 1995, the NewLeaf potato is the first commercial crop to be protected against insect pest through biotechnology. Thanks to a gene from a variety of the B.t. bacteria, the NewLeaf Potato is resistant to the Colorado potato beetle.

• **Posilac[®] Bovine Somatotropin (Produced by Monsanto), Recombinant Bovine Somatotropin, (rBST)** - BST is a naturally occurring protein hormone in cows that induces them to produce milk. rBST improves milk production by as much as 10 to 15 percent and is now used by farmers whose herds represent over 30 percent of the nation's cows. It was approved by the FDA in 1993.

• **Roundup[®] Ready Cotton (Produced by Monsanto)** - Approved in 1996, Roundup Ready cotton tolerates both topical and post-directed applications of Roundup herbicide.

• **Roundup Ready[®] Soybeans (Produced by Monsanto)** - Introduced in 1996, Roundup Ready soybeans allow growers to apply Roundup herbicide over the top during growing season. The result is dependable, superior weed control with no effect on crop performance or yield.

• **YieldGard[™] Insect-Protected Corn (Produced by Monsanto)** - The YieldGard gene provides control of the European corn borer throughout the corn plant throughout the season.

• **NatureGard[®] Hybrid Seed Corn (Produced by Mycogen)** - These corn plants express a protein toxic to European Corn borer which will allow for less use of insecticides.

• **Chy Max[®] (fermentation-derived) (Produced by Pfizer, marketed by Chr. Hansen's)** - Chy Max[®] is another version of chymosin, an enzyme that causes milk to coagulate. It is an advanced fermentation ingredient that is of higher purity, quality and activity than natural rennet.

• **VitroGraft[®] Grapevine Plants (Produced by Vinifera, Inc., a wholly owned subsidiary of Epitec, Inc.)** - VitroGraft[®] grafted grapevine plants represent the highest-quality planting material available to the U.S. grapevine industry. Rootstock and scion materials are in-house disease tested and grafted using proprietary green-grafting techniques.

• **Increased Pectin Tomatoes (Produced by Zeneca Plant Sciences)** - Tomatoes that have been genetically modified to remain firm longer and retain pectin during processing into tomato paste.

Agricultural Biotechnology Products

Expected on the Market Within Six Years

- **Genetically Engineered Cotton Fiber (Produced by Agracetus, Inc.)** - This biotech product will have enhanced fiber performance, reduce dye-shop pollution and improve textile manufacturing efficiency.
- **Liberty Link™ Soybean, cotton, sugar beet and rice (Produced by AgrEvo®)** - These Liberty Link™ crops will be available in Canada and/or the United States. Like Liberty Link™ corn, when used together with Liberty™ herbicide, they will allow farmers greater flexibility and environmental soundness in weed control.
- **Seed Link Corn (Produced by AgrEvo®)** - These plants provide a more reliable pollination control system for corn seed production. The use of the Seed Link System eliminates the need for hand or mechanical detasseling.
- **Insect Protected Corn (Produced by AgrEvo®/Plant Genetics System)** - These plants express a protein toxic to various Lepidopteran pests, which allow less insecticide usage. Unlike insect protected crops on the market today, the toxin in these plants binds to a different site in the insect's mid-gut, providing an advantage to insect resistance management programs
- **IMI™ Wheat Seed (Produced by American Cyanamid)** - American Cyanamid is cooperating with universities and public and private laboratories and seed companies to develop wheat varieties tolerant to imidazoline herbicides. Imidazolinone herbicides are flexible, environmentally friendly and provide contact and residual control of weeds common to wheat production, including ones not controlled by currently registered wheat herbicides.
- **IMI™ Rice Seed (Produced by American Cyanamid)** - American Cyanamid is cooperating with universities and public and private seed companies to develop rice varieties tolerant to imidazolinone herbicides. Imidazolinone herbicides are flexible, environmentally friendly and provide superior contact and residual control of weeds.
- **IMI™ Sugar Beet Seed (Produced by American Cyanamid)** - American Cyanamid is cooperating with universities and seed companies to develop sugar beet varieties tolerant to imidazolinone herbicides. Imidazolinone herbicides are flexible, environmentally friendly and provide superior contact and residual control of weeds.
- **BXN plus Bt Cotton (Produced by Calgene, Inc.)** - These cotton plants will require less chemical herbicide and insecticide to lower grower input costs and to achieve greater crop yield. Initial varieties are in field trials. Market introduction is planned for 1998.
- **Insect Protected Tomatoes (Produced by Calgene, Inc.)** - These tomato plants will require less chemical insecticides to achieve higher yields.

● **High-Stearate Oil (Produced by Calgene, Inc.)** - High-stearate oil is an ingredient in margarine, shortenings and other food ingredients that would not require hydrogenation, thus reducing the expense.

● **High-Myristate Oil (Produced by Calgene, Inc.)** - This will be a less-expensive and more-abundant source of raw materials for soaps and detergents.

● **Medium Chain Fatty Acids/Medium Chain Triglycerides (Produced by Calgene, Inc.)** - This will be a less-expensive source of raw materials for high-performance lubricants, nutritional formulas and high-energy foods.

● **High Sweetness Tomato (Produced by Calgene)**- Tomato plants that produce high flavor tomatoes.

● **Disease Resistant Strawberry (Produced by Calgene, Inc.)** Strawberry plants that give improved crop yields and longer shelf life.

● **High Sweetness Strawberry (Produced by Calgene, Inc.)**- High quality fresh strawberries with improved flavor.

● **Genetically Engineered Fruits and Vegetables with Longer Post-Harvest Shelf Life (Produced by Agritope, Inc., a wholly owned subsidiary of Epitepe, Inc.)** - Using ethylene-control technology, Agritope, Inc., has created delayed-ripening, longer-lasting tomatoes, raspberries and strawberries.

● **AquaAdvantage® Salmon, Tilapia, Trout, Flounder (Produced by A/F Protein)** - The AquaAdvantage® salmon, tilapia, trout, and flounder have the capability of growing from egg to market size (8 to 10 lb.) in 1 to 1 1/2 years. Conventional fish breeding techniques require three years to bring a fish to market. This new salmon could make fish more plentiful, decrease overfishing of wild salmon and lower consumer costs. A/F Protein expects to introduce the AquaAdvantage® salmon within four to six years to a public for whom salmon is an increasingly popular food.

● **Ripening-Controlled Cherry Tomatoes (Produced by DNAP Holding Corporation)** - Using the same technology as in its Endless Summer™ fresh market tomato, the company has developed cherry tomatoes with longer market life, improved flavor and better harvest traits through ripening control.

● **Seedless Mini-Melon (Produced by DNAP Holding Corporation)** - This mini-melon is specially bred for its convenient single-serve size and flavor.

● **Sweeter Peas (Produced by DNAP Holding Corporation)** - Sugar snap peas have been modified for sweeter flavor and higher yield by controlling the conversion of sugar to starch using Transwitch® technology. Pea plants are currently in field evaluations.

● **Firmer Peppers (Produced by DNAP Holding Corporation)** - This sweet pepper has been modified using Transwitch® technology to remain firmer after harvest. Pepper plants are currently in field evaluations.

● **Sweeter Peppers (Produced by DNAP Holding Corporation)** - This pepper has been modified to be sweeter and tastier by overexpressing a gene for sweetness. Pepper plants are in early stages of seed increase and field evaluation.

● **Ripening-Controlled Bananas and Pineapples (Produced by DNAP Holding Corporation)** - Using the same ripening control technology as in its Endless Summer™ tomato, the company is developing banana and pineapple varieties with extended market life.

● **Strawberry (Produced by DNAP Holding Corporation)** - The company is improving the market life of fresh strawberries by using Transwitch® technology to keep fruit firmer after harvest and adding genes to resist disease.

● **High-Solids Potato (Produced by Monsanto)** - Monsanto has developed a higher-solids (or starch content) potato by introducing a starch-producing gene from a soil bacteria into a potato plant. With the reduction in the percentage of water in the genetically improved potato, less oil is absorbed during processing, resulting in a reduction of cooking time and costs, better-tasting french fries and an economic benefit to the processor.

● **Roundup Ready® Canola (Produced by Monsanto)** - Roundup Ready canola allows growers to apply Roundup® herbicide over the top of the crop during the growing season, for superior weed control with enhanced crop safety.

● **Roundup Ready® Sugarbeets (Produced by Monsanto)** - Roundup Ready sugarbeets are tolerant of Roundup® herbicide and provide growers with a new weed-control option while the crop is growing.

● **Roundup Ready® Corn (Produced by Monsanto)** - Roundup Ready corn allows over-the-top applications of Roundup® herbicide during the growing season for superior weed control.

● **New-Leaf® Y Insect-and Virus-Protected Potatoes (Produced by Monsanto)** - These potatoes protect themselves against the Colorado potato beetle and the potato virus Y.

● **Second-Generation Bollgard® Insect-Protected Cotton (Produced by Monsanto)** - This cotton controls insect pests, like the original Bollgard cotton, but using a different mode of action to help growers manage insect resistance concerns.

● **High-Stearate Soy Oil (Produced by Monsanto)** - This is a functional oil with healthier properties for margarines and shortenings. High-stearate oil requires no hydrogenation and contains no trans-fatty acids, which increase cholesterol.

● **Bt Sunflower, Soybeans, Canola, and Wheat (Produced by Mycogen Corp.)** - These crops will express a protein toxin providing protection against various caterpillar and beetle pests.

- **Fresh Market Tomato (Produced by Zeneca Plant Sciences)** - Zeneca is modifying the tomatoes for enhanced flavor, color and increased antioxidant vitamin content.
- **Banana (Produced by Zeneca Plant Sciences)** - Zeneca is developing an inherent resistance to Black Sigatoka and modifying ripening characteristics in bananas. This will reduce the need for chemical fungicides as well as improve the agronomics of production and the quality to the consumer.
- **Modified Lignin in Paper Pulp Trees (Produced by Zeneca Plant Sciences under separate agreements with Shell Forestry and Nippon Paper)** - By making lignin easier to remove from cellulose -- the primary ingredient in paper -- paper makers can make high quality paper with less energy and bleaching which results in benefits to both the paper processor and the environment.

Source: BIO Member Survey

Biopesticides, Herbicide Resistance and Natural Protections for Plants

Biopesticides

Several biopesticides¹¹ are in use today. Biopesticide products are based on natural agents such as microorganisms and fatty acid compounds. They are toxic only to targeted pests (such as the European corn borer) and do not harm humans, animals, fish, birds and beneficial insects. In addition, because biopesticides act in unique ways, they can control pest populations that have developed tolerance to chemical pesticides.

One of the most common microorganisms used in biologically based pesticides is the *Bacillus thuringiensis*, or B.t., bacterium. Several of the proteins produced by the B.t. bacteria, principally in the coating the bacteria forms around itself, are lethal to individual species of insects. By using B.t. bacteria in pesticide formulations, target insects can be eliminated without relying on chemically based pesticides.

It is also possible to use pheromones in pest control. Pheromones are naturally occurring substances that insects produce to attract mates. In pest control, pheromones are used to attract insects away from crop plants. In recent years, for example, pheromone-based traps were used to control fruit fly infestations in California. European corn borers, one of the most prevalent pests, costs the nation \$1.2 billion in crop damage each year.

A biopesticide is any material of natural origin used in pest control derived from living organisms, such as bacteria, plant cells or animal cells.

Herbicide Resistance

Planting conditions good for crop plants will also sustain unwanted weeds that can reduce crop yield. To prevent this, herbicides are sprayed on crops. Often, herbicides must be applied several times during the growing cycle, at great expense to the farmer and possible harm to the environment.

Using biotechnology, it is possible to make crop plants tolerant of specific herbicides. When the herbicide is sprayed, it will kill the weeds but have no effect on the crop plants. This lets farmers reduce the number of times herbicides have to be applied and reduces the cost of producing crops and damage to the environment.

Natural Resistance to Pests and Viruses

We can, today, transplant the genetic information that makes a given bacterium — such as the B.t. bacterium — lethal only to a specific insect (but not to humans or animals) into plants on which that insect feeds. The plant that once was a food source for the insect now kills it. This process, which has no effect whatsoever on humans or other species, means that it becomes less necessary to spray crops with chemical pesticides to control infestations.

Biopesticide Products Currently on the Market

- **Laginex™ Bioinsectide** (Produced by AgraQuest, Inc.)- This product is effective for controlling a wide range of mosquito larvae in rice, wetlands and other bodies of water.
- **Disease Free Kleentek™** (Produced by Crop Genetics International) - This product increases yield of sugar per acre.
- **Spod-X™** (Produced by Crop Genetics International) - Spod-X™ uses a naturally occurring insect virus to control the beet armyworm. The beet armyworm is becoming resistant to many chemical insecticides. Spod-X™ is safer to use and better for the environment.
- **Aspire™** (Produced by Ecogen) - Aspire™ is a biofungicide used to protect fresh produce from post-harvest rot. It is used on citrus, pome fruits, berries and grapes. The active ingredient is a naturally occurring yeast that is harmless to all nontargeted organisms.
- **Foil® Bioinsecticide** (Produced by Ecogen) - Foil® is effective against the Colorado potato beetle, European corn borer, armyworms and loopers.
- **Condor® Bioinsecticide** (Produced by Ecogen) - This product is effective against the tobacco budworm, cotton bollworm, the soybean looper, velvetbean caterpillar, green clover worm, gypsy moth and spruce budworm.

• **Cutlass® Bioinsecticide (Produced by Ecogen)** - This is a broad-spectrum bioinsecticide effective against the beet armyworm, cabbage looper, diamondback moth, cabbage webworm and imported cabbageworm.

• **Otinem® Insecticide, Bee-scent® and No-Mate® (Produced by Ecogen).**

• **AQ-10® (Produced by Ecogen)** - AQ-10® is a biofungicide that protects crops from powdery mildew. It is used on strawberries, grapes, tomatoes, cucurbits and ornamentals. It reduces the use of conventional fungicides.

• **Match® (Produced by Mycogen)**-Controls broad spectrum of caterpillars in vegetables, field crops, nuts, grapes, turf, stored grain, and ornamental and nursery crops.

• **MVP® (Produced by Mycogen)** - This product is used on tree fruits and nuts, vines, cotton and vegetables to control leaf-eating caterpillar pests.

• **M-Peri™ (Produced by Mycogen)** - This product is used on corn to combat the European corn borer.

• **M-Pede™ (Produced by Mycogen)** - M-Pede is used on fruits, vegetables, grapes and ornamentals to resist soft-body insects and powdery mildew.

• **DeMoss™ (Produced by Mycogen)** - This product is used on roofs, buildings, sidewalks and greenhouses to resist moss, algae and lichens.

• **Thinex® (Produced by Mycogen)**- This product is used for blossom thinning in apples, pears, and fruits.

• **M/C® (Produced by Mycogen)**- M/C is used on vegetables to control various caterpillart pests.

Source: BIO Member Survey

Biopesticide Products Expected on the Market Within Three Years

• **Corn, Soybeans and Canola Resistant to Liberty™ (Produced by AgrEvo)** - Liberty™ is a herbicide made from a naturally occurring substance that impedes ammonia detoxification, which kills plants. Since it affects both crop plants and unwanted weeds, AgrEvo has modified corn, soybean and canola plants to be resistant to Liberty™. The Liberty system™ will allow farmers greater flexibility and environmental soundness in weed control.

• **QST 153 Biofungicide (AgraQuest, Inc.)**- For diseases of grapes, vegetables, and fruit (downy mildews, bunch rot, gray mold, brown rot).

- **OST 177 Biofungicide (AgraQuest, Inc.)**-For diseases of grapes, other fruits and vegetables, turf and ornamentals (Powdery mildew, gray mold, scab, damping off.)
- **QST 776 Insect Repellent (AgraQuest, Inc.)**- Natural product for repelling mosquitoes, ticks, and other biting insects.
- **Ecologix[™] Cockroach Bait (Produced by Dominion Biosciences)** - This is the first commercial product developed from a unique insect growth regulator technology. It is highly effective in eliminating insect populations, yet completely nontoxic to users, pets and the environment.
- **Leone[™] Biofungicide (Produced by Dominion Biosciences)** - This product controls a number of plant diseases by relying on highly active, antimicrobial "predator" bacteria. These naturally derived biochemicals offer a new mode of action for effective and safe control of disease-causing microorganisms.
- **Crymax[™] (Produced by Ecogen)** - Crymax[™] is a genetically engineered bioinsecticide that is very effective against a broad range of pests. It will be used on vegetables, trees, nuts and vines.
- **EG7826[™] (Produced by Ecogen)** - This will be a genetically modified insecticide that will control the fall armyworm, a major insect pest affecting sweet corn.
- **Scythe[™] Herbicide (Produced by Mycogen)** - This is used for horticulture and landscape management to combat a broad spectrum of weeds.

Source: BIO Member Survey

B.t.-Based and Other Biological Control Agents

A number of products are in development that will control insects as well as conventional insecticides, thereby reducing the use of these products.

B.t. technology is used to develop and specially formulate a line of biotoxin and fatty acid based products for field testing in the poultry and livestock industries.

