Six

ETHICAL ASPECTS IN INTRODUCING GENETICALLY MODIFIED ORGANISMS FOR PUBLIC HEALTH PURPOSES

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1. Introduction

Currently, researchers in several locations are working to develop genetically modified (GM) mosquitoes for control of vectors that transmit diseases such as dengue fever, malaria, and Chagas disease. The use of GM insects for control of human disease can be consistent with common ethical norms of society. The approach raises few intrinsic ethical issues. Still, before we release any GM insects, we need to assess potential impact on the environment and on human health. We need to establish universal minimal standard of risk assessment, applicable to disease vectors, because diseases and vectors can cross national and continental borders. Stakeholders should consider ethical issues including community engagement, informed consent, group consent, and relations between researchers and local populations. Each community needs to decide its policy guidance for ethical genetic engineering and to negotiate agreements with neighboring countries.

2. The Ethics of Disease Prevention

Because of the widely held ethical principle that human life is worth saving, we usually see global support of efforts to improve existing and develop new approaches for preventing, diagnosing, treating, and controlling infectious diseases that cause loss of human life.[1] But societies are vastly diversified, exhibiting a wide range of worldviews and social structures. Despite consensus on the overall goal, methods to achieve these goals, including the extent to which risks to human health, damage to the environment and other living organisms, and how economic costs are balanced with the need to invest in other goals, have sparked intense debates.

Well-defined principles basic to resolving ethical dilemmas can help decision makers construct policy decisions that are more informed. The principle that we should love the life given to us (self-love) implies that each person should enjoy autonomy (self-rule) to work independently out how to balance ethical dilemmas and choices.[2] The Universal Declaration of Human Rights of

1948 started with the premise that all human beings possess equal rights and deserve the opportunity to exercise autonomy. Persons who do not enjoy some basic level of health cannot make choices commonly accepted as normal. Poverty also restricts choice for many people, and in areas plagued with high incidence of infectious insect borne diseases, we often find widespread poverty as well.[3]

At present, we see a great inequality between rich and poor nations in the direction and priorities of research, and in the distribution of and access to benefits that might come from this research. Under any ethical theory, the presence of diseases that threaten the lives more than a billion people worldwide provides a compelling impetus for efforts to eradicate the diseases. Around the world, we see wide diversity in the risks that members of different communities face from infectious diseases due to individual genetic variation in resistance to infectious disease agents, in individuals' nutritional state and immediate environment, families' economic situation with respect to providing barriers to vectors and disease, and in access to preventative and therapeutic medicines. Working towards better global equity is a goal that attempts to meliorate the impoverished conditions into which some people are born and to improve their opportunities to thrive. Rawlsian justice holds this as an ethical mandate. John Rawls, in *A Theory of Justice*, argues that efforts should be made to minimize the variation in all social factors because no one knows before they are born into which situation they will be born. Therefore, everyone would wish for equal opportunity and equal exposure to risk. All people should have the opportunity to be born and grow up in an environment free of infectious diseases, if that ideal achievable. [4]

Human beings have used technology in efforts to make their lives easier and better for thousands of years. The ethical principle of beneficence supports the development of science and medicine, and its provision to those who suffer, because we should continue to make life better. Beneficence is based on the belief that all people have an intrinsic motivation to love doing good instead of harm, expressed as compassion.[5] Efforts that work toward the betterment of others have a universal moral mandate.

The ethical principle of nonmaleficence, do no harm, dictates that we should be reasonably cautious about premature use of a technology before potential risks are understood. Recently some proponents have advocated a total precautionary principle for genetic engineering, which means that no technology with any known risk should be attempted.[6] The Cartagena Protocol on Biosafety, an international, legally binding agreement that regulates international movement of living modified organisms (LMOs), advises this extreme caution.[7] Since no human action can be guaranteed to have zero risk, in practice, these principles are used to assess the relative safety of technology and are central to any public health program.[8]