Mycogen, Ecogen and Ciba Geigy Ag Group are three of the companies developing these products.

- **Baculovirus Insecticides (Produced by American Cyanamid)**-These products express insect-specific toxins and control Lepidoteran pests at levels similar to chemical insecticides.
- **Agree[®] (Produced by Ciba Geigy Ag Group - Ciba Crop Protection)** - This is a B.t.-based bioinsecticide designed to control pests that affect tobacco, corn and soybean plants.

- **Design®** (Produced by Ciba Geigy) - Design® is a B.t.-based bioinsecticide for cotton and soybeans.

- **Exhibit®** (Produced by Ciba Geigy) - Exhibit® is a parasitic nematode for control of insects on ornamental plants and turf.

- **M-Press** (Produced by Mycogen)-This product will be used to control the fall army worm in sweet corn and other vegetable crops.

Source: The Biotechnology Industry Organization

Insect-, Virus- and Herbicide-Resistant Plants Under Development

- **Herbicide-Tolerant Plants (Produced by American Cyanamid)** American Cyanamid is working with universities and public and private laboratories and seed companies to develop a number of crop plants to tolerate imidazolinone herbicides while achieving cost effective contact and residual control of weeds.

Crops under development for tolerance to imidazolinone herbicides:

Wheat
Rice
Sugar beets

- **Herbicide-Tolerant Plants (Produced by Monsanto)** - Monsanto has genetically modified a number of crop plants to tolerate its Roundup® herbicide. This natural tolerance lets farmers reduce herbicide applications while achieving cost-effective broad-spectrum weed control using a product well known for its favorable environmental characteristics.

Crops tolerant to Roundup® Herbicides:

Canola/Oilseed Rape
Corn
Sugarbeets

- **B.t. Cotton, Alfalfa, Canola and Sunflower (Produced by Mycogen)** - Plants that express a protein toxic to various insect pests, which will allow for less use of insecticides.

Source: BIO Member Survey

How Agricultural Biotechnology Is Regulated

Since combining specific genes from donor and host plants does not alter the basic nature of the host plant, the result of genetic modification is predictable and can be carefully controlled. As with any new variety of food, the developers test extensively for safety, quality and other factors.

The Food and Drug Administration (FDA) is responsible for approving the safety of all foods and new food ingredients. In addition, all producers are required to ensure the safety and quality of anything they introduce into the food supply.

The U.S. Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) impose safety requirements and/or performance standards on the development of pesticides, herbicides and genetically modified test crops. Examples of tests include crops with improved disease resistance and animal vaccines produced from biotech microorganisms.

The EPA regulates the use of chemicals, including pesticides in the environment. With this authority, EPA must approve any field test of biotech products with new properties.

The FDA may require that genetic modifications that significantly alter the nutritional value of the host food, use genetic material from outside the traditional food supply or use known allergens be subject to strict pre-market testing and regulatory oversight.

The FDA also requires that any genetically modified food product that significantly alters the host food's nutritional value or uses material from a known allergen be clearly labeled. For example, any product that used a gene from a peanut, which is a potential allergen, would be subject to testing and labeling requirements. The FDA also has the authority to order unsafe products off the market.



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

G-7 SUMMIT BRIEFING PAPER

RE LABELING OF GENETICALLY MODIFIED CROPS:

- It will not be in the best interests of the U.S. biotechnology industry, seed companies, farmers, grain shippers or processors to have the potential trade problems over labeling, that we face with this year's harvest of corn and soybeans elevated to the G-7 level.
- USTR and USDA are leading a coordinated effort to stave off imposition by the E.U. of mandatory requirements that all genetically modified crops be segregated and labeled.
- The National Academy of Sciences long ago established there is no higher degree or different risk posed by genetically modified crops as compared with conventional crops. Japan and Canada have joined the U.S. and the European Union in approving genetically modified soybeans and corn for import.
- The agreement over labeling in Europe is politically motivated, with anti-biotechnology groups like Greenpeace leading the opposition.
- The U.S. needs to be directly and constantly involved in working out an acceptable solution which protects agricultural exports from this country, now in excess of \$50 billion annually, from unreasonable requirements concerning segregation and labeling.
- The Biotechnology industry feels strongly this can best be accomplished through coordinated government/industry efforts headed by USTR and USDA. G7 involvement would be lengthy and uncertain and ought to be avoided at all cost, should it be proposed.

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Biotechnology Works: In Agriculture

Take a walk through the produce section of a supermarket today and you may see some interesting new products. Even if your visit is in the dead of winter, you might find red, vine-ripened tomatoes that rival the taste of a home-grown garden variety. Unlike the home-grown fruit, however, these tomatoes will stay fresh up to two weeks after they're harvested.

A little farther down the produce aisle you may see baby whole carrots, sweet red mini-peppers, nearly seedless green peppers and tastier cherry tomatoes, all just right for healthy, delicious snacks.

All of these nutritious, high-quality foods are products of a new approach to farming called biotechnology. Biotechnology is the next step in techniques, gained over centuries of experience, in improving plants and animals to produce better nutrition, flavor and yield.

But that's only the beginning. Let's look ahead to what we'll find in our produce aisle in a few short years. In addition to several different brands of tomatoes that stay fresh longer, you may find longer-lasting strawberries and raspberries, broccoli and cauliflower. You could also see seedless mini-melons, sweeter snap peas and potatoes that absorb less oil when cooked. Potatoes, sugarbeets, melons, corn, bananas, pineapples and strawberries will also be naturally resistant to insects and plant viruses, all thanks to biotechnology.

Elsewhere in both today's and tomorrow's supermarkets, many processed foods have been, or will be, improved through the use of biotechnology. Most of today's hard cheese products, for example, are made with a biotech enzyme called chymosin. This is produced by genetically engineered bacteria to be purer and more plentiful than its naturally occurring counterpart, rennet.

Feeding the World Through Biotechnology

While the United States and other developed nations produce surpluses of staples like rice, corn and other grains, many countries are not self-sufficient. Often, this is because of climate or other environmental limitations that make it difficult to grow conventional crop plants. Biotechnology may make it possible to "customize" the genetic makeup of crop plants so they can grow in exceptionally dry or wet, hot or cold climates. This could make self-sustaining agriculture a reality for people in areas of the world that aren't currently able to feed their population.

Increased crop yield, greater flexibility in growing environments, less use of chemical pesticides and improved nutritional content make agricultural biotechnology, quite literally, the future of the world's food supply.

Environmental Benefits of Agricultural Biotechnology

Beyond biotechnology's agricultural and economic benefits, the industry offers great promise in increasing crop yields without greater reliance on traditional chemical pesticides. For example, proteins that are toxic only to certain insects, and harmless to all other animals and people, are

produced by the *Bacillus thuringiensis*, or B.t., bacterium, organism that occurs naturally in soil. By transplanting the genes that produce those proteins into crop plants, we can make the plant toxic to pests that normally feed on it. This makes it possible to reduce our reliance on chemical pesticides.

Other agricultural biotechnology products, like modified pulp trees for use in paper production, will allow manufacturers to use less water and other natural resources, and to produce less waste from the production stream, while producing higher-quality materials.

Agricultural Biotechnology: Building on Centuries of Science

Traditional agriculture has relied for centuries on crossbreeding and hybridization to improve the quality and yield of crops and to overcome natural obstacles such as plant viruses and pest infestations. Crossbreeding and hybridization involve the controlled breeding of plants and animals with desirable traits (or that lack undesirable characteristics) to produce offspring that have the best traits of the parent organisms.

In today's world, virtually every plant and animal grown commercially for food or other applications is a product of crossbreeding and/or hybridization.⁸ Unfortunately, these processes are often costly, time-consuming, inefficient and subject to significant practical limitations. For example, producing corn with natural resistance to certain insects could take dozens of generations of traditional crossbreeding, if it is possible at all.

In addition, some of the other methods for controlling challenges to a plant's survival (i.e., insects, plant diseases and viruses, weeds) can currently be addressed only through the use of chemical pesticides that may harm the environment.

But there is another way. We can, for example, take the gene responsible for creating the chemical that makes the bacteria toxic specifically to the insect and transfer it to a plant. The plant's cells take up the new genetic information as their own and produce the protein, which protects it from the insect without the help of chemically based pesticides.

⁸ Many of our most common plants -- including corn, potatoes, tomatoes and strawberries -- bear little resemblance to their ancestor plants that developed in nature, prior to improvement by humans.

Biotechnology Agricultural Products **on the Market**

● **Liberty Link™ Corn (Produced by AgrEvo®)**- Introduced in 1997, Liberty Link™ Corn allows growers to apply Liberty™ herbicide over the top during the growing season. This results in weed control with no effect on crop performance or yield. Liberty Link™ Corn hybrids are offered by seed company partners; Liberty™ herbicide is offered by AgrEvo®.

● **Liberty Link™ Canola (Produced by AgrEvo®)**- Introduced in 1995, Liberty Link™ Canola allows growers to apply Liberty™ herbicide over the top during the growing season. This results in weed control with no effect on crop performance or yield.

● **IMI-CORN® (Produced by American Cyanamid)**- Introduced in 1992, imidazolinone tolerant and resistant corn allows growers to apply the flexible and environmentally friendly imidazolinone herbicides to corn. Registration of LIGHTNING™ herbicide, a new imidazolinone specifically for use on IMI-CORN®, was approved by the EPA on March 31, 1997. One postemergence application of LIGHTNING™ herbicide provides both contact and residual control of broadleaf and grassy weeds resulting in maximum yield potential.

● **IMI™ Canola Seed (Produced by American Cyanamid)**- Introduced in 1995, imidazolinone tolerant canola allows growers to apply environmentally friendly imidazolinone herbicides to canola. In Canada, registration of ODYSSEY™ herbicide, a new imidazolinone for use on imidazolinone tolerant canola, was approved on April 4, 1997. One postemergence application of ODYSSEY™ herbicide provides both contact and residual control of hard-to-control broadleaf and grassy weeds resulting in maximum yield potential.

● **Freedom II™ Squash (Produced by Asgrow)** - Squash with a natural resistance to plant viruses.

● **BXN® Cotton (Produced by Calgene, Inc.)** - BXN® cotton plants that require less chemical herbicides.

● **FLAVR SAVR™ Tomato (Produced by Calgene, Inc.)** - The Flavr Savr™ is a high-quality, fresh market tomato that has been modified using antisense technology⁹ to ripen on the vine.

● **Laurical® (Produced by Calgene, Inc.)** - A less-expensive source of high-quality raw materials for soaps, detergents and cocoa butter replacement fats. Rapeseed plants with more than 35 percent laurate in oil have been produced.

● **CIBA Maximizer™ Hybrid Corn (Produced by Ciba Seeds)** - This corn is modified to have natural protection against the European corn borer, one of the most devastating insect pests in modern U. S. agriculture.

⁹Antisense technology involves taking the gene in the tomato that is responsible for softening, creating a duplicate of that genetic sequence in reverse and inserting it in the tomato. The new genetic information effectively "turns off" the softening process, which allows the tomato to ripen longer on the plant.

• **DEKALB[®] Insect-Protected Hybrid Corn (Produced by DEKALB Genetics Corporation)**- Approved in 1997, select DEKALB leader hybrids are now available with built-in protection against the European corn borer.

• **DEKALB GR Hybrid Corn (Produced by DEKALB Genetics Corporation)**: Approved in 1996, DEKALB GR hybrids provide growers the added weed control benefits of over the top glufosinate herbicide application during the growing season.

• **FreshWorld Farms[®] Tomato (Produced by DNAP Holding Corporation)** - The FreshWorld Farms[®] tomato is a premium, fresh market tomato developed through somaclonal variation¹⁰ to have superior color, taste and texture and a 10- to 14-day shelf life.

• **FreshWorld Farms Endless Summer[®] Tomato (Produced by DNAP Holding Corporation)** - The Endless Summer[™] tomato is a genetically engineered version of the FreshWorld Farms[®] tomato on the market since April 1993, and shares its superior color, taste and texture. What's new is its greatly extended shelf life of more than 30 to 40 days after harvest. Company scientists used Transwitch[®] technology to suppress production of ethylene, the hormone that causes tomatoes and other fruits to ripen. It is the company's first whole-food product developed through recombinant DNA technology.

• **FreshWorld Farms[®] Carrot Bites (Produced by DNAP Holding Corporation)** - FreshWorld Farms[®] carrot bites are crisp, juicy baby whole carrots that are peeled and washed, ready-to-eat, in one-pound bags.

• **FreshWorld Farms[®] Sweet Mini-Peppers (Produced by DNAP Holding Corporation)** - The FreshWorld Farms[®] sweet mini-pepper has a novel sweet taste, deep red color and is nearly seedless. It was developed through anther culture, an advanced breeding technique that captures and stabilizes preferred characteristics such as taste, texture and low seed count.

• **FreshWorld Farms[®] Cherry Tomatoes (Produced by DNAP Holding Corporation)** - The FreshWorld Farms[®] cherry tomato is specially bred for superior taste, color and texture. It is sold through distributors and supermarket chains in the mid-Atlantic, Northwest and Midwest regions.

• **High Oleic Acid Soybeans (Produced by DuPont Agricultural Products)** These soybeans produce an oil containing higher levels of oleic acid (82-85%) than found in currently available soybean oil (24%) and also containing lower levels of saturated fat. The oil will fit applications that require stability without the need of chemical hydrogenation."

• **High pH Tolerant Corn Hybrids (Produced by Garst Seed Company)**-These corn hybrids are capable of growing successfully on the severely alkaline soils which characterize the Western US corn belt.

• **Gray Leaf Spot Resistant Corn Hybrids (Produced by Garst Seed Company)**- Corn hybrids tolerant to the disease *Cercospora* spp., which attacks corn hybrids in the central and south eastern corn belt.

Somaclonal variation is a biotechnology process that involves breaking a plant sample down to its individual cells, putting the cells in a growth medium and regenerating new plant "clones" from the cells. The new plants will have a broad diversity of characteristics. The new plants with the desired characteristics are then used to create new plant lines through traditional breeding techniques.

● **"G-Stac"™ Corn Hybrids (Produced by Garst Seed Company)** - Corn hybrids featuring "stacked" genes providing multitask capability. For example, hybrids which contain genes for the control of European Corn borer (Bt), genes for resistance to Liberty herbicide and genes for resistance to Imidazolone herbicide all in the same corn hybrid.

● **Chymogen® (Produced by Genencor International and Marketed by Chr. Hansen's)** - Chymogen is the biotechnology-produced version of an enzyme (chymosin) found in calves that makes milk curdle to produce cheese. Because it is produced through biotechnology, it is purer, more plentiful and eliminates variability in the quality and availability of calves' stomachs. It is used in approximately 60 percent of all hard cheese products made today.

● **Bollgard® Insect-Protected Cotton (Produced by Monsanto)** - Introduced in 1996, cotton with Monsanto's Bollgard gene is protected against cotton bollworms, pink bollworms and tobacco budworms.

● **NewLeaf® Insect-Protected Potato (Produced by Monsanto)** - Introduced in 1995, the NewLeaf potato is the first commercial crop to be protected against insect pest through biotechnology. Thanks to a gene from a variety of the B.t. bacteria, the NewLeaf Potato is resistant to the Colorado potato beetle.

● **Posilac® Bovine Somatotropin (Produced by Monsanto), Recombinant Bovine Somatotropin, (rBST)** - BST is a naturally occurring protein hormone in cows that induces them to produce milk. rBST improves milk production by as much as 10 to 15 percent and is now used by farmers whose herds represent over 30 percent of the nation's cows. It was approved by the FDA in 1993.

● **Roundup® Ready Cotton (Produced by Monsanto)** - Approved in 1996, Roundup Ready cotton tolerates both topical and post-directed applications of Roundup herbicide.

● **Roundup Ready® Soybeans (Produced by Monsanto)** - Introduced in 1996, Roundup Ready soybeans allow growers to apply Roundup herbicide over the top during growing season. The result is dependable, superior weed control with no effect on crop performance or yield.

● **YieldGard™ Insect-Protected Corn (Produced by Monsanto)** - The YieldGard gene provides control of the European corn borer throughout the corn plant throughout the season.

● **NatureGard® Hybrid Seed Corn (Produced by Mycogen)** - These corn plants express a protein toxic to European Corn borer which will allow for less use of insecticides.

● **Chy Max® (fermentation-derived) (Produced by Pfizer, marketed by Chr. Hansen's)** - Chy Max® is another version of chymosin, an enzyme that causes milk to coagulate. It is an advanced fermentation ingredient that is of higher purity, quality and activity than natural rennet.

● **VitroGraft® Grapevine Plants (Produced by Vinifera, Inc., a wholly owned subsidiary of Epitope, Inc.)** - VitroGraft® grafted grapevine plants represent the highest-quality planting material available to the U.S. grapevine industry. Rootstock and scion materials are in-house disease tested and grafted using proprietary green-grafting techniques.

● **Increased Pectin Tomatoes (Produced by Zeneca Plant Sciences)** - Tomatoes that have been genetically modified to remain firm longer and retain pectin during processing into tomato paste.