The ethical issues raised by biotechnology are often the same ones that we debated in applied ethics long before we had modern biotechnology.[9] We can view ethics in terms of ecocentric, biocentric, or anthropocentric concerns. Ecocentric concerns, those that value the ecosystem as a whole, find expres-

sion in environmental concerns. Reverence for life applies to every member of the whole ecosystem.[10] Biocentric thinking emphasizes the value of individual organisms, whether plant or animal. Anthropocentric thinking focuses on human individuals. Trends have emerged for more ecocentric views to be included in recent legislation, with protection of ecosystems as a primary goal. While isolating distinct issues is useful, separating human nature from social interactions is not realistic because almost all of human life is composed of social activity, involving many relationships between people and the ecosystem. Different ethics apply when human activity, for example agriculture or urbanization, attempts to either dominate nature or harmonize with the environment.

Literature contains a variety of definitions for health, disease, disability, and meaningful human life. Working to alleviate disease and empower individuals to reach their potential are universal goals for the progress of humankind. Authors apply different persons in the same culture and have a wide range of differences between cultures. Working to alleviate disease and empower individuals to reach their potential are universal goals for the progress of humankind that cross all definitions.

We can apply the basic ethical principles of autonomy, justice, beneficence, and nonmaleficence to decision making in the face of a range of bioethical dilemmas found in medical and environmental ethics. Whether further ethical principles can always be derived from these has been debated,[11] but the general consensus is that these four principles are fundamental across a range of cultures.[12] The emphasis on individuals' rights that has been a feature of theories of bioethics in North America is less developing countries. Other ethics theories focus on the community. These theories hold that individual rights or are not well suited to the community structure of some societies.

3. Bioethics and Molecular Entomology

Genetically modified organisms (GMOs) can be used for public health purposes in a variety of ways. Control of disease vectors is an emerging practical possibility. We already have a long history of altering the behavior of vectors so that they cannot transmit pathogens to human beings.[13] Insects have also long been the targets of attention in agriculture and medicine. While few intrinsic ethical concerns about killing insect pests exist, ecocentric approaches to ethics do raise some objections to modification of ecosystem components, and we need to more seriously address those concerns.

People of many cultures have developed biotechnologies as they cohabitate with non-human animal species in the wider biological and social community. Biotechnology means biological science applied especially in genetic engineering and recombinant DNA technology. For the purpose of this paper, I will focus on biotechnology that uses living organisms, especially GMOs, in the production of goods or services. Modern biotechnology is founded on the same tradition of plant and animal breeding that gave rise to agricultural societies. Since the

mid1990s, a growing number of countries have sold foods produced from GMOs.[14] Fierce international debates have argued the environmental and human health aspects of genetically modified (GM) foods, but so far, science has demonstrated no harmful effects of GM foods on human health.[15] Some independent organizations, voicing concern about the environmental impact of gene transfer, have submitted reports containing a wealth of useful information about the technology and commentary on relevant ethical issues to several governments for consideration.[16]

Genetic engineering allows genes exchange of genes in a controlled manner between different species. Since its invention in 1974, it has conjured up images of hope and dread. Public opinion is mixed, but the general approach has global support beyond the dreams of its pioneering scientists.

With the emergence of genomic sequencing, we have now mapped the human DNA, dozens of pathogens, and some disease vectors, for example, *Anopheles gambiae*, the mosquito that carries malaria.[17] Molecular entomology, the study of DNA and the proteins it encodes in insects, is emerging as a serious scientific approach to insect control.[18]

The United Nations Development Program (UNDP)/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) addressed the concept of genetic control of insect vectors at a 1991 meeting on use of genetically modified (GM) mosquitoes to replace disease vectors. TDR's Steering Committee for Molecular Entomology has outlined a three-pronged approach towards developing genetically modified mosquitoes for malaria control, with similar approaches for dengue fever and Chagas' disease.[19]

The paradigmatic genetic research design with GM organisms works out genetic transformation of the insects in the laboratory and then tests their behavior and vector characteristics before releasing them into the environment. First researchers study the host-parasite interaction. Then they develop methods to transform the vector. Human beings are at risk of harm from naturally occurring pathogen-transmitting vectors. The primary purpose of the project to create modified vectors is to reduce these risks to human beings. For these studies to be successful, trials need to be conducted that demonstrate reduced risk compared with naturally occurring vectors before the modified vectors are released. Finally, they look at population ecology and genetics. Except in cases where scientists use sterile insects to replace the whole population to eliminate the species in an area endemic for disease transmission, researchers explore mechanisms that would safely spread the new gene among vectors in the wild, eventually replacing the population of harmful vectors with non-harmful insects.[20]

Releasing GM insects raises questions the safety of the procedure. We need to thoroughly investigate possible effects of introducing GM insects into the environment and on other species. Issues regarding the desirability and morality of humankind changing entire elements of nature are also legitimate areas of ethical reflection.

While interested parties debate whether to use of funds to combat infectious disease using genomics and biotechnology or devote their limited funds

to implementing practical measures to curb vectors and pathogens in the field, we find wide agreement that genetic modification of disease vectors will become a major strategy in the future.[21]

4. Intrinsic Ethical Issues of Genetic Engineering

Studies have compared ethical issues inherent in the process of genetic engineering compared to traditional methods of animal and plant breeding. In genetic engineering, we achieve more precise control of genetic transformations and accomplish cross-species DNA transfer that would not ordinarily occur in nature.

DNA transfer does occur between species, sometimes even between kingdoms, in nature. We know, too, that insects are subject to naturally occurring genetic flux. Genetic engineering does not accomplish results that would never occur in nature. Because the DNA changes can be precisely designed with a stated beneficial purpose, a targeted genetic change made through genetic engineering should be safer than naturally occurring fluctuations or mutations because the change occurs under more control and only after careful deliberation of potential consequences. Still, public opinion surveys have shown opposition to cross-species gene transfer.

Does genetic integrity of organisms in the ecosystem have an intrinsic value that humankind ought not change? If we restrict genetic engineering to intra-species changes, our work would mimic the natural ways that organisms evolve changes in genetic structure, eliminating this ethical concern.

Other ethical issues raised address the *telos* (purpose) of an organism. Teleology is the branch of moral philosophy that studies ultimate causes in nature. A teleological explanation describes phenomena by their design, purpose, or final cause. Some philosophers believe that purpose and design, endowed by a Creator, exist in nature. Some philosophers believe that the ability to alter the *telos* of an organism has profound implications, whereas others say that altering the *telos* has little meaning in the context of human modification of nature.[22] If we believe that every organism has a purpose, then the *telos* is an intrinsic characteristic, and genetic engineering alters the *telos* or beingness of an organism. Whether changes and control through genetic engineering are significantly different from changes made by human beings to animals and plants in farming and modern life is debatable. If we consider this issue in a historical context, we see that affluent cultures have controlled nature in significant ways, for example, through irrigation and sanitation projects. In some developing countries, limited resources have limited the extent to which similar control has been feasible. The ethical issue focuses on whether, and to what extent, human beings may legitimately exercise control over nature.[23]

5. Animal Rights Concerns

An ethical concern in the discussion of animal welfare is whether animals suffer or feel pain. Those who believe that insects do not feel pain argue that manipulating insects has no intrinsic wrongness.[24] For those who believe that insects feel pain, even if we consider the idea of making so-called vegemals, animals that do not feel pain, we are still manipulating life for human purposes without considering the interests of the animal.[25] Animal rights proponents' concern is that living organisms should not merely be treated as a means to the ends desired by human beings. More ethical concern has been voiced about modifying higher order animals, especially sentient ones, than about engineering insect vectors.

In addition to concern for so-called intrinsic characteristics (pain, sentience, consciousness), human society has also placed extrinsic value on some animals. For example, some animals, such as the American eagle, are national symbols, and some people express greater concern about harming them than other animals. We also see biodiversity concerns regarding endangered species, some of which have been expressed by the Convention on Biological Diversity.