Agricultural Biotechnology Products

Expected on the Market Within Six Years

- **Genetically Engineered Cotton Fiber (Produced by Agracetus, Inc.)** - This biotech product will have enhanced fiber performance, reduce dye-shop pollution and improve textile manufacturing efficiency.

- **Liberty Link™ Soybean, cotton, sugar beet and rice (Produced by AgrEvo®)** - These Liberty Link™ crops will be available in Canada and/or the United States. Like Liberty Link™ corn, when used together with Liberty™ herbicide, they will allow farmers greater flexibility and environmental soundness in weed control.

- **Seed Link Corn (Produced by AgrEvo®)** - These plants provide a more reliable pollination control system for corn seed production. The use of the Seed Link System eliminates the need for hand or mechanical detasseling.

- **Insect Protected Corn (Produced by AgrEvo®/Plant Genetics System)** - These plants express a protein toxic to various Lepidopteran pests, which allow less insecticide usage. Unlike insect protected crops on the market today, the toxin in these plants binds to a different site in the insect's mid-gut, providing an advantage to insect resistance management programs

- **IMI™ Wheat Seed (Produced by American Cyanamid)** - American Cyanamid is cooperating with universities and public and private laboratories and seed companies to develop wheat varieties tolerant to imidazoline herbicides. Imidazolinone herbicides are flexible, environmentally friendly and provide contact and residual control of weeds common to wheat production, including ones not controlled by currently registered wheat herbicides.

- **IMI™ Rice Seed (Produced by American Cyanamid)** - American Cyanamid is cooperating with universities and public and private seed companies to develop rice varieties tolerant to imidazolinone herbicides. Imidazolinone herbicides are flexible, environmentally friendly and provide superior contact and residual control of weeds.

- **IMI™ Sugar Beet Seed (Produced by American Cyanamid)** - American Cyanamid is cooperating with universities and seed companies to develop sugar beet varieties tolerant to imidazolinone herbicides. Imidazolinone herbicides are flexible, environmentally friendly and provide superior contact and residual control of weeds.

- **BXN plus Bt Cotton (Produced by Calgene, Inc.)** - These cotton plants will require less chemical herbicide and insecticide to lower grower input costs and to achieve greater crop yield. Initial varieties are in field trials. Market introduction is planned for 1998.

- **Insect Protected Tomatoes (Produced by Calgene, Inc.)** - These tomato plants will require less chemical insecticides to achieve higher yields.

● **High-Stearate Oil (Produced by Calgene, Inc.)** - High-stearate oil is an ingredient in margarine, shortenings and other food ingredients that would not require hydrogenation, thus reducing the expense.

● **High-Myristate Oil (Produced by Calgene, Inc.)** - This will be a less-expensive and more-abundant source of raw materials for soaps and detergents.

● **Medium Chain Fatty Acids/Medium Chain Triglycerides (Produced by Calgene, Inc.)** - This will be a less-expensive source of raw materials for high-performance lubricants, nutritional formulas and high-energy foods.

● **High Sweetness Tomato (Produced by Calgene)**- Tomato plants that produce high flavor tomatoes.

● **Disease Resistant Strawberry (Produced by Calgene, Inc.)** Strawberry plants that give improved crop yields and longer shelf life.

● **High Sweetness Strawberry (Produced by Calgene, Inc.)**- High quality fresh strawberries with improved flavor.

● **Genetically Engineered Fruits and Vegetables with Longer Post-Harvest Shelf Life (Produced by Agritope, Inc., a wholly owned subsidiary of Epitepe, Inc.)** - Using ethylene-control technology, Agritope, Inc., has created delayed-ripening, longer-lasting tomatoes, raspberries and strawberries.

● **AquaAdvantage® Salmon, Tilapia, Trout, Flounder (Produced by A/F Protein)** - The AquaAdvantage® salmon, tilapia, trout, and flounder have the capability of growing from egg to market size (8 to 10 lb.) in 1 to 1 1/2 years. Conventional fish breeding techniques require three years to bring a fish to market. This new salmon could make fish more plentiful, decrease overfishing of wild salmon and lower consumer costs. A/F Protein expects to introduce the AquaAdvantage® salmon within four to six years to a public for whom salmon is an increasingly popular food.

● **Ripening-Controlled Cherry Tomatoes (Produced by DNAP Holding Corporation)** - Using the same technology as in its Endless Summer™ fresh market tomato, the company has developed cherry tomatoes with longer market life, improved flavor and better harvest traits through ripening control.

● **Seedless Mini-Melon (Produced by DNAP Holding Corporation)** - This mini-melon is specially bred for its convenient single-serve size and flavor.

● **Sweeter Peas (Produced by DNAP Holding Corporation)** - Sugar snap peas have been modified for sweeter flavor and higher yield by controlling the conversion of sugar to starch using Transwitch® technology. Pea plants are currently in field evaluations.

● **Firmer Peppers (Produced by DNAP Holding Corporation)** - This sweet pepper has been modified using Transwitch® technology to remain firmer after harvest. Pepper plants are currently in field evaluations.

● **Sweeter Peppers (Produced by DNAP Holding Corporation)** - This pepper has been modified to be sweeter and tastier by overexpressing a gene for sweetness. Pepper plants are in early stages of seed increase and field evaluation.

● **Ripening-Controlled Bananas and Pineapples (Produced by DNAP Holding Corporation)** - Using the same ripening control technology as in its Endless Summer™ tomato, the company is developing banana and pineapple varieties with extended market life.

● **Strawberry (Produced by DNAP Holding Corporation)** - The company is improving the market life of fresh strawberries by using Transwitch® technology to keep fruit firmer after harvest and adding genes to resist disease.

● **High-Solids Potato (Produced by Monsanto)** - Monsanto has developed a higher-solids (or starch content) potato by introducing a starch-producing gene from a soil bacteria into a potato plant. With the reduction in the percentage of water in the genetically improved potato, less oil is absorbed during processing, resulting in a reduction of cooking time and costs, better-tasting french fries and an economic benefit to the processor.

● **Roundup Ready® Canola (Produced by Monsanto)** - Roundup Ready canola allows growers to apply Roundup® herbicide over the top of the crop during the growing season, for superior weed control with enhanced crop safety.

● **Roundup Ready® Sugarbeets (Produced by Monsanto)** - Roundup Ready sugarbeets are tolerant of Roundup® herbicide and provide growers with a new weed-control option while the crop is growing.

● **Roundup Ready® Corn (Produced by Monsanto)** - Roundup Ready corn allows over-the-top applications of Roundup® herbicide during the growing season for superior weed control.

● **New-Leaf® Y Insect-and Virus-Protected Potatoes (Produced by Monsanto)** - These potatoes protect themselves against the Colorado potato beetle and the potato virus Y.

● **Second-Generation Bollgard® Insect-Protected Cotton (Produced by Monsanto)** - This cotton controls insect pests, like the original Bollgard cotton, but using a different mode of action to help growers manage insect resistance concerns.

● **High-Stearate Soy Oil (Produced by Monsanto)** - This is a functional oil with healthier properties for margarines and shortenings. High-stearate oil requires no hydrogenation and contains no trans-fatty acids, which increase cholesterol.

● **Bt Sunflower, Soybeans, Canola, and Wheat (Produced by Mycogen Corp.)** - These crops will express a protein toxin providing protection against various caterpillar and beetle pests.

- **Fresh Market Tomato (Produced by Zeneca Plant Sciences)** - Zeneca is modifying the tomatoes for enhanced flavor, color and increased antioxidant vitamin content.
- **Banana (Produced by Zeneca Plant Sciences)** - Zeneca is developing an inherent resistance to Black Sigatoka and modifying ripening characteristics in bananas. This will reduce the need for chemical fungicides as well as improve the agronomics of production and the quality to the consumer.
- **Modified Lignin in Paper Pulp Trees (Produced by Zeneca Plant Sciences under separate agreements with Shell Forestry and Nippon Paper)** - By making lignin easier to remove from cellulose — the primary ingredient in paper — paper makers can make high quality paper with less energy and bleaching which results in benefits to both the paper processor and the environment.

Source: BIO Member Survey

Biopesticides, Herbicide Resistance and Natural Protections for Plants

Biopesticides

Several biopesticides¹¹ are in use today. Biopesticide products are based on natural agents such as microorganisms and fatty acid compounds. They are toxic only to targeted pests (such as the European corn borer) and do not harm humans, animals, fish, birds and beneficial insects. In addition, because biopesticides act in unique ways, they can control pest populations that have developed tolerance to chemical pesticides.

One of the most common microorganisms used in biologically based pesticides is the *Bacillus thuringiensis*, or B.t., bacterium. Several of the proteins produced by the B.t. bacteria, principally in the coating the bacteria forms around itself, are lethal to individual species of insects. By using B.t. bacteria in pesticide formulations, target insects can be eliminated without relying on chemically based pesticides.

It is also possible to use pheromones in pest control. Pheromones are naturally occurring substances that insects produce to attract mates. In pest control, pheromones are used to attract insects away from crop plants. In recent years, for example, pheromone-based traps were used to control fruit fly infestations in California. European corn borers, one of the most prevalent pests, costs the nation \$1.2 billion in crop damage each year.

A biopesticide is any material of natural origin used in pest control derived from living organisms, such as bacteria, plant cells or animal cells.

Herbicide Resistance

Planting conditions good for crop plants will also sustain unwanted weeds that can reduce crop yield. To prevent this, herbicides are sprayed on crops. Often, herbicides must be applied several times during the growing cycle, at great expense to the farmer and possible harm to the environment.

Using biotechnology, it is possible to make crop plants tolerant of specific herbicides. When the herbicide is sprayed, it will kill the weeds but have no effect on the crop plants. This lets farmers reduce the number of times herbicides have to be applied and reduces the cost of producing crops and damage to the environment.

Natural Resistance to Pests and Viruses

We can, today, transplant the genetic information that makes a given bacterium — such as the B.t. bacterium — lethal only to a specific insect (but not to humans or animals) into plants on which that insect feeds. The plant that once was a food source for the insect now kills it. This process, which has no effect whatsoever on humans or other species, means that it becomes less necessary to spray crops with chemical pesticides to control infestations.

Biopesticide Products Currently on the Market

- **Laginex™ Bioinsectide** (Produced by AgraQuest, Inc.)- This product is effective for controlling a wide range of mosquito larvae in rice, wetlands and other bodies of water.
- **Disease Free Kleentek™** (Produced by Crop Genetics International) - This product increases yield of sugar per acre.
- **Spod-X™** (Produced by Crop Genetics International) - Spod-X™ uses a naturally occurring insect virus to control the beet armyworm. The beet armyworm is becoming resistant to many chemical insecticides. Spod-X™ is safer to use and better for the environment.
- **Aspire™** (Produced by Ecogen) - Aspire™ is a biofungicide used to protect fresh produce from post-harvest rot. It is used on citrus, pome fruits, berries and grapes. The active ingredient is a naturally occurring yeast that is harmless to all nontargeted organisms.
- **Foil® Bioinsecticide** (Produced by Ecogen) - Foil® is effective against the Colorado potato beetle, European corn borer, armyworms and loopers.
- **Condor® Bioinsecticide** (Produced by Ecogen) - This product is effective against the tobacco budworm, cotton bollworm, the soybean looper, velvetbean caterpillar, green clover worm, gypsy moth and spruce budworm.

✓ **Cutlass® Bioinsecticide (Produced by Ecogen)** - This is a broad-spectrum bioinsecticide effective against the beet armyworm, cabbage looper, diamondback moth, cabbage webworm and imported cabbageworm.

- **Otinem® Insecticide, Bee-scent® and No-Mate® (Produced by Ecogen).**

- **AQ-10® (Produced by Ecogen)** - AQ-10® is a biofungicide that protects crops from powdery mildew. It is used on strawberries, grapes, tomatoes, cucurbits and ornamentals. It reduces the use of conventional fungicides.

- **Mattech® (Produced by Mycogen)** - Controls broad spectrum of caterpillars in vegetables, field crops, nuts, grapes, turf, stored grain, and ornamental and nursery crops.

- **MVP® (Produced by Mycogen)** - This product is used on tree fruits and nuts, vines, cotton and vegetables to control leaf-eating caterpillar pests.

- **M-Peri™ (Produced by Mycogen)** - This product is used on corn to combat the European corn borer.

- **M-Pede™ (Produced by Mycogen)** - M-Pede is used on fruits, vegetables, grapes and ornamentals to resist soft-body insects and powdery mildew.

- **DeMoss™ (Produced by Mycogen)** - This product is used on roofs, buildings, sidewalks and greenhouses to resist moss, algae and lichens.

- **Thinex® (Produced by Mycogen)** - This product is used for blossom thinning in apples, pears, and fruits.

- **M/C® (Produced by Mycogen)** - M/C is used on vegetables to control various caterpillars pests.

Source: BIO Member Survey

Biopesticide Products Expected on the Market Within Three Years

- **Corn, Soybeans and Canola Resistant to Liberty™ (Produced by AgrEvo)** - Liberty™ is a herbicide made from a naturally occurring substance that impedes ammonia detoxification, which kills plants. Since it affects both crop plants and unwanted weeds, AgrEvo has modified corn, soybean and canola plants to be resistant to Liberty™. The Liberty system™ will allow farmers greater flexibility and environmental soundness in weed control.

- **QST 153 Biofungicide (AgraQuest, Inc.)** - For diseases of grapes, vegetables, and fruit (downy mildews, bunch rot, gray mold, brown rot).

- **OST 177 Biofungicide (AgraQuest, Inc.)**-For diseases of grapes, other fruits and vegetables, turf and ornamentals (Powdery mildew, gray mold, scab, damping off.)
- **QST 776 Insect Repellent (AgraQuest, Inc.)**- Natural product for repelling mosquitoes, ticks, and other biting insects.

● **Ecologix™ Cockroach Bait (Produced by Dominion Biosciences)** - This is the first commercial product developed from a unique insect growth regulator technology. It is highly effective in eliminating insect populations, yet completely nontoxic to users, pets and the environment.

● **Leone™ Biofungicide (Produced by Dominion Biosciences)** - This product controls a number of plant diseases by relying on highly active, antimicrobial "predator" bacteria. These naturally derived biochemicals offer a new mode of action for effective and safe control of disease-causing microorganisms.

● **Crymax™ (Produced by Ecogen)** - Crymax™ is a genetically engineered bioinsecticide that is very effective against a broad range of pests. It will be used on vegetables, trees, nuts and vines.

● **EG7826™ (Produced by Ecogen)** - This will be a genetically modified insecticide that will control the fall armyworm, a major insect pest affecting sweet corn.

● **Scythe™ Herbicide (Produced by Mycogen)** - This is used for horticulture and landscape management to combat a broad spectrum of weeds.

Source: BIO Member Survey

B.t.-Based and Other Biological Control Agents

A number of products are in development that will control insects as well as conventional insecticides, thereby reducing the use of these products.

B.t. technology is used to develop and specially formulate a line of biotoxin and fatty acid based products for field testing in the poultry and livestock industries.

Mycogen, Ecogen and Ciba Geigy Ag Group are three of the companies developing these products.

● **Baculovirus Insecticides (Produced by American Cyanamid)**-These products express insect-specific toxins and control Lepidoteran pests at levels similar to chemical insecticides.

● **Agree® (Produced by Ciba Geigy Ag Group - Ciba Crop Protection)** - This is a B.t.-based bioinsecticide designed to control pests that affect tobacco, corn and soybean plants.

- **Design®** (Produced by Ciba Geigy) - Design® is a B.t.-based bioinsecticide for cotton and soybeans.

- **Exhibit®** (Produced by Ciba Geigy) - Exhibit® is a parasitic nematode for control of insects on ornamental plants and turf.

- **M-Press** (Produced by Mycogen)-This product will be used to control the fall army worm in sweet corn and other vegetable crops.

Source: The Biotechnology Industry Organization

Insect-, Virus- and Herbicide-Resistant Plants Under Development

- **Herbicide-Tolerant Plants (Produced by American Cyanamid)** American Cyanamid is working with universities and public and private laboratories and seed companies to develop a number of crop plants to tolerate imidazolinone herbicides while achieving cost effective contact and residual control of weeds.

Crops under development for tolerance to imidazolinone herbicides:

Wheat

Rice

Sugar beets

- **Herbicide-Tolerant Plants (Produced by Monsanto)** - Monsanto has genetically modified a number of crop plants to tolerate its Roundup® herbicide. This natural tolerance lets farmers reduce herbicide applications while achieving cost-effective broad-spectrum weed control using a product well known for its favorable environmental characteristics.

Crops tolerant to Roundup® Herbicides:

Canola/Oilseed Rape

Corn

Sugarbeets

- **B.t. Cotton, Alfalfa, Canola and Sunflower (Produced by Mycogen)** - Plants that express a protein toxic to various insect pests, which will allow for less use of insecticides.

Source: BIO Member Survey

How Agricultural Biotechnology Is Regulated

Since combining specific genes from donor and host plants does not alter the basic nature of the host plant, the result of genetic modification is predictable and can be carefully controlled. As with any new variety of food, the developers test extensively for safety, quality and other factors.

The Food and Drug Administration (FDA) is responsible for approving the safety of all foods and new food ingredients. In addition, all producers are required to ensure the safety and quality of anything they introduce into the food supply.