While perhaps only followers of the Jain religion in India refrain from killing insects that are considered human pests on moral grounds, some others might object to insects for other reasons. We wonder whether manipulating insects to eliminate disease vectors would be more acceptable to persons with these ecocentric worldviews than traditional methods of insect control that attempt to eradicate entire insect populations.

The total number of species affected by genetic modification of vectors would be significantly less than the number of species affected by use of insecticides. Still some argue that we should not modify or eradicate even insects because human beings should not modify the ecosystem. Proponents of this view fail to recognize that all human activity modifies the ecosystem in some way.

6. Consent from Trial Participants

The ethical principle of autonomy dictates that all research participants should give informed consent before receiving any intervention that has a reasonable risk of causing harm.[26] Obtaining individual informed consent is problematic in some developing countries,[27] due to the limited resources and commonly more paternalistic models of health-care delivery. Adequate investment of time and provision of suitable materials should mitigate these problems and us to obtain informed consent from individuals at direct risk, even if the exact cultural interpretation of the informed consent process may vary among countries.[28]

The risks may not just be those that arise directly from the ability of the vector to carry the target pathogen. There could be a negative impact on human health by altering the behavior of blood-feeding insects. In the case of

insects that cannot be restricted to a designated geographic area because they fly for example, the concepts of human subject and informed consent need to be extended beyond focus on the individual.

Basic ethical issues pertain to vector collection and field studies. Many such studies have relied on a researcher waiting for a vector to land on a human host, and then capturing it, hoping to do so before the vector transmits the pathogen to the human bait. On ethical grounds, we question whether researchers could design safer field study methods that do not expose human persons to risk.

The approach developed for population genetics studies may be useful where the community and local authorities are involved in the decision-making process. Accepted protocol for informed consent requires researchers to provide information to potential participants. Disseminating information about the plans and progress of the project and obtaining the consent of any person potentially affected by the release of transgenic insects would constitute ethical conduct of research trials, regardless of whether national guidelines mandate these procedures.

People who lack the means to express their preferences might be abused by the lack of individual or community consent for research in anthropology and epidemiology.[29] In some cases, research forewent participatory dialogue with the local community and neglected to inform participants of potential risks of participation in the research. Often researchers did not seek informed consent and did not offer benefit sharing.

If a study involves human beings, oversight by an ethics committee or Institutional Review Board (IRB) is wise. Increasing numbers of countries have codified these requirements, charging researchers with specified legal responsibilities, typically about the conduct of research or clinical practice at the local and national levels. The IRB usually requires that each human subject in a medical trial give informed consent to be involved in the project.

An international consulting committee for TDR has published model operational procedures and ethical guidelines for the establishment of IRBs.[30] These guidelines are not sufficient for the broad question of how to obtain informed consent for a public health intervention involving thousands of persons where the benefits are not yet demonstrated. A project to introduce transgenic insects will need an ethics committee with a broad overview, while regional ethics committees to consider local issues.

To consider the issue at a local level, as required for obtaining appropriate informed consent, a local ethics committee (or IRB if associated with an institution) open to the target communities is essential. Cultural differences dictate differences in the way informed consent should be obtained.[31] The modified Declaration of Helsinki and the draft Council for International Organizations of Medical Sciences guidelines outline the accepted norm in international ethical guidelines.[32] In cases involving bilateral research collaboration, researchers should adopt the most stringent ethical standards of participating countries, but doing so creates problems for populations with lower literacy levels and different common sense social assumptions than the rich

sponsoring countries. The ultimate decisions should be made by the local ethics committee based on the international standards.

Privacy issues arise when questionnaires containing personal data are stored. For public health purposes, all information about individuals involved must linked to other data, but to ensure privacy, the data should only be identifiable by a designated person who uses a coding frame entered into a computer not linked to a network.