The U.S. Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) impose safety requirements and/or performance standards on the development of pesticides, herbicides and genetically modified test crops. Examples of tests include crops with improved disease resistance and animal vaccines produced from biotech microorganisms.

The EPA regulates the use of chemicals, including pesticides in the environment. With this authority, EPA must approve any field test of biotech products with new properties.

The FDA may require that genetic modifications that significantly alter the nutritional value of the host food, use genetic material from outside the traditional food supply or use known allergens be subject to strict pre-market testing and regulatory oversight.

The FDA also requires that any genetically modified food product that significantly alters the host food's nutritional value or uses material from a known allergen be clearly labeled. For example, any product that used a gene from a peanut, which is a potential allergen, would be subject to testing and labeling requirements. The FDA also has the authority to order unsafe products off the market.

FRENCH PROPOSAL

Human cloning:

We have taken note with great concern of recent scientific experiments which could open the way to reproductive human cloning. We agree that the prohibition of any form of reproductive human cloning needs both strict domestic legislation and close international cooperation to adapt current international law. We are encouraged by the reflections underway within national ethics committees as well as in various regional and international fora. We are determined to give a strong impetus to their work with a view to arriving as soon as possible at a universal ban on reproductive human cloning.

OUR PROPOSED REDRAFT

~~We are hopeful that the recently reported breakthrough in entire animal cloning will yield enormous medical and agricultural benefits. We have also taken note with great concern that this scientific advance could open the way to using this technology (by which we mean somatic cell nuclear transfer technology) to create a child. We agree on the need for appropriate domestic legislation and close international cooperation to prohibit the use of somatic cell nuclear transfer to create a child while countries explore ethical and scientific implications in greater depth. We are encouraged by the reflections already underway within national ethics committees as well as in various regional and international fora. We are determined to give a strong impetus to their work with a view to arriving as soon as possible at a universal moratorium on the use of somatic cell nuclear transfer to create a child.~~

We have taken note that further development of the technology that enabled the recent cloning of a ~~lamb~~ ^{Sheep} offers promise of

maritime security; to exchange information on the most effective security practices for international special events; and to strengthen cooperation and consultation with other nations and groups.	
{EC:}[Human cloning:	[EC]: <i>heading, add:</i> "<u>Reproductive Human Cloning</u>" [EC]: <i>include bracketed text.</i>
39. We have taken note with great concern of recent scientific experiments which could open the way to reproductive human cloning. We agree that the prohibition of any form of reproductive human cloning needs both strict domestic legislation and close international cooperation to adapt current international law. We are encouraged by the reflections underway within national ethics committees as well as in various regional and international fora. We are determined to give a strong impetus to their work with a view to arriving as soon as possible at a universal ban on reproductive human cloning.]	[J]: <i>sent 1, 2, 4, replace:</i> "~~reproductive human cloning~~" with "<u>the use of cloning for the replication of human individuals</u>" [J]: <i>sent 2, add/delete:</i> "We agree... domestic legislation <u>or other measures</u> and close international cooperation ~~to adapt current international law.~~" [UK]: <i>delete para. -- alternative redraft, add/delete:</i> "We have taken note with great concern of recent scientific experiments which could open further the way to reproductive human cloning. <u>We regard the deliberate cloning of human beings as ethically unacceptable.</u> We agree that the ~~prohibition of any form of reproductive human cloning needs both strict domestic legislation and close international co-operation to adapt current international law~~ <u>this issue needs to be addresses through close international co-operation.</u> We are encouraged by the ~~reflections underway within national ethics committees as well as in various regional and international fora~~ <u>serious attention being give, both nationally and internationally, to the implications of this technology, and the reputation recently adopted by the World Health Assembly in May 1997.</u> We are determined to give a strong impetus to their work with a view to arriving as soon as possible at a universal ban on reproductive human cloning. <u>This will provide a measured approach to the debate on which techniques are, and which are not, acceptable.</u>" [EC]: <i>last sent., add/delete:</i> "<u>While recognising the considerable</u>

	potential benefits for basic research, agriculture and human health from cloning research, wWe are nevertheless determined to give a strong impetus to their the work of the national ethics committees with a view to arriving as soon..."
<u>[Space Station]</u>	
40. We [welcome] {J, UK:}[look forward to] the signing of the Agreement to establishing an international space station. This is an excellent example of international cooperation in carrying out large and promising projects in the field of exploration and peaceful uses of outer space.]	[J]: support bracketed text 2. [UK]: support bracketed text 2.
<u>United Nations Reform</u>	
41. We reaffirm the crucial role of the United Nations in fostering global partnership and sustainable development. To this end, we support thorough-going reform and welcome progress that has occurred since our meetings in Halifax and Lyon. We welcome Secretary General Kofi Annan's recent reform proposals and support their rapid implementation; we also look forward to additional proposals. We remain committed to working with all UN members to realize these reforms.	[J]: sent 1, add: "...United Nations in maintaining international peace and security as well as in fostering..." [UK]: sent. 3, add/delete: "...we also look forward to additional proposals the Secretary-General's more extensive proposals next month."
42. In order for the UN to cope with the challenges of the 21st century, financial reform should proceed together with necessary reform measures in other areas. The UN system must be placed on a firm financial footing through full and timely payment of obligations, and development of a more logical and equitable scale of assessments. Budgets throughout the UN system should be scrutinized with emphasis on prioritization and maximum operating efficiency. We look forward to the Secretary General's specific	

FRENCH PROPOSAL

Human cloning:

We have taken note with great concern of recent scientific experiments which could open the way to reproductive human cloning. We agree that the prohibition of any form of reproductive human cloning needs both strict domestic legislation and close international cooperation to adapt current international law. We are encouraged by the reflections underway within national ethics committees as well as in various regional and international fora. We are determined to give a strong impetus to their work with a view to arriving as soon as possible at a universal ban on reproductive human cloning.

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We have taken note that further development of the technology that enabled the recent cloning of a ~~lamb~~ ^{Sheep} offers promise of

	view to reinforcing further their organizational structure, based upon the thorough reform of UNEP. Consideration should also be given to the advisability of creating in the medium term a global environmental umbrella organization of the UN, with UNEP as a major pillar, that would assume the catalyst role for, and coordination of, international cooperation and policy-setting in the field of government.
25. We reaffirm the importance of the Global Environmental Facility as the leading multilateral funding mechanism for the global environment. We will work to strengthen its finances and enhance its effectiveness. In this regard, we support a successful replenishment of the Facility.	[F]: <i>last sent., add:</i> "...of the Facility with fair burden sharing among donors. We note the need to address the question of arrears." [C]: <i>set out GEF concentrations: biodiversity, climate change, ozone and international waters.</i>
<u>Infectious Diseases</u>	
26. Infectious diseases, such as drug-resistant tuberculosis, malaria, and HIV/AIDS are responsible for a third of all deaths in the world. In many parts of the world, infectious diseases and deaths from infectious disease have risen sharply in the last decade for a variety of reasons, including the emergence of drug-resistant microbes and the increased movement of people and products. In the coming year, our governments will promote more effective coordination of international responses to outbreaks; promote development of a global surveillance network, building upon existing national and regional surveillance systems; and help to build medical and institutional capacity to prevent, detect and control infectious diseases globally including efforts to explore the use of regional stocks of essential vaccines, therapeutics, diagnostics and other materials.	[G]: <i>last sent., delete:</i> "...control infectious diseases globally including efforts to explore the use of regional stocks of essential vaccines, therapeutics, diagnostics and other materials" [UK]: <i>sent. 2, add:</i> "...emergence of drug-resistant microbes, the re-emerging of some vaccine-preventable diseases, and the increased movement..." [C]: <i>sent. 1, 2, add:</i> "...deaths in the world. They pose significant challenges to the health, security and financial resources of the global community. In many parts of the world..." [C]: <i>sent. 3, replace:</i> "medical-institutional" with "public health" [C]: <i>last sent., delete:</i> "...control infectious diseases globally including efforts to explore... and other materials." [EC]: <i>sent. 1, add/delete:</i> "Infectious diseases, such as including childhood pneumonia, diarrhoea, drug-resistant tuberculosis,..."

	[EC]: <i>sent. 2, add:</i> "...variety of reasons, including <u>significant shortcomings in public health control programmes</u>, the emergence of..." [EC]: <i>last sent., add/delete:</i> "...including efforts to <u>secure the availability</u> ~~explore the use of regional stocks~~ of essential vaccines,..."
27. Central to this work will be strengthening and linking existing activities in and among each of our countries, and in other fora, especially the World Health Organization (WHO). We support the efforts of the WHO and endorse the recent World Health Assembly resolutions regarding the quality of biological and pharmaceutical products.	[C]: <i>sent. 1, add/delete:</i> "...and in other fora, especially <u>through</u> the World Health Organization (WHO)." [C]: <i>delete sent. 2.</i>
28. Preventing the transmission of HIV infection and the development of AIDS is an urgent global public health imperative. While prevention and treatment methods must be pursued, the development of a safe and effective vaccine against AIDS holds the best chance of limiting, and eventually eliminating, the threat of this disease. We will {I, G, UK, C, EC*:[work to]} provide the investments necessary to accelerate AIDS vaccine research, and together will enhance international scientific cooperation and collaboration. Cooperation among scientists and governments in the developed and developing world and international agencies will be critical. We call on other states to join us in this endeavor.	[J]: <i>sent 2:</i> "...the development of a safe and effective vaccines against AIDS..." [I]: <i>include bracketed text.</i> [G]: <i>include bracketed text.</i> [G]: <i>sent. 4, add:</i> "...and international agencies <u>and in particular the UNAIDS program</u> will be critical." [UK]: <i>include bracketed text.</i> [UK]: <i>sent. 3, add:</i> "We will {work to} ~~provide the~~ <u>ensure that investments necessary are used effectively</u> to accelerate AIDS vaccine research..." -- <i>if unacceptable, then:</i> "We will {work to} provide the <u>investments resources</u> necessary to accelerate " [C]: <i>include bracketed text.</i> [EC]: <i>sent. 2, add/delete:</i> "...of a safe, ~~and~~ effective <u>and accessible</u> vaccine against <u>AIDS could constitute a key factor for</u> ~~holds the best chance of~~ limiting, and eventually eliminating..." [EC]: <i>include bracketed text (sent. 3) -- with amendment:</i> "We will

	{work <u>together</u> to} provide..." [EC]: <i>sent. 3, add:</i> "...necessary to accelerate <u>AIDS prevention and AIDS vaccine research</u>..." [EC]: <i>sent. 4, add/delete:</i> "...governments <u>and communities</u> in the developed and developing world <u>and regional</u> and international <u>agencies organisations</u> will be critical."
29. The Joint United Nations Program on HIV/AIDS (UNAIDS) must help expand the scale and quality of the response to HIV/AIDS. As a group and with others, we will work to assure that it has resources adequate to fulfill its mandate.	[J] <i>sent. 1, replace:</i> "...HIVE/AIDS (UNAIDS) ~~must~~ <u>should</u> help...)
<u>Nuclear Safety</u>	
30. We reaffirm our commitments from the 1996 Moscow Summit on Nuclear Safety and Security to give an absolute priority to safety in the use of nuclear energy. We note that further substantial progress is still required in the countries of Central and Eastern Europe and in the Newly Independent States, especially by strengthening regulatory authorities, enhancing reactor safety and improving safety culture. We consider further joint efforts to this end a major priority. In this regard, we attach the greatest importance to the full implementation of the Nuclear Safety Account agreements.	
31. We note with satisfaction the entry into force by the Nuclear Safety Convention and the preparations now underway for the first review meeting to be held in April 1999. We applaud the rapid progress made in developing the Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management. We welcome the forthcoming adoption of the Protocol to amend the Vienna Convention on civil liability for	[J]: <i>delete sent. 4.</i> [G]: <i>sent. 4, add/delete:</i> "...consideration to joining ~~this~~ <u>these</u> new conventions." [UK]: <i>delete sent. 4 -- or -- revert to May 17 text.</i> [C]: <i>sent. 2, add:</i> " Waste Management <u>and encourage</u>

maritime security; to exchange information on the most effective security practices for international special events; and to strengthen cooperation and consultation with other nations and groups.	
[EC:] [Human cloning:]	[EC]: <i>heading, add: “Reproductive Human Cloning”</i> [EC]: <i>include bracketed text.</i>
39. We have taken note with great concern of recent scientific experiments which could open the way to reproductive human cloning. We agree that the prohibition of any form of reproductive human cloning needs both strict domestic legislation and close international cooperation to adapt current international law. We are encouraged by the reflections underway within national ethics committees as well as in various regional and international fora. We are determined to give a strong impetus to their work with a view to arriving as soon as possible at a universal ban on reproductive human cloning.]	[J]: <i>sent 1, 2, 4, replace: “~~reproductive human cloning~~” with “<u>the use of cloning for the replication of human individuals</u>”</i> [J]: <i>sent 2, add/delete: “We agree... domestic legislation <u>or other measures</u> and close international cooperation to ~~adapt current international law.~~”</i> [UK]: <i>delete para. -- alternative redraft, add/delete: “We have taken note ~~with great concern~~ of recent scientific experiments which could open further the way to reproductive human cloning. <u>We regard the deliberate cloning of human beings as ethically unacceptable.</u> We agree that ~~the prohibition of any form of reproductive human cloning needs both strict domestic legislation and close international co-operation to adapt current international law~~ <u>this issue needs to be addresses through close international co-operation.</u> We are encouraged by the ~~reflections underway within national ethics committees as well as in various regional and international fora~~ <u>serious attention being give, both nationally and internationally, to the implications of this technology, and the reputation recently adopted by the World Health Assembly in May 1997.</u> We are determined to give a strong impetus to their work with a view to arriving as soon as possible at a universal ban on ~~reproductive human cloning.~~ <u>This will provide a measured approach to the debate on which techniques are, and which are not, acceptable.</u>”</i> [EC]: <i>last sent., add/delete: “While recognising the considerable</i>

	potential benefits for basic research, agriculture and human health from cloning research. wWe are nevertheless determined to give a strong impetus to ~~their~~ <u>the work of the national ethics committees</u> with a view to arriving as soon..."
<u>[Space Station]</u>	
40. We [welcome] {J, UK:}[look forward to] the signing of the Agreement to establishing an international space station. This is an excellent example of international cooperation in carrying out large and promising projects in the field of exploration and peaceful uses of outer space.]	[J]: <i>support bracketed text 2.</i> [UK]: <i>support bracketed text 2.</i>
<u>United Nations Reform</u>	
41. We reaffirm the crucial role of the United Nations in fostering global partnership and sustainable development. To this end, we support thorough-going reform and welcome progress that has occurred since our meetings in Halifax and Lyon. We welcome Secretary General Kofi Annan's recent reform proposals and support their rapid implementation; we also look forward to additional proposals. We remain committed to working with all UN members to realize these reforms.	[J]: <i>sent 1, add:</i> "...United Nations <u>in maintaining international peace and security as well as in fostering...</u> " [UK]: <i>sent. 3, add/delete:</i> "...we also look forward to <u>additional proposals the Secretary-General's more extensive proposals next month.</u> "
42. In order for the UN to cope with the challenges of the 21st century, financial reform should proceed together with necessary reform measures in other areas. The UN system must be placed on a firm financial footing through full and timely payment of obligations, and development of a more logical and equitable scale of assessments. Budgets throughout the UN system should be scrutinized with emphasis on prioritization and maximum operating efficiency. We look forward to the Secretary General's specific	

Office of International Affairs



Department of Health and Human Services

Room 639-H, HHH Building

200 Independence Avenue, S.W.

Washington, D.C. 20201

Telephone: 202-690-6174

Fax: 202-690-7127

Internet: DHOHMAN@OS.DHHS.GOV

Date: 6/12

To: Elizabeth Dyer

Organization: _____

Telephone: _____

Fax: _____

Number of pages: 2

From: David E. Hohman
Director, OIA

MESSAGE:

Per com.

39. We have taken note ~~with great concern~~ of recent scientific experiments ~~which that~~ could open the way to ~~reproductive human cloning~~ creation of a new individual genetically identical to an existing (or previously existing) person -- i.e., a delayed genetic twin. We agree that the ~~prohibition of any~~ this form of reproductive human cloning needs both ~~should be prohibited by~~ strict domestic legislation and close international cooperation to ~~adapt current international law.~~ We are encouraged by the reflections underway within national ethics committees as well as in various regional and international fora. We are determined to give strong impetus to their work ~~with a view to arriving as soon as possible at a universal ban on reproductive human cloning.~~

David
Per conversation

Bill Raulo
6/11/97

Legislation

Key policy decisions

- Savings clause
- State preemption
- Sunset
- Penalties
- review body -
NBAC?
OTHER?
How detailed?

Smoke free

Council of Europe's steering committee on
bioethics is scheduled to meet
June 17th to 20th -

▶ 36 member states. 6 special guests; observer
EC 15 members -

from



Human cloning:

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THE WHITE HOUSE

WASHINGTON

97 MAY 30 PM 7:42

May 29, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: JACK GIBBONS
Assistant to the President for Science and Technology

ELENA KAGAN
Deputy Assistant to the President for Domestic Policy

SUBJECT: CLONING POLICY OPTIONS

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We recommend: (1) that you support domestic legislation banning human cloning, and that you announce specific legislation at the top of your June 10th press conference; and (2) that the U.S. support the gist of France's proposed cloning paragraph while insisting on critical modifications.

NBAC's Findings and Recommendations

In its draft final report, NBAC unanimously concludes that "it is morally unacceptable for anyone . . . to attempt to create a child" using the technology that created Dolly the sheep: somatic cell nuclear transfer -- that is, the transfer of the nucleus from an adult somatic (non egg or sperm) cell into an enucleated egg. NBAC bases this conclusion on safety concerns, finding that the technology is "likely to involve substantial risk to the potential child." The report also states that "serious ethical concerns... require a great deal more widespread and careful thought and public deliberation before this technology should be used."

NBAC also concludes, however, that other forms of "human cloning" -- such as the cloning of DNA sequences, cell lines, and tissues (which do not involve the creation of entire human beings) -- are scientifically important and not ethically problematic. Moreover, NBAC finds that animal cloning is ethically acceptable and promises important benefits. The Commission thus cautions that restrictions on cloning not impede these activities.

The Commission notes that current restrictions effectively prohibit federally funded and regulated entities from attempting to clone a human being through somatic cell nuclear transfer. However, fertility clinics and other privately-funded clinical and research establishments face no prohibition on human cloning, and NBAC questions whether some of these organizations will adhere to a voluntary moratorium.

Accordingly, NBAC's draft final report calls for carefully-worded national legislation prohibiting anyone from "attempting to create a child through somatic cell nuclear transfer techniques." The Commission specifies that the legislation should include a sunset provision and that, prior to the sunset date, an oversight body should review and report on the status of somatic cell nuclear transfer technology and the ethical and social issues associated with its use in humans. NBAC also recommends that the U.S. cooperate with other countries to enforce mutually-supported cloning restrictions.

National Legislation

We recommend that you embrace NBAC's proposal to establish a narrowly crafted time-limited legislative moratorium. Legislation is the only way to establish a comprehensive, enforceable prohibition on cloning entire human beings in all publicly and privately funded research and clinical activities. If carefully written, the ban will not preclude important research.

Reaction to proposed legislation will be mixed. A national and international consensus is emerging that attempting to apply the technology used to clone Dolly to humans is morally wrong. The American Medical Association has conveyed this view to NBAC, and the World Medical Association has issued a similar statement. Given NBAC's recommendation, we expect many in the scientific and ethics communities to accept a legislative moratorium.

But some who agree that cloning a human being using somatic cell nuclear transfer is morally unacceptable will oppose a legislated moratorium. In particular, the biotechnology and pharmaceutical industries strongly oppose legislation. These two industries are deeply concerned that a legislative debate will produce broadly drawn language that impairs critical research. Some academic researchers may share this view. Fertility clinics also may oppose legislation, but to date have not signaled a position.

Finally, some in the right-to-life community will argue from the other side that NBAC's proposed approach does not go far enough. This community will push for a comprehensive ban on the creation of embryos, through any means, for research purposes (i.e., not for the purposes of creating a child). The Administration has applied this restriction to federally-funded research, but opposed legislation on the subject. This is an issue NBAC declined to review, and we do not recommend revisiting it in this context.

We recommend that you announce your support for legislation and propose specific legislative language on June 10, at your scheduled press conference, three days after NBAC's

recommendation will become public. We anticipate that the release of NBAC's report will prompt Congressional hearings and legislative proposals. By acting quickly you can maintain your leadership on the issue and carefully frame the legislative debate, making clear the value of biotechnology research and the danger of overly broad regulation, while calling for the prohibition of an unethical use of a specific technology.

Approve ____ Disapprove ____

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The U.S. biotechnology and pharmaceutical industries strongly oppose including any paragraph on cloning in the communique. They fear that it will not be carefully drafted and may inadvertently extend to the cloning of DNA, cells, and tissues as well as entire human beings. Further, industry is concerned that a statement on cloning ultimately could provide cover for protectionist efforts to restrict U.S. biotechnology products and activities.

Nevertheless, we recommend that the Administration support the French proposal with critical modifications. Specifically, we suggest that the U.S. insist on changes to: (1) affirm the potential medical and agricultural benefits of cloning technology; (2) limit the prohibition to ~~"the use of somatic cell nuclear transfer technology to create a child"~~ ^{the} and (3) propose a time-limited moratorium instead of a ban. USDA and HHS support this position.

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WASHINGTON

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THE WHITE HOUSE

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Approve ____ Disapprove ____

Attachment

Date: 05/30/97 Time: 09:27

REPORT: EUROPEANS CONCERNED ABOUT GENETICALLY MODIFIED CROPS

London-May 30-FWN/UPI--THE BRITISH RETAIL CONSORTIUM and eight other European retail trade associations have sent an open letter to the U.S. grain industry warning of possible segregation of genetically modified crops.

The Wall Street Journal reports the letter warns consumers are squeamish over biotechnology and that could mean U.S. corn and soybean shipments will no longer be welcome after this year.

The letter warns that several member nations of the European Union might require the complete segregation of genetically modified crops from traditional varieties if U.S. companies don't act voluntarily.

The letter said, "Otherwise, the 1996 U.S. harvest of genetically modified (soybeans and corn) could indeed be the last to be welcomed in Europe."

The Journal reported that some European supermarket executives have already complained about their inability to label food products such as bread when they contain ingredients made from genetically modified crops.

The letter is supported by groups from Denmark, Finland, France, Germany and Sweden.

Europe imports about \$2.5 billion of U.S. soybeans annually and the Clinton Administration has indicated to industry officials it would contest before the World Trade Organization any attempts by the European Union to hinder imports of genetically modified crops.

THE WHITE HOUSE

WASHINGTON

CLOSE HOLD

May 28, 1997

MEMORANDUM FOR: Toby Donenfeld, Office of the Vice President
Nancy Ann Min, Office of Management and Budget
Bill Corr, Dept. of Health and Human Services
Greg Frasier, Dept. of Agriculture
Elgie Holstein, Dept. of Energy

FROM: Elizabeth Drye, Domestic Policy Council
Rachel Levinson, Office of Science and Technology Policy

SUBJECT: Paragraph on Cloning for Denver Summit

The French have proposed a paragraph on cloning for inclusion in the Summit of the Eight joint communique. **We need your comments on the text -- and on our proposed revised text - by 5:00 pm Thursday, May 29. Please fax your Department's comments to Elizabeth Drye at 456-7431.** In reviewing the texts, please keep the following in mind:

- 1) The National Bioethics Advisory Commission is scheduled to complete its report the week of June 9th. We will ask our negotiators to reserve the right to modify the U.S. position pending the completion and our review of this report. We expect, however, that NBAC will recommend a legislative ban.
- 2) We will recommend to our negotiators that the U.S. not actively advocate including a paragraph on cloning, and that the U.S. oppose including the paragraph if it remains broadly drawn.
- 3) Three other countries have stated their reactions to the French proposal. The German's support it. The Canadians want to delete the final sentence regarding a "universal ban" (note that we suggest modifying the last sentence to read "universal moratorium"). The Japanese are not yet prepared to comment without further technical review.

If you have any questions, please contact Rachael (202-456-6137) or Elizabeth (202-456-5573). Thanks in advance for your review.

Attachment

cc: Sherman Boone, National Economic Council

FRENCH PROPOSAL

Human cloning:

We have taken note with great concern of recent scientific experiments which could open the way to reproductive human cloning. We agree that the prohibition of any form of reproductive human cloning needs both strict domestic legislation and close international cooperation to adapt current international law. We are encouraged by the reflections underway within national ethics committees as well as in various regional and international fora. We are determined to give a strong impetus to their work with a view to arriving as soon as possible at a universal ban on reproductive human cloning.

OUR PROPOSED REDRAFT

We are hopeful that the recently reported breakthrough in entire animal cloning will yield enormous medical and agricultural benefits. We have also taken note with great concern that this scientific advance could open the way to using this technology (by which we mean somatic cell nuclear transfer technology) to create a child. We agree on the need for appropriate domestic legislation and close international cooperation to prohibit the use of somatic cell nuclear transfer to create a child while countries explore ethical and scientific implications in greater depth. We are encouraged by the reflections already underway within national ethics committees as well as in various regional and international fora. We are determined to give a strong impetus to their work with a view to arriving as soon as possible at a universal moratorium on the use of somatic cell nuclear transfer to create a child.

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Alan F. Holmer
PRESIDENT



May 28, 1997

The Honorable Daniel K. Tarullo
Assistant to the President
for International Economic Policy
The White House
Washington, D.C. 20500

Dear Dan:

I write to you in your role as the sherpa preparing the President for the Denver Summit. The President has announced his intention to seek, at the Summit, international cooperation to develop an AIDS vaccine within 10 years. President Chirac reportedly will seek international support at the Summit to ban the cloning of entire human beings. Since Denver is shaping up to be a pharmaceutical as well as economic Summit, I offer the expertise of the pioneer pharmaceutical and biotechnology industries to ensure that the President is accurately and comprehensively prepared on these and any related issues. We would be pleased to provide whatever information would prove helpful to you, other White House officials, your staff, or interested agencies.

In particular, we urge your attention to the expected proposal of President Chirac regarding the cloning of entire human beings. PhRMA member companies are complying with the President's call for a voluntary moratorium on privately-funded research aimed at cloning entire human beings. Anyone concerned about the health and welfare of the American people (or, indeed, the people of any nation) is anxious to distinguish clearly between (1) the cloning of *entire* human beings, and (2) the cloning of animals or human genes, cells and tissues and research for the purpose of developing medicines to help families by preventing, curing and treating diseases. We are concerned about:

- any proposal of a *legislative* ban on the cloning of entire human beings, because of the risks that even a narrowly targeted, carefully drafted proposal could be enlarged in the unpredictable legislative process or subsequently misinterpreted in litigation; and
- any use of the shorthand term "human cloning" (or its equivalent in other languages), which could be misinterpreted to include the beneficial activities of cloning human genes, cells or tissues – an engine of biomedical research essential to promote the public health.

Pharmaceutical Research and Manufacturers of America

1100 Fifteenth Street, NW, Washington, DC 20005 • Tel: 202-835-3420 • FAX: 202-835-3429

The Honorable Daniel K. Tarullo
May 28, 1997
Page Two

Therefore, if the Summit participants discuss any proposal by President Chirac related to the cloning of entire human beings, we urge that:

- the term uniformly used, orally and in any written communication, be strictly limited to "cloning of *entire* human beings";
- the President never use the shorthand term "human cloning";
- the President proactively seek to clarify the distinction between the cloning of *entire* human beings, and the cloning of human genes, cells and tissues; and
- any oral discussions or written communication explicitly affirm the value and importance of the cloning of human genes, cells and tissues, the cloning of animals, and biomedical (including genetic) research involving such cloning activities, all for the purpose of discovering and developing new medicines with which to help and heal patients.

Finally, we recognize the President's recent identification of privacy protections as one of four "ethical guideposts" regarding the beneficial use of science. We strongly support the need to maintain the confidentiality of patient-identifiable medical (including genetic) information, and the need for a patient's informed consent to any research involving that patient-identifiable data. However, certain pending legislative proposals (e.g., S.422, the Genetic Confidentiality and Nondiscrimination Act) aimed at promoting these objectives would unduly impede biomedical research, to the unintended detriment of individual patients. If, at the Summit, the President advocates enhanced privacy protections, we urge him also to stress explicitly the value and importance of biomedical research and the aim to promote privacy protections without unduly impeding such research.

PhRMA and our member companies remain ready to provide any assistance needed to facilitate a productive Summit.

Sincerely,



Alan F. Holmer

The Honorable Daniel K. Tarullo
May 27, 1997
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Attachments:

Tab 1 - PhRMA Position on Cloning of *Entire* Human Beings
Tab 2 - An AIDS Vaccine: Pioneering Science
Tab 3 - Protection of Patient-identifiable Biomedical Information and
Promotion of Biomedical Innovation
Tab 4 - The Promise of Genomics for Human Healthcare
Tab 5 - PhRMA Genomics Primer
Tab 6 - Glossary on Genomics
Tab 7 - Legal Protection for Biotechnological Inventions in Europe
Tab 8 - TRIPS 1999 Review

cc: Secretary Donna Shalala
Dr. Jack Gibbons
Dr. Harold T. Shapiro

bcc: Elizabeth Drye

Policy Statement on Cloning

PhRMA member companies will comply with the voluntary moratorium on cloning of human beings proposed by President Clinton on March 4, 1997. PhRMA companies are not cloning entire human beings. The advent of cloning whole animals from adult cells raises basic, important questions for all of us. We welcome the President's request for advice about the ethical and legal implications of recent scientific advances from the National Bioethics Advisory Commission. Our society should consider these issues seriously and seek a common understanding.

PhRMA member companies are dedicated to the discovery and development of new medicines that help and heal human beings. To promote drug discovery and thereby help more patients, PhRMA member companies need to conduct genetic research. In their ceaseless search for new cures, pharmaceutical and biotechnology researchers use human genes, proteins, cells, tissues or organs under the highest ethical standards which are the cornerstone of our industry.

The hundreds of millions of patients PhRMA members serve in the United States and around the world are not harmed by the moratorium with which our members choose to comply while society considers the serious ethical and legal implications of any cloning of an entire human being. However, their hopes for better treatments and even cures would be devastated if PhRMA members were to delay genetic research. To try to fulfill as many of these hopes as possible, PhRMA members will continue to conduct genetic research under the highest ethical standards.

[Approved by PhRMA Genomics KIT, March 23, 1997]

An AIDS Vaccine: Pioneering Science

American research-based pharmaceutical companies have led the way in developing new antiviral protease inhibitors. In combination with two older AIDS medicines, this new class of drugs reduces the HIV virus that causes AIDS to undetectable levels in many patients. While *not* a cure, it fuels new hopes in many AIDS patients. Many people with AIDS now can return to school or work and plan for graduations or promotions rather than their own funerals.

The breakthrough protease inhibitors are the fruit of over ten years of intense, tenacious and breathtakingly expensive research in basic and applied science. Normally the talented researchers at the National Institutes of Health and in academia conduct most of the basic research. Identified only 14 years ago, the HIV virus required extensive study of how it invades the body, replicates, mutates and continues its cellular invasions – 10 to 30 billion times a day in each HIV patient! Government and academic researchers such as Drs. Harold Varmus, David Baltimore, Anthony Fauci, Robert Gallo and David Ho helped expand the horizons of scientific knowledge about retroviruses generally and the HIV virus specifically.

So did the U.S. pioneer pharmaceutical and biotechnology companies. As Dr. Ho (TIME's 1996 Man of the Year for his AIDS work) said recently, the pharmaceutical industry actually did most of the "heavy lifting" on AIDS basic research.¹ U.S. companies invested hundreds of millions of dollars beginning in the mid-1980s to study AIDS and HIV and seek to discover both antiviral treatments and a possible vaccine.

AIDS experts are hopeful, but not certain, that a vaccine can be developed. AIDS vaccine development is particularly difficult because:

- We still know so relatively little about this new disease. Despite over 70 years of knowledge about the common cold, we still do not have a vaccine to prevent it.
- The HIV virus replicates 10 to 30 billion times each day in each patient, with high mutation rates.
- The HIV/AIDS virus actually is six or more different strains, each of which could require a different vaccine.
- It preemptively invades the body's immunological vanguard, the white blood or T cells, crippling the body's normal defenses.
- Animal species in which to test AIDS vaccine candidates are highly problematic.
- When a vaccine is finally developed that survives animal testing, multi-year human clinical trials will be required to test its safety and efficacy. Only with FDA approval following all these animal and human trials can a vaccine become available for patients. Yet despite the pioneer company's brilliant science and investment of hundreds of millions of dollars in R&D, it suffers unlimited liability for runaway, potentially crushing judgments for economic damages, pain and suffering, and even

¹ "Cocktail Hour," The Washington Post Magazine, May 18, 1997, at 13.

punitive damages. Liability for punitive damages in these circumstances lacks any basis in reason or morality, and discourages vaccine R&D.

Even if government, academic, and/or industry researchers succeed in developing an HIV/AIDS vaccine, no one knows the duration of its success rate. A vaccine that could trigger sufficient immune responses to one strain or variant of the virus may not succeed with future mutations or strains.

Despite all these difficulties, the U.S. pharmaceutical companies that make vaccines press onward – just as the industry did earlier with respect to the breakthrough development of protease inhibitors for AIDS and vaccines for measles, mumps, rubella, hepatitis A and B, influenza and varicella. The medicines and vaccines developed by the American pharmaceutical companies have helped reduce child mortality, for example, by 68 percent over the past 30 years.

Protection of Patient-Identifiable Biomedical Information
and Promotion of Biomedical Research

Patients deserve to have their medical information kept in strictest confidence by those to whom they entrust it. But patients also deserve to have answers to their unmet medical needs. Federal policy needs to accomplish these twin objectives by establishing national requirements for the collection and use of patient-identifiable biomedical information that will protect patients' privacy and allow appropriate access to data that are essential to biomedical research progress. These requirements should encompass all patient-identifiable biomedical information, including genetic information.