Some public health interventions have targeted children without obtaining informed consent. Proponents of these procedures have claimed a therapeutic imperative that presumes children are incompetent to give informed consent, but if they had the capability to understand what is good for them, would want to be involved in programs that would assist them to avoid disease. Critics have charged that in these cases, researchers should obtain informed consent from parents or legal guardians before they subject their children to any interventions.

In family settings where interventions might affect anyone in the family, the question arises whether researchers should obtain informed consent from every individual family member. In these matters, researchers should consider local cultural norms. In some cultures, every individual of reproductive age (mature adults) should be consulted. In those cases, family consensus and individual consent is appropriate.

Researchers should obtain agreement and understanding of children in the community through suitable materials. An efficient way to reach parents might be through communicating with children in schools. Since children are at higher risk for many of the diseases under study, they stand to benefit more, and most parents may want to be involved in the trial, because of the potential benefit to their children instead of themselves. But children should not be exposed to direct risk from therapeutic trials unless no alternative exists. In a community involved in a GM vector trial, researchers would not expect any direct risks to the human population. Normal procedures that do not require additional consent from children could be applied.

7. Duty to the Community when Experimental Manipulations Are done on the Environment instead of on Individuals

Because the control population for a study may also be at high risk of contracting the studied disease, recent research ethics debates have questioned whether researchers have an obligation to the local population to use the best available means of disease control whenever they enter an area for a study. Ethically, we might need some other vector reduction measures when making any interventional study in an area. This thinking could lead to the conclusion that a researcher may ethically be compelled also to provide the best available proven alternative to the study population.

This might sound like an ethically compassionate approach, but one that would confound the research design. International guidelines' treatment of pla-

cebo-controlled trials, for example, the Declaration of Helsinki, have been based on medical drug studies as the paradigm. This paradigm is not an apt one to apply to genetic research on disease vectors where the treatment involves altering the environment instead of giving a specified drug to an individual. Provision of the proven alternative to the area of study alters the dynamics of the disease so that the results of the vector field trial differ from what the results would have been had no established alternative been provided. Such an approach would render any conclusions we draw about the experimental treatment questionable.

8. Environmental Risks and Public Consensus

A variety potential ecological and health risks are associated with the release of GM organisms. To date, researchers have reported successful environmental risk containment in over 10,000 field trials of GMOs released into the environment in a variety of countries.

We can consider environmental risk from either an anthropocentric or ecocentric approach.[33] Identified risks include the possibility of horizontal transfer of the novel genes to non-target organisms and possible disturbance of insect ecology.[34] Although human beings cannot consent for other organisms to be modified per se, in scenarios where, in addition to effects on direct subjects, research trials can be expected to present potential harm to other non-human members of a biological community, or where interventions in the environment might affect human beings residing in that environment, researchers should seek community consensus on the proposed intervention.

People evince variations across cultures in their beliefs about nature and life.[35] In some cultures, for example, in New Zealand, people have expressed concerns over the need to preserve the native fauna and flora, which many in the Maori community consider wrong to modify. Some people are willing to sacrifice themselves to protect the environment. Another example of this phenomenon is the preservation of sacred groves in India, done now for thousands of years, even during times of severe crisis and human death. In this case, nearly all the people of that community are willing to die instead of damage a part of the environment that they cherish. Such strong convictions often correlate with religious beliefs about spiritual life after physical death.[36]

Potential risks to the agricultural systems of rural communities also require assessment because animal diseases transmitted by vectors pose risks to farming families. In addition, there may also be risks to wild animals in surrounding areas, which in some ecocentric environmental views have more intrinsic rights to be left undisturbed than domesticated animals.[37] This calls for broad ecological understanding of the ecological impact beyond public health.