As a matter of principle, there should be no artificial distinctions between medical information and genetic information regarding their accessibility and use. The confidentiality of patient-identifiable medical and genetic information should enjoy the same protections for the same reasons: to assure the privacy of the patient, and to facilitate trust (and thus disclosure) between patient and physician. The genetic information and more general medical information conveyed in family histories, as well as the coexistence of this information in medical records, call for consistent and uniform treatment.

Pharmaceutical firms already are highly sensitive to maintaining confidentiality of the data they use in conducting clinical studies that result in new medicines. Clinical trial information should continue to be protected as it is now, by FDA requirements for privacy and informed consent. These rules are carefully designed to protect patients' privacy while permitting essential safety and efficacy surveillance of the trials.

In addition to recognizing existing requirements for clinical studies, any new legislation or regulations should preserve researchers' access to the full range of potentially useful information about the incidence, prevalence, and outcomes of illness -- as long as individuals' privacy is properly safeguarded. Only those data sources that directly identify individuals need to be kept confidential. Encrypted or anonymized data sources should be freely available to researchers.

Requirements for protecting confidentiality of biomedical information and for research access to this information should be uniform across all states. Inconsistencies relevant in state laws could discourage or prevent needed research by diminishing the protections afforded to medical research projects.

The Promise of Genomics for Human Healthcare

The international outpouring of public and private investment in genomics - the study of genes and their function - has led to extraordinary advances in human biology and medicine. By helping scientists to understand the complex causes of unconquered human diseases, genomics is already contributing to the discovery of innovative medicines, vaccines, and diagnostic tests. Through its contribution to all of these areas, genomics holds the promise of an integrated approach to healthcare that may actually prevent, rather than just treat, disease.

Biological Research

- Genes contain the instructions for making the molecules that do the work in our bodies. These molecules, known as proteins, are essential for all normal body functions, and changes in their activity or amount underlie most diseases. Recent developments in genomics allow scientists to study genes on a very large scale - tens of thousands of new genes have been discovered each year since 1993 - building a catalog of genes which will one day encompass all human genes. By using this catalog of genes and the information they provide about the corresponding proteins, researchers are able to make biological discoveries in days that previously would have taken years, and to make great progress in understanding the causes and nature of complex diseases. For example:
 - Genomics is helping us to understand the interplay of genetic and environmental factors underlying severe obesity. Genomic research in mice has led to the discovery of at least four genes which may play an important role in the development of obesity in humans. This research has led to the discovery of novel potential therapeutic approaches, one of which is already in clinical trials. The research is also leading to a deeper understanding of the link between diabetes and obesity.
 - Genomic research is rapidly identifying the genetic changes associated with several major cancers. Some of these changes seem to be associated with an increased risk of developing cancer. Other changes appear to occur once a cancer has already developed, and are related to increased severity or progression of disease. Discovery of these changes may contribute to new therapeutic, diagnostic, and prognostic approaches.

Therapeutics

- There is a direct relationship between gene discovery and the identification of new drugs. There are estimated to be 100,000-120,000 different genes, each one containing the instructions for making one (or sometimes more than one) protein. Most drugs that we use today work by binding to a specific protein, altering its activity to achieve the desired outcome (e.g. improve symptoms, eradicate infection). The more genes we can identify, the more targets that are available for discovering new drugs. For example, breakthrough drugs for hypertension, depression, migraine, schizophrenia, and ulcers all act on a type of protein called a receptor. Before the development of genomics, only a few new receptors were discovered each year. Now, genomics has resulted in the discovery of hundreds of new receptors. By discovering novel receptors and other important proteins at an unprecedented rate, genomics is rapidly opening the horizons for discovery of new or improved treatments for currently unconquered diseases.
- Proteins can also function as drugs themselves, not just as drug targets. Protein drugs are useful when the body makes too little of an important protein, or where the presence of unusually large amounts of a protein can reverse or arrest a disease process. Protein drugs were made possible by the first biotechnology revolution: the industrial-scale production of proteins through genetic engineering. Patients who have had heart attacks and receive clot-dissolvers, patients with renal failure who receive anemia-combating erythropoietin, and people with diabetes who receive human insulin are among the current beneficiaries of protein drugs. Through genomics, scientists have discovered many previously unknown proteins which can be explored for use as potential drugs.
- Gene therapy, the introduction of genetic material into cells of the body, may open additional therapeutic possibilities. Research is in progress to explore whether gene therapy can be used to replace defective or missing genes, to correct the detrimental genetic changes that occur in tumor cells, and to direct the body's own cells to produce protein drugs. Though still facing technical hurdles, gene therapy offers promise for disorders associated with single genes, including hemophilia, sickle cell anemia, thalassaemia, Gauchers Disease, and Huntingtons chorea, as well as for more complex diseases such as diabetes and Alzheimers disease.
- In diseases such as dementia and severe obesity, several disease processes (which may actually be very different) have come to be classified as a single disease only because medical science lacks the information and tools to distinguish them. It is therefore difficult or impossible to discover drugs that treat the full spectrum of these complex disease syndromes, and it is equally difficult to identify the most effective course of treatment for each patient.

However, with the detailed understanding of disease mechanisms from genomic research, we may be able to accurately identify each specific disease process. This knowledge will allow researchers to design therapeutic discovery research efforts and clinical trials that target these specific disease types, and will help physicians to select the treatment approach that will have the greatest benefit.

Diagnostics

- Discovery of new genes can lead to new diagnostics for the early detection of diseases, permitting timely use of drugs and other therapies, and in some cases preventing irreversible damage. Commercially available gene-based diagnostics include tests for hemophilia A and B, phenylketonuria, retinoblastoma, and sickle-cell anemia. Diagnostics may not only help diagnose disease, but also enhance the development of therapeutics by helping researchers to understand the differences among people in their responses to medicines.

Vaccines

- The ultimate goal of medical research is to prevent disease. Genomic research has supplied immunity-stimulating proteins for a vaccine against hepatitis B, a viral infection that can lead to cirrhosis, liver failure, and liver cancer. Further genomic research may yield vaccine discoveries with the potential to protect against AIDS and various cancers. Also, gene therapy approaches may be used to introduce genes (DNA vaccines) that direct the body's own cells to produce vaccines.

Integrated Healthcare

- One of the most powerful aspects of genomics research is its potential to provide a comprehensive understanding of the entire disease process, including the genetic and environmental factors that increase or decrease risk, the detailed molecular changes that accompany each stage of the disease's progress, and the differences between people which affect their responses to treatment. This integrated knowledge may provide the basis for an unprecedented approach to healthcare, in which recognition of the specific stage of the disease process in an individual patient may allow front-line medical workers to select the exact, personalized combination of diagnostic, therapeutic, and preventative measures which will be most effective. Ideally, a full understanding of the causes of a disease will allow physicians to predict the risk of developing that disease before it appears, and to implement preventative measures to stop the disease from ever developing. One research group, for example, has found that individuals with genetic mutations associated with defective DNA-repair enzymes are at

increased risk of developing one of the most common heritable cancers, hereditary nonpolyposis colorectal cancer. If this mutation is detected, careful monitoring may allow early detection of tumor development and surgical intervention to prevent more aggressive disease.

Ethics

- The activities of PhRMA member companies in genomics will be guided by the high ethical standards which are the cornerstone of the pharmaceutical industry. Our member companies engage in genomic research for the purpose of improving human healthcare, and we endorse an open and informed public dialogue on all aspects of genomic research.

In summary, genomics is providing the tools to crack the previously impenetrable mysteries of disease. With the genetic catalog - the "instruction manual" for the active molecules in our bodies - we can gain a much greater understanding of the physiological differences between disease and health. With this understanding, we can realize the promise of genomics: new and more effective ways to diagnose, treat, cure, and perhaps even prevent diseases.

PhRMA Genomics Primer

Introduction

Genomics -- or the study of all the genes in an organism, including their sequences, structure, regulation, interaction and products -- is a powerful new instrument of basic pharmaceutical research. The identification of a number of disease-related genes is providing scientists with important new tools for understanding the underlying mechanisms of many illnesses. Genomics research has the profound potential to lead to better diagnosis, treatment and, ultimately, to the prevention and cure of many diseases in the future.

Most human diseases have a genetic component. A person's susceptibility to disease can vary based on a combination of his or her genetic make-up and environmental factors such as diet, exercise and exposure to toxic substances. More than 4,000 known genetic diseases are associated with single genes; in addition, such common conditions as cancer, heart disease, allergies, and arthritis are the result, at least in part, of interactions among multiple genes.

Genomes, Genes and Gene Products

Our genes are made of DNA, a long, threadlike molecule coiled inside our cells. DNA has a unique, "double helix" shape, making it resemble a spiral staircase. The steps of this DNA "ladder" consist of four nucleotide bases -- adenine(A), guanine (G), cytosine (C) and thymine (T). These bases pair off with each other in a defined way: adenine (A) and thymine (T) align together, as do guanine (G) and cytosine (C). Genes are really pieces of DNA written in a four-letter code, with each letter corresponding to one of four nucleotide bases.

Looked at this way, genes become the "paragraphs" in this DNA language, and a certain sequence of As, Gs, Cs and Ts constitute the recipe for the specific protein encoded by that gene. Genes vary in length - an average gene may be about 2,000 base pairs long. The collection of all of the genetic information needed for making the structural and functional components of an organism, and for passing on this "blueprint" to the next generation, is called its genome. There are estimated to be some 50,000 to 150,000 genes in the human genome, packaged into 23 pairs of chromosomes (46 total) like beads on a string.

Genes organize the production of proteins that are crucial to many cellular processes. Some proteins contribute to the basic internal structure of the cell. Others act as catalysts in metabolic reactions and are involved in embryonic development and the differentiation of tissues and organs.

DNA itself does not produce proteins. Instead, the information in a length of DNA is used to construct a Messenger RNA (mRNA) molecule, which then serves as a template for the synthesis of proteins. In the first stage of this process, called transcription, the double helix of the DNA molecule unwinds, and the mRNA is synthesized by an enzyme (RNA polymerase) which "reads" the code from the DNA base pairs on one strand. The sequence of bases in the newly-made mRNA matches up with the corresponding bases (A with T and G with C). After the copy is completed, the DNA double helix reforms and the RNA strand is released out of the cell nucleus as a single strand.

The mRNA then travels to a cellular structure called a ribosome, where it is "translated" into a protein. During this stage of the process, called translation, mRNA molecules that are thousands of bases long code for proteins that are composed of hundreds to thousands of specifically-arrayed amino acids. Protein synthesis is mediated in the ribosomes by other small RNA molecules (called transfer RNA or tRNA) that read the genetic code three bases at a time and direct an enzyme to add appropriate amino acids to the growing end of the new protein chain.

In most organisms, genes arrayed along a molecule of DNA are separated from one another by hundreds of thousands of bases that do not code for proteins. Some of these spacers, however, are functional; they include base sequences involved in the regulation of the expression of neighboring genes. The development and various activities of an organism reflect the different patterns of gene expression taking place in different cells for varying times and durations. In fact, genes are often turned on and off by regulatory elements that are themselves the products of other genes.

Genes will probably be found to cause disease through a variety of mechanisms. The proteins for which the genes code may be defective in terms of their function, or they may be expressed at too low or too high a level, or they may be expressed at the wrong time or in the wrong tissues -- mistakes that often result in disease.

A Brief Overview of Genomics Research

Genomics research has had a short, but impressive history. It was only 40 years ago, in the 1950's, that the structure of DNA was characterized by James Watson and Francis Crick in one of the most important scientific discoveries of the 20th Century. Nearly twenty years later, in the early 1970's, recombinant DNA technology was developed to enable the cloning of DNA outside the cells of the natural host. The ability to clone DNA (removing selected pieces of an organism's DNA and inducing it to replicate in unrelated cells) allowed scientists to study interesting pieces of these important strands, as well as the proteins for which they code. DNA research efforts were significantly broadened in 1975 with the introduction of DNA sequencing technologies. Knowing the sequence of a piece of DNA -- or the order in which the base pairs line up along the molecule -- also meant that scientists could determine the order of the amino acids that comprise the protein for which the DNA codes.

Fueled by the immense potential inherent in ultimately understanding how differences in gene sequences affect human health, a worldwide initiative to sequence the entire human genome was begun in the mid-1980's. The governments of the United States, Japan and the several European countries established laboratories and funding sources devoted to genome sequencing. In the United States, the Congress officially launched the Human Genome Project by appropriating funds to both the Department of Energy (DOE) and the National Institutes of Health (NIH). The agencies then created both separate and joint multi-disciplinary committees, and working groups to administer the project.

The focus of the Human Genome Project is the characterization of the human genome -- the complete collection of human genetic material, including the estimated 50,000 to 150,000 genes contained in human DNA. While the DOE efforts are concentrated in three national laboratories respected for their expertise in technology and technology development, the NIH initiative has evolved into the National Institute for Human Genome Research (NIHGR), an independent funding unit with authority to award grants and contracts.

The NIH and DOE jointly published a report in 1990 that contained the goals of the U.S. Human Genome Project, for the short term (following five years), but also for the project's anticipated completion in 2005. Updated in 1993, the goals include: creating genetic and physical maps of the human genome; refining methods for gene identification; completing the sequencing of the genomes of specific animal models and organisms; creating and operating databases and database tools which provide easy access to mapping and sequencing data (and which help to interpret the data), and examining the ethical, legal and social implications of the Human Genome Project.

Similar efforts to study the human genome have been launched in Great Britain, France, Italy, Japan and other countries. In order to coordinate these multiple international efforts, the Human Genome Organization (HUGO) was created in 1988. Called the "U.N. for the human genome," it comprises a founding council of scientists from 17 countries, with a mission to encourage international collaboration through coordination of research, exchange of data and research techniques, training and debate on the implications of the projects.

Over the past several years, private industry has invested heavily in gene-based research with the hope of creating novel healthcare products and services. Biotechnology companies have been founded expressly to sequence DNA, and genomics has become an integral part of the drug discovery efforts of a growing number of major pharmaceutical companies. The science of genomics demands knowledge of a variety of disciplines. Experts from molecular genetics, biochemistry and bioinformatics are working together at these companies to advance research programs.

The Potential of Genomics for Advances in Healthcare

Genomic technologies will trigger progress across the broad spectrum of healthcare: therapy, diagnosis, and prediction of susceptibility to disease. The progress will be incremental, each step building on the previous one, and often the complexity of disease will allow diagnosis before cure. It is to be hoped that genomic techniques will facilitate more expeditious development of conventional therapies through a more focused attack on the specific cause of disease. Identifying genes that play a role in disease enables targeting of the proteins for which the genes encode. These proteins -- such as enzymes and cellular receptors -- can then serve as new and precise targets for drug discovery.

DNA-based diagnostics enable the early detection of disease with a genetic component, permitting timely use of existing drugs and therapies, and sometimes preventing irreversible damage. Often the complexity of disease will allow diagnosis before a cure is available. In such cases, diagnostics can enhance the development of treatments by helping researchers to understand the differences in patient responses to experimental medicines. Advances in diagnostics can also facilitate the development of new treatments by providing new definitions of the nature of the disease, thereby dividing the patient populations more specifically than can be done with symptomology and existing medical tests. Further, genetic linkage analysis of a familial variant of a disease-causing gene can stimulate research to take new directions. DNA-based diagnostics are already available for diseases such as hemophilia A & B, phenylketonuria, retinoblastoma and sickle-cell anemia.

Prenatal genetic analysis, when indicated by family history, can give potential parents and their physicians information about whether a child will suffer from a seriously debilitating or fatal genetic condition; it can also relieve them of that concern. Using genetic analysis, hundreds of diseases can be diagnosed prenatally, including severe combined immunodeficiency disease (SCID), Tay Sachs Disease and Downs Syndrome.

Genomic techniques can be used to assess individuals predisposition to disease based on their genetic makeup. Awareness of such risk permits an individual to monitor any environmental cofactors -- diet or exposure to UV, chemicals or radiation -- that can exacerbate a genetic predisposition, and in some instances allow them to make lifestyle choices that reduce the level of risk.

Advances in genomics research, such as new DNA vaccine technology, could help prevent the onset of disease. These advances could eliminate suffering from disease symptoms as well as the suffering associated with some treatments and cures. For example, the development of a cancer vaccine could decrease the need for debilitating anticancer therapies.

Another approach is gene therapy -- inserting new genes into target cells of the body to replace or compensate for defective genes. In the neurologic and psychiatric fields alone, disorders that might be susceptible to this approach include Alzheimer's disease, Huntington's disease and schizophrenia.

Ethical, Legal and Social Implications

While human genomics research does not pose any new ethical dilemmas, the use of data arising from such research presents challenges that need to be addressed. Therefore, investigation of the ethical, legal and social implications of genomics research is an essential issue for the Human Genome Project, and for society at large. The Ethical, Legal and Social Issues (ELSI) task force of the Human Genome Research Program was established by the NIH and DOE to identify and address issues arising from genomics research. These issues include ensuring responsible clinical integration of new genetic technologies, protection of privacy and the fair use of genetic information, and professional and public education.

The ELSI program is also proposing policy options for governing human genome research and its applications.

Rapid development of new testing techniques and DNA-based diagnostic tests raises questions about their appropriate use beyond the research setting. The NIHGR ELSI program has supported a number of studies to identify issues and develop policy recommendations regarding the delivery of genetic tests into clinical practice. Some of their basic recommendations include:

- **Autonomy** -- As a patient, you should be able to decide for yourself whether to have a genetic test to learn about your genetic makeup, and you should not be tested against your will.
- **Access to Information and Informed Consent** -- You should be able to obtain important information about what a genetic test can and cannot tell you.
- **Privacy and Confidentiality** -- You should have the right, as a patient, to keep the results of a genetic test to yourself. You also have the right not to learn the results of a test.
- **Benefits and Risk** -- Knowing the results of genetic tests should help an individual, such as allowing a patient an improved health outcome.

Many other groups are addressing the issues that accompany genomics research, including national and international policy forums, bioethics centers, and industry representatives, such as PhRMA and BIO. State and federal legislators are also actively debating topics associated with DNA samples and genetic information. Two issues have been emphasized in these debates: confidentiality of individually-identifiable patient medical information and discrimination by employers and insurers. (See "PhRMA Principles for Maintaining Patient Confidentiality"). Legislation has been introduced and, in some cases, passed to address these concerns.

The contribution of genomics research to the study of disease is now widely recognized by the academic and industry research communities as well as by patients and the broader society. As our knowledge of genomics continues to grow, society must continue to examine the issues involved in order to protect individual rights, while encouraging research efforts that will lead to disease diagnosis, prevention, treatments and cures.

[Approved PhRMA Genomics KIT, May 22, 1997]

Glossary of Genomics Terms

acquired genetic mutation, see *somatic cell genetic mutation*

allele: one of a number of different forms of a *gene*. Each person inherits two alleles for each gene, one allele from each parent. These alleles may be the same or may be different from one another. See *dominant allele*, *recessive allele*.

Alzheimer's disease: a disease characterized by, among other things, progressive loss of memory. The development of Alzheimer's disease is thought to be associated at least in part with possessing certain *alleles* of the *gene* which encodes *apolipoprotein E*.

amino acid: one of twenty different molecules that combine to form *proteins*. The *sequence* of amino acids in a protein determines the protein's structure and function. See *peptide*.

analyte: the substance which a laboratory test aims to detect. In cholesterol testing, for example, the analyte is cholesterol. In *genetic testing*, the analyte could be, for example, a specific *allele* or *genetic mutation*.

antibody: a *protein* produced by the *immune system* in humans and higher animals, which binds to a specific *antigen*. When antibodies bind to corresponding antigens they set in motion a process to eliminate the antigens.

antigen: a foreign substance that, when introduced into the body, can stimulate an *immune response*. See *antibody*.

antisense: a piece of *nucleic acid*, typically created in the lab, which has a *sequence* exactly opposite to an *mRNA* molecule made by the body. *mRNA* molecules made by the body serve as templates for the synthesis of *protein* (see *transcription*). Since the "antisense" *mRNA* molecule binds tightly to its mirror image, it can prevent a particular protein from being made.

apoptosis: the process which, when functioning normally, programs *cells* to self-destruct at an appropriate moment in an *organism's* life-cycle. If the apoptotic process malfunctions in a cell, uncontrolled cell growth may result, which can contribute to the development of *cancer*. Such disruption of apoptosis may be associated with an inherited *genetic mutation* or a *somatic cell genetic mutation*.

apolipoprotein E (Apo E): certain *alleles* of the *gene* which encodes the *protein* apolipoprotein E have been reported to be associated with the development of heart disease and *Alzheimer's disease*.

autosomal recessive disorder, see *autosome* and *recessive allele*

autosome: any *chromosome* that is not involved in determining an *organism's* sex. Humans have 22 pairs of autosomes in each cell.

base: one of the molecules – adenine, guanine, cytosine, thymine, or uracil – which form part of the structure of *DNA* and *RNA* molecules. The order of bases in a *DNA* molecule determines the structure of *proteins* encoded by that *DNA*. See *nucleotide*.

base pair (bp): two complementary *nucleotide bases* joined together by chemical bonds. The two strands of the *DNA* molecule are held together in the shape of a *double helix* by the bonds between base pairs. The base adenine pairs with thymine, and guanine pairs with cytosine.

bioinformatics: the science of informatics as applied to biological research. Informatics is the management and analysis of data using advanced computing techniques. Bioinformatics is particularly important as an adjunct to *genomics* research, because of the large amount of complex data this research generates.

biotechnology: the application of biological research techniques to the development of products which improve human health, animal health, and agriculture.

BRCA1 and BRCA2: two *genes* which normally help to restrain *cell* growth, but which can contain certain *genetic mutations* associated with the development of breast and ovarian *cancer*. Note, however, that inherited BRCA1 and BRCA2 mutations are thought to account for less than 10% of all breast and ovarian cancers. Recent evidence suggests that *somatic cell genetic mutations* (i.e., non-inherited genetic mutations) in these two genes may also play a role in the development of cancer.

cancer: a term describing a broad range of diseases, all characterized by uncontrolled *cell* growth. Cancer is always caused by a malfunction in an *organism's* genetic material. This malfunction could be caused by an inherited *genetic mutation* or by a *somatic cell genetic mutation* (i.e., a genetic mutation acquired during an individual's lifetime). See *apoptosis*, *BRCA1* and *BRCA2*, *leukemia*, *Li-Fraumeni syndrome*, *melanoma*, *oncogene*, *p53*, and *suppressor gene*.

carrier: an individual who has inherited an *allele* which plays a role in disease, but who also has a normal allele which is a *dominant allele*. In most cases, carriers suffer no ill-effects from the disease-related allele, however they may pass the allele on to their children.

cDNA, see *complementary DNA*

cell: the basic subunit of any living thing, typically containing genetic material, an energy-producing system, and other components, all surrounded by a wall and/or membrane.

chromosome: The *DNA* in a *cell* is divided into structures called chromosomes. Chromosomes are large enough to be seen under a microscope. In humans, all cells other than *germ cells* usually contain 46 chromosomes: 22 pairs of *autosomes* and either a pair of *X chromosomes* (in females) or an *X chromosome* and a *Y chromosome* (in males). In each pair of chromosomes, one chromosome is inherited from an individual's father and one from his or her mother.

clone: A term which is applied to *genes*, *cells*, or entire *organisms* which are derived from – and are genetically identical to – a single common ancestor gene, cell, or organism, respectively. Cloning of genes and cells to create many copies in the laboratory is a common procedure essential for biomedical research. Note that several processes which are commonly described as cell “cloning” give rise to cells which are almost but not completely genetically identical to the ancestor cell. “Cloning” of organisms from embryonic cells occurs naturally in nature (e.g. with the occurrence of identical twins). The laboratory cloning of a sheep using the genetic material from a cell of an adult animal has recently been reported.

cloning: the process of producing a genetically identical copy – or *clone*.

codon: a set of three *nucleotide bases* in a *DNA* or *RNA sequence*, which together code for a unique *amino acid*. For example, the set AUG (adenine, uracil, guanine) codes for the amino acid methionine.

complementary DNA (cDNA): cDNA is *DNA* that is synthesized in the lab from *mRNA* templates.

conserved, see *evolutionarily conserved*

cross-licensing: a legal agreement in which two or more parties which have potentially conflicting *patent* claims strike a deal to share rights to the product or process in question.

deletion: in the process of *DNA replication*, a deletion occurs if a *nucleotide* or series of nucleotides is not copied. Such deletions may be harmless, may result in disease, or may in rare cases be beneficial.

deoxyribonucleic acid, see *DNA*

diagnosis: the act of identifying the presence of a disease.

DNA (deoxyribonucleic acid): the molecule that encodes genetic information. DNA is a double-stranded helix held together by bonds between *pairs of nucleotides*. See *base*, *base pair*, and *double helix*.

DNA bank: a service which stores *DNA* extracted from blood samples or other human tissue. DNA samples stored in the DNA bank may be used, for example, to help individuals and their physicians to trace the pattern of disease in families, or for the purposes of future medical research.

DNA diagnostics, see *genetic testing*

DNA probe: a piece of single-stranded *DNA*, typically labeled so that it can be detected (for example, a radioactive or fluorescent label can be used), which can single out and bind with (and only with) another specific piece of DNA. DNA probes can be used to determine which *sequences* are present in a given length of DNA or which *genes* are present in a sample of DNA.

DNA repair genes: *genes* which code for *proteins* which correct “mistakes” in *DNA sequences*. When these genes are altered, mutations may be able to accumulate in the *genome*, ultimately resulting in disease. See *genetic mutation*, *p53* and *suppressor gene*.

DNA replication: the process of making copies of strands of *DNA*. Existing DNA is used as a template for synthesizing the new strands.

DNA sequence, see *full gene sequence and partial gene sequence*

DNA sequencing, see *sequencing*

dominant allele: an *allele* which will be expressed in (i.e. affect the *phenotype* of) an *organism*, regardless of the characteristics of its counterpart allele. For example, the allele for brown eyes is dominant over the allele for blue eyes, so a person inheriting a “blue-eye” allele from one parent and a “brown-eye” allele from the other will almost always have brown eyes. See *gene expression* and compare *recessive allele*.

double helix: the shape of the *DNA* molecule. The DNA molecule has been described as resembling a twisted ladder or a spiral staircase.

enzyme: a *protein* that facilitates a biochemical reaction in a *cell*. In general, these biochemical reactions would not occur if the enzyme is not present. For example, an enzyme can facilitate (also called “catalyze”) the destruction of another protein by breaking the bonds between *amino acids*. An enzyme of that type is called a “protease.”

evolutionarily conserved: a “conserved” *sequence* in a *DNA* molecule or *protein* molecule is a sequence that has remained largely unchanged throughout evolution.

ex vivo: pertaining to a biological process or reaction taking place outside of a living *cell* or *organism*. Compare *in vivo*.

exogenous DNA: *DNA* which has been introduced into an *organism* but which originated outside that organism (e.g. material inserted into a *cell* by a *virus*).

exon: exons are those portions of a *gene* which code for *proteins*. See *intron* and *splicing*.

expressed sequence tag (EST): a short strand of *DNA* (approximately 200 *base pairs* long) which is part of a *cDNA*. Because an EST is usually unique to a particular *cDNA*, and because *cDNAs* correspond to a particular *gene* in the *genome*, ESTs can be used to help identify unknown genes and to map their position in the genome.

expression, see *gene expression*

full gene sequence: the complete order of *bases* in a *gene*. This order determines which *protein* a gene will produce.

gene: a length of *DNA* which codes for a particular *protein*, or in certain cases a functional or structural *RNA* molecule.

gene expression: the process by which the information in a *gene* is used to create *proteins*.

gene product: the *protein* produced by a *gene*.

gene therapy, see *germ line gene therapy* and *somatic cell gene therapy*. Gene therapy of either kind should be clearly distinguished from the use of *genomics* to discover new targets for drug discovery and new diagnostic tools.

genetic code: the set of *codons* in *DNA* or *mRNA*. Each codon is made up of three *nucleotides* which call for a unique *amino acid*. For example, the set AUG (adenine, uracil, guanine) calls for the amino acid methionine. The *sequence* of codons along an *mRNA* molecule specifies the sequence of amino acids in a particular *protein*.

genetic engineering: altering the genetic material of *cells* or *organisms* in order to make them capable of making new substances or performing new functions.

genetic map: a map of a *genome* which shows the relative positions of the *genes* and/or *markers* on the *chromosomes*.

genetic marker, see *marker*

genetic mutation: a change in the *nucleotide sequence* of a *DNA* molecule. Genetic mutations are a kind of *genetic polymorphism*. The term “mutation,” as opposed to “polymorphism,” is generally used to refer to changes in *DNA sequence* which are not present in most individuals of a species and either have been associated with disease (or

risk of disease) or have resulted from damage inflicted by external agents (such as *viruses* or radiation).

genetic polymorphism: a difference in *DNA sequence* among individuals, groups, or populations (e.g. a genetic polymorphism might give rise to blue eyes versus brown eyes, or straight hair versus curly hair). Genetic polymorphisms may be the result of chance processes, or may have been induced by external agents (such as *viruses* or radiation). If a difference in DNA sequence among individuals has been shown to be associated with disease, it will usually be called a *genetic mutation*. Changes in DNA sequence which have been confirmed to be caused by external agents are also generally called “mutations” rather than “polymorphisms.”

genetic predisposition: susceptibility to a disease which is related to a *genetic mutation*, which may or may not result in actual development of the disease.

genetic testing: the analysis of an individual’s genetic material. Among the purposes of genetic testing could be to gather information on an individual’s *genetic predisposition* to particular health condition, or to confirm a *diagnosis* of genetic disease.

genome: all the genetic material in the *chromosomes* of a particular organism; its size is generally given as its total number of *base pairs*.

genomic healthcare: healthcare which utilizes advances made by the science of *genomics*.

genomics: the study of *genes* and their function. Recent advances in genomics are bringing about a revolution in our understanding of the molecular mechanisms of disease, including the complex interplay of genetic and environmental factors. Genomics is also stimulating the discovery of breakthrough healthcare products by revealing thousands of new biological targets for the development of drugs, and by giving scientists innovative ways to design new drugs, vaccines and *DNA diagnostics*. Genomics-based therapeutics include “traditional” small chemical drugs, *protein drugs*, and potentially *gene therapy*.

genotype: the particular genetic pattern seen in the *DNA* of an individual. “Genotype” is usually used to refer to the particular pair of *alleles* that an individual possesses at a certain location in the *genome*. Compare *phenotype*.

germ cell: sperm and egg *cells*, and their precursors. Germ cells have only one set of *chromosomes* (23 in all), while all other cells have two copies (46 in all).

germ line gene therapy: Germ line gene therapy involves the insertion of normal *genes* into *germ cells* or fertilized eggs in an attempt to create a beneficial genetic change which can be transmitted to an organism’s *offspring* (for example, to correct for a genetic trait associated with disease). If a change is introduced via germ line gene therapy, that change

may be present in the offspring from birth in every cell in the body. See *genomics*, and compare *somatic cell gene therapy*.

germ line genetic mutation: a *genetic mutation* in the *germ cells*. Such mutations, unlike *somatic cell genetic mutations*, can be transmitted to an *organism's* offspring. Germ line mutations are also known as "hereditary mutations."

hemophilia: a condition in which an individual lacks the factors in blood which helps blood to clot (to prevent bleeding) in the event of an injury. Hemophilia is a *monogenic disorder* and an *X-linked recessive disorder*.

hereditary genetic mutation, see *germ line genetic mutation*

human gene therapy, see *somatic cell gene therapy* and *germ line gene therapy*

Human Genome Project: an international research effort aimed at discovering the full sequence of *bases* in the human *genome*. Led in the United States by the National Institutes of Health and the Department of Energy.

immune response: a physiological response produced in humans and higher animals, to defend the body against the introduction of foreign material. "Hay fever," for example, is the response sometimes produced by the human *immune system* to the inhalation of pollen. See *antibody* and *antigen*.

immune system: a biological defense system that has evolved in vertebrates to protect them against the introduction of foreign material (such as pollen, or invading micro-organisms) and to prevent the body from developing *cancer*. See also *immune response* and *antigen*.

in vitro: Pertaining to a biochemical process or reaction taking place in a test-tube (or more broadly, in a lab) as opposed to taking place in a living *cell* or *organism*. Compare *in vivo*.

in vivo: Pertaining to a biological process or reaction taking place in a living *cell* or *organism*. Compare *ex vivo* and *in vitro*.

informatics, see *bioinformatics*

intron: a length of *DNA* which is interspersed among the *protein-coding sequences* (*exons*) in a *gene*. Introns are transcribed (see *transcription*) into *mRNA* but are then cut out of the mRNA sequence before *protein* synthesis occurs. See *splicing*.

kilobase (kb): a length of *DNA* equal to 1000 *nucleotides*.

leukemia: *cancer* of the blood *cells*, which forms in cells developing in bone marrow.

Li-Fraumeni syndrome: a *genetic predisposition to cancer*, due to the presence of a *genetic mutation* in the *p53 suppressor gene*.

library: a set of *clones of DNA sequences* from an *organism's genome*. A particular library might include, for example, clones of all of the DNA sequences expressed in a certain kind of *cell*, or in a certain organ of the body (see *gene expression*).

linkage: "Linkage" refers to the tendency of certain *genes* to be inherited together. Two *genes* are said to be "linked" if they are often inherited together, due to their close proximity on a *chromosome*. See *marker*.

mapping, see *genetic map*

marker: a *sequence of bases* at a unique physical location in the *genome*, which varies sufficiently between individuals that its pattern of inheritance can be tracked through families and/or it can be used to distinguish among *cell* types. A marker may or may not be part of a *gene*. *Markers* are essential for use in *linkage* studies and *genetic maps* to help scientists to narrow down the possible location of new genes, and to discover the associations between *genetic mutations* and disease.

megabase (Mb): a length of *DNA* equal to one million *nucleotides*.

melanoma: a *cancer* of certain skin cells known as melanocytes.

Mendelian disorder, see *monogenic disorder*

messenger RNA (mRNA): the *DNA* of a *gene* is transcribed (see *transcription*) into mRNA molecules, which then serve as a template for the synthesis of *proteins*.

monogenic disorder: a disorder which is caused by mutations in just one *gene* (such as hemophilia), as opposed to *polygenic disorders* (such as hypertension) which involve the interaction of several genes. Monogenic disorders are also known as "single-gene disorders," or as "Mendelian disorders" because their inheritance patterns tend to follow the genetic laws first described by Gregor Mendel. See *genetic mutation*.

mRNA, see *messenger RNA*

multifactorial disorder, see *polygenic disorder*

multigenic disorder, see *polygenic disorder*

mutagen: a substance that induces mutations in DNA. See *genetic mutation*.

mutation, see *genetic mutation*

newborn screening: testing tissue samples from newborns to detect abnormalities which may be associated with disease.

nucleic acid: one of the family of molecules which includes the *DNA* and *RNA* molecules. Nucleic acids were so named because they were originally discovered within the nucleus of cells, but they have since been found to exist outside the nucleus as well. See *nucleotide*.

nucleotide: the "building block" of *nucleic acids*, such as the *DNA* molecule. A nucleotide consists of one of four *bases* – adenine, guanine, cytosine, or thymine – attached to a phosphate-sugar group. In *DNA* the sugar group is deoxyribose, while in *RNA* (a *DNA*-related molecule which helps to translate genetic information into *proteins*), the sugar group is ribose, and the base uracil substitutes for thymine. Each group of three nucleotides in a *gene* is known as a *codon*. A *nucleic acid* is a long chain of nucleotides joined together, and therefore is sometimes referred to as a "polynucleotide."

oncogene: a *gene* which is associated with the development of *cancer*.

organism: a living being whose physiological functions are carried out by subunits, or "organs" (like a heart or a liver), which are separate in function but mutually dependent.

p53: a *suppressor gene*. Certain *genetic mutations* in p53 cause *Li-Fraumeni syndrome*.

partial gene sequence: the order of *bases* in a segment of *DNA* which forms a part of a *gene*.

patent: a grant issued by the government, which gives the patent holder the right to exclude others from making, using, or selling a patented invention for a certain term. In most countries, including the United States, the term begins on the date on which the patent issues and ends 20 years from the date on which the application for the patent was filed. In the United States, patents are granted on inventions which meet the requirements of novelty, non-obviousness, and utility. A patent holder cannot use a patented invention dominated by the patent of another, absent a license or cross-license. See *cross-licensing*.

peptide: two or more *amino acids* chained together by a bond called a "peptide bond." A *protein* is a long chain of amino acids joined together in this way, and therefore is sometimes referred to as a "polypeptide." Some proteins contain more than one polypeptide chain.

phenotype: a set of observable physical characteristics of an individual *organism*. A single characteristic can be referred to as a "trait," although a single trait is sometimes also called a phenotype. For example, blond hair could be called a trait or a phenotype, as could obesity. A phenotype can be the result of many factors, including an individual's *genotype*, environment, and lifestyle, and the interactions among these factors.

polygenic disorder: a disorder which involves the interaction of several *genes* (such as hypertension), as opposed to *monogenic disorders* (such as hemophilia) which are associated with mutations in just one gene. Environmental or lifestyle factors may also be involved. Polygenic disorders are also known as “multifactorial” or “multigenic” disorders. See *genetic mutation*.

polymerase chain reaction (PCR): a method for creating millions of copies of a particular segment of *DNA*. If a scientist needs to detect the presence of a very small amount of a particular *DNA sequence*, PCR can be used to amplify the amount of that sequence until there are enough copies available to be detected.

polymorphism, see *genetic polymorphism*

polynucleotide, see *nucleotide*

polypeptide, see *peptide*

predictive gene tests: the examination of a sample of an individual's *DNA* to identify *genetic mutations* which may be associated with a heightened risk of developing disease in the future.

predisposition, see *genetic predisposition*

prenatal diagnosis: the examination of *cells* from a fetus (usually obtained from the amniotic fluid surrounding the fetus, the placenta, or the umbilical cord) to search for alterations which might be associated with disease.

presymptomatic testing: a test for a disease-causing *allele* in a person who is not manifesting any symptoms of disease.

promoter: a segment of *DNA* located at the “front” end of a *gene*, which provides a site where the *enzymes* involved in the *transcription* process can bind on to a *DNA* molecule, and initiate transcription. Promoters are critically involved in the regulation of *gene expression*.

protein: a biological molecule which consists of many *amino acids* chained together by *peptide* bonds. The sequence of amino acids in a protein is determined by the sequence of *nucleotides* in a *DNA* molecule. As the chain of amino acids is being synthesized, it is also folded into higher order structures shaped, for example, like helices or like flat sheets. Proteins are required for the structure, function, and regulation of *cells*, tissues, and organs in the body.

protein drug: a drug whose main constituent is a *protein*. This protein could be identical to a protein made by the body, or it could be a protein designed in the lab to mimic a naturally occurring protein.

recessive allele: an *allele* which will only result in a specific *phenotype* when its counterpart allele is also recessive, or when no counterpart allele exists. "Autosomal recessive disorders" develop in individuals who inherit two mutant copies of a *gene* which is located on one of the *autosomes*. When a recessive gene associated with disease occurs on certain parts of the *X chromosome*, the disease (*hemophilia* is an example) is known as an "X-linked recessive disorder." X-linked recessive disorders may occur more often in men than in women, because men inherit only one copy of the gene (since they have only one X chromosome). Compare *dominant allele*.

recessive disorder: a disorder associated with a *recessive allele*.

recombinant DNA: *DNA* molecules that have been created by combining DNA from different sources.

regulatory gene: a *gene* which controls the *protein*-synthesizing activity of other genes.

restriction endonuclease: an *enzyme* which cuts the *DNA* molecule in highly specific locations. For example, the restriction enzyme known as *Bam HI* cuts DNA only at a specific 6-base *sequence*.

ribosome: the *cell* structures within which *protein* synthesis occurs.

RNA (ribonucleic acid): a molecule similar to *DNA*, which helps in the process of decoding the genetic information carried by DNA. See *nucleotide*.

sequence: the order of *nucleotides* in a *DNA* or *RNA* molecule, or the order of *amino acids* in a *protein*. See *full gene sequence* and *partial gene sequence*.

sequencing: determining the order of *nucleotides* in a *DNA* or *RNA* molecule, or determining the order of *amino acids* in a *protein*.

single-gene disorder, see *monogenic disorder*

somatic cell gene therapy: somatic cell gene therapy involves the insertion of *genes* into *cells* for therapeutic purposes, for example to induce the treated cells to produce a *protein* that the body is missing. It does not affect the genetic makeup of a patient's offspring, and generally does not change all, or even most, cells in the recipient. Somatic cell gene therapy is only one way of applying the science of *genomics* to improve healthcare. Others include the use of *genomics* to yield new targets for drug discovery, to refine the process of drug development and to discover new diagnostics. Compare *germ line gene therapy*.

somatic cell genetic mutation: a *genetic mutation* in a *somatic cell*. Such mutations, which are not inherited from parents but occur during the lifetime of an *organism*, are often known as “acquired genetic mutations.” Somatic cell genetic mutations are not passed on to offspring. Compare *germ line genetic mutation*.

somatic cell: a somatic cell is any *cell* of the body except for *germ cells* (sperm cells and egg cells) and their precursors.

splicing: the removal of *introns* from the sequence of *mRNA*. When an mRNA molecule is synthesized from a *DNA* template, introns are transcribed (see *transcription*) along with *exons*. In the splicing process, this material is cut out and the exons are joined together to form a continuous coding *sequence*.

suppressor gene: a *gene* which helps to reverse the effects of damage to an individual's genetic material, typically effects which might lead to uncontrolled *cell* growth (as would occur in *cancer*). A suppressor gene may, for example, code for a *protein* which checks genes for misspellings, and/or which triggers a cell's self-destruction if too many *genetic mutations* have accumulated.

technology transfer: the process of transferring discoveries made by basic research institutions to the commercial sector, to be developed into useful products and services.

transcription: the process during which the information in a length of *DNA* is used to construct an *mRNA* molecule. Compare *translation*.

transfer RNA (tRNA): *RNA* molecules which bond with *amino acids* and transfer them to *ribosomes*, where *protein* synthesis is completed.

transgenic organism: an *organism* whose *genome* has been altered by the incorporation of foreign, or *exogenous* *DNA*.

translation: the process during which the information in *mRNA* molecules is used to construct *proteins*. Compare *transcription*.

tRNA, see transfer RNA

tumor-suppressor gene, see suppressor gene

virus: viruses consist of a piece of *nucleic acid* covered by *protein*. Viruses can only reproduce by infecting a *cell* and using the cell's mechanisms for self-replication. They can cause disease; modified viruses can also be used as a tool in *gene therapy* to introduce new *DNA* into a cell's *genome*.

wild type: the form of an *organism* that occurs most frequently in nature.

X chromosome: one of the two sex *chromosomes*. Females normally carry two X chromosomes. Compare *Y chromosome*.

X-linked recessive disorder, see *recessive allele*

Y chromosome: one of the two sex *chromosomes*. Males normally carry one *X chromosome* and one Y chromosome.

Approved PhRMA Genomics KIT, May 22, 1997

Legal Protection of Biotechnological Inventions in Europe

Biotechnology investment and research in Europe have been impeded by disparities in the content and interpretation of national patent laws. A proposed EC directive, which would have established a uniform patent system for biological inventions throughout Europe, was rejected by the European Parliament in 1995, even after many changes had been made to accommodate Parliament's concerns. The European Commission has drafted a new directive that addresses Parliament's other objections to the earlier proposal.

The U.S. government is urged to endorse the adoption of the Commission's proposed Directive and to encourage European Union officials, in particular Members of Parliament, of the desirability for the EU to have a Directive which will standardize protection for biotechnology throughout Europe.

Three European institutions are involved in this legislative process. The Economic and Social Committee, an advisory body representing unions, employers and professionals, has issued a strongly positive opinion. The Council of Ministers, which has the final say, is expected to support the draft almost unanimously. The Parliament, which has amending and vetoing rights, will again be the toughest hurdle to take. There are clear signs, though, that the European Socialists, who were instrumental in the negative vote two years ago, are now largely supporting the new draft.

The Legal Affairs Committee of the European Parliament is to conclude the article-by-article discussion by the end of May. As expected, the debate has concentrated on article 3 ("the human body and its elements") and 9 ("inventions considered unpatentable"). Both are likely to be rewritten by the rapporteur in consensus language which would remain consistent with the spirit of the Commission draft and have the support of all Committee members except the Greens and a few sympathizers in other political groups. Together with an amendment calling for an Ethics Committee, but without specifying its terms of reference, this would allow for the withdrawal of the vast majority of the 204 amendments presently tabled and for a simplified vote.

Despite efforts to the contrary by the Greens and their allies, the Committee appears resolved to have this vote before July 2, which could still allow for a plenary vote before the summer recess if the same resolve prevails at the level of the presidency and the chairs of the political groups. In this way, Council and Commission could still agree on a "Common Position"* during the British presidency (first half of 1998), which is strongly supportive of the directive. The Austrian presidency (second half of 1998), under heavy pressure from a national anti-biotech campaign, would at best be non-committal and at worst shelve the draft until 1999.

TRIPS 1999 Review

Article 27.3 of the WTO Agreement on Trade-Related Intellectual Property Rights (TRIPS) provides an outline for the standards of protection of biotechnology. It specifies what WTO members may exclude from patentability and also provides for a review of the provisions of this paragraph in 1999, four years after the entry into force of the Agreement establishing the WTO.

The research-based pharmaceutical industry believes Article 27.3 should be strengthened. Certain anti-patent forces including India will seek to use the opportunity of these renegotiations to weaken the provisions of TRIPS, including Article 27.3. We strongly urge the U.S. government to anticipate and counter such effort by preparing now to seek enhanced and stronger intellectual property protection under the TRIPS.

During the Summit the President should avail himself of any opportunity during side conversations to urge the strengthening of TRIPS and its accelerated implementation to promote innovation.

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Chairman Dr Onora O'Neill, CBE, FBA Executive Secretary Mr David Shapiro

FAX MESSAGE

Date: 12 June 1997

To: Jack Gibbons
Office of Science & Technology Policy
The White House

Fax No: 001-202-456-6021

Pages to follow: 2

EMBARGOED until 0001 on 13 June 1997

Dear Dr Gibbons

New instructions for Denver World Economic Summit: cancel ban on human cloning, but consider xenotransplantation

There follows an article which will appear in tomorrow's *Financial Times*. It argues that the World Economic Summit does not need to discuss human cloning yet. It should, however, urgently address the infectious disease issues around xenotransplantation.

The message, I take it, is the same as the NBAC's.

With all good wishes,

Yours sincerely,
David Shapiro

DAVID SHAPIRO
Executive Secretary

Rec'd 6/12/97
Science
Policy
Smith
JHG

EMBARGOED until 0001 on 13 June 1997

Will the G7 blunder in bioethics?

It's xenografts, stupid, not cloning

David Shapiro

Next week's (June 20-22) world's economic summit in Denver is due to discuss human cloning. It is the first time such a forum has addressed an issue in medical ethics, but it has chosen the wrong one.

Human cloning was put on the agenda by French president Jacques Chirac following the media furore about Dolly, the sheep cloned at the Roslin Institute near Edinburgh.

Human cloning for the moment is a fantasy. It is frightening that, in the moral panic over human cloning, a worldwide ban as suggested by Chirac may cut us off from the benefits of the institute's research. These include new insights into cell biology which advance our understanding both of cancer and of ageing.

There is, however, a new medical technique that does call for urgent and international regulation: xenotransplantation, or the use of animal organs genetically engineered for transplant into humans. The technique promises to end a worldwide shortage of organs for human transplantation, if it works: serious doubts still remain about graft rejection and physiology. There is also a risk - however slight - of transferring into humans a new animal virus or retrovirus.

So worldwide regulation and a cautious approach should be taken: we should not wantonly risk an epidemic. This approach would minimise the very slight risk of transferring a serious new disease into humans to the point where the benefits of the new technique should far outweigh the minuscule risks.

To do this requires international cooperation. The lead ought to be given by the G7 group of industrialised countries and, for that matter, by the European Union.

Xenotransplantation, unlike human cloning, is at the point of technical feasibility. Transplant surgeons in Cambridge and at Columbia University in New York are raring to go. It is said that a protocol for a series of experiments on humans has already been with the relevant committees for two years. It has been delayed for the US Government to decide how to regulate xenotransplantation. There is now an international consensus about how this should be done.

Four major reports have now been published, two each in the UK and the US, and the World Health Organisation has international guidelines in preparation. The two UK reports by the Nuffield Council on Bioethics in March 1996 and by the Department of Health this January recommended a national committee to supervise xenotransplantation.

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But the Nuffield report explicitly and the health department report implicitly pointed to the need for international agreement. One stumbling block has been US reluctance to contemplate national regulation in this area. The US Institute of Medicine's report of July 1996 was pussyfooting about national regulation. Fortunately the US Public Health Service has been more robust: last autumn it published suitably rigorous draft guidelines on the infectious disease issues in xenotransplantation.

The US Food and Drug Administration had set a foolishly lax precedent in authorising a bone marrow transplant to an Aids patient from a baboon known to be suffering from a suspect virus. Now, however, it proposes to treat xenografts under a strict regime. The transplant community awaits a worldwide initiative.

So why has Chirac chosen to call for human cloning to be on the G7 agenda? The hype that surrounded the unveiling of Dolly is partly responsible. A second slip was made by Ian Wilmut, who led the research team at the institute. He was widely reported to have said "You might expect to make significant progress in one or two years" in applying his methods to the cloning of humans.

His prefatory remarks were less widely reported and indicated anxiety that a hypothetical human cloning experiment would require the sacrifice of a high proportion of the annual UK supply of human eggs available for all forms of in-vitro fertilisation (IVF). And all that for the random chance of producing a single human clone.

In any case, such work is already illegal in all the major research nations except the US. Bill Clinton, US president, should not expect an inappropriate worldwide ban merely because the US political élite has been too cowardly to establish appropriate regulation of embryo research.

Chirac is right, however, in asking us to look at the ethics of human cloning. This needs time and careful reflection. The report presented to him by the French National Consultative Committee for the Ethics of Biomedicine was rapidly compiled. Its exposition of the science is in the best traditions of French clarity. Its moral arguments, alas, suggest that the Committee felt the need to justify the media hype and the moral panic. They read as though the Committee feared that if any human cloning were authorised anywhere, then humans might give up on normal sexual reproduction.

It seems odd, but necessary, that the Anglo-Saxons have to remind the French of the joys of sex. The Denver summit should surely concentrate on the pressing serious issue of xenotransplantation. Human cloning may safely be left to a later summit when the hype has faded.

*The author is executive secretary of the Nuffield Council on Bioethics
and a member of UNESCO's International Bioethics Committee.*