Since 2001, researchers conducting trials of GM insects have instrumental in developing regulatory systems for oversight of GMOs/LMOs, but most countries in the world still have not established systems for oversight of GM insect field releases.[38]

Although many surveys have assessed public opinion about GMOs, few surveys ask people about their views on introducing GM vectors or pathogens for disease control. Survey results indicate that people consider GM plants less risky than GM microbes, animals, or human beings. GM insects for public health purposes appear to be intermediate in the scale of benefits and risk perception. A Japanese national sample collected in Japan indicated that 33 percent of the respondents thought use of genetic engineering to make mosquitoes unable to be a vector for human diseases like malaria or Japanese encephalitis would be acceptable; only 16 percent said it would not, but 50 percent said they did not know. Another question showed 54 percent of respondents voiced approval for environmental release of mosquitoes that do not transmit human disease, and an approximately equal number supported release of GM disease-resistant crops, with 19 percent disagreeing.[39]

Knowledge is a necessary but not sufficient condition for the acceptance of biotechnology. In surveys of scientists and the public in Japan between 1991 and 2000, for example, well-educated scientists were often as skeptical of biotechnology as the public were. They shared the same types of concerns.[40]

The failure of the government authorities to protect public health in cases such as Mad Cow disease outbreaks has resulted in higher public trust of non-governmental organizations (NGOs) such as environmental groups that often lobby against genetic engineering. In addition, the media sometimes disproportionately reports negative aspects of genetic engineering because these risks of technology appeal to the media and many people.[41] As a result, the late 1990s saw a dramatic drop in public support for biotechnology in every country surveyed. We believe that all stakeholders, even opponents of scientific research, should be included in open dialogue about research priorities. But for meaningful informed decision making, reports of scientific activities should be accurate and reported without bias.

The widespread effects of introducing GM vectors and pathogens into the environment demands that the consent process be modified for a community model instead of on isolated individuals on which drug trial consent paradigms were developed. We need to tailor the process to each community in which we propose interventions.

The question of whether every citizen has to consent to public health interventions is not a new one, but with the current social transition from paternalistic societies to autonomous societies where informed consent and free choice are valued, we see this ethical issue increasingly emphasized.[42]

Any initial trial proposal might be confronted with the "not in my backyard" philosophy. Socially powerful persons can be quite effective at blocking trials they perceive to be risky, or, conversely, at attracting social resources towards themselves and away from weaker persons in the community. Ethical practice requires equity in distribution of risks and benefits. One way to ensure this would be to commit to a local community that, if the trial were successful, the full-scale intervention would include them from the beginning. In this way, populations willing to bear potential risks would receive compensa-

tion in the form of early benefits when the full-scale safe and effective control program is implemented.

Finally, before they propose field trials to local communities, researchers have first gained commitment that financial resources to conduct the research will be available, and that that sustainable use of any control tool developed will be affordable to them.

9. Ethics of Technology Choices

Some ethicists have debated whether we should concentrate limited research dollars on developing technologies that rectify problems or on studies to learn how to prevent those problems from occurring. Not all local communities will share the modern scientific worldview that technical healing is desirable or better than other options. If we hope to gain their trust and willing cooperation, we need to be flexibility in which approaches we investigate to eradicate disease. In the past, paternalistic interventions were imposed on citizens. Civil rights movements have empowered people to make these decisions independently.

International debates over the morality of obtaining patents have featured several ethical issues such as the balance between benefit gained from intellectual property innovation rewards versus exclusive licenses for production of producst. Critics have made strong calls against patenting medical innovations because, in some cases, medical products have been priced well beyond the means of many in the population to afford. Laws on intellectual property vary between countries, despite attempts to harmonize these laws among industrialized countries and members of the World Trade Organization (WTO). Some developing countries are not members of the WTO. Often whether a country will join WTO hinges on intellectual property rights (IPR) issues.

Another concern voiced by some scientists and the public is that genetic engineering is somehow unnatural. We need to examine this issue closely for consistency with other expressed values. Presented with the threat of contracting disease or the need to combat disease already contracted, most people have few concerns about using other unnatural remedies such as pesticides and pharmaceuticals. We could question whether opposition based on the practice being unnatural is consistent with other expressed values.

Given that most mosquitoes do not transmit disease to human beings, we could argue that the natural state of a mosquito is one that does not act as a disease vector. We could conclude, therefore, that modifying a mosquito that does transmit diseases into one that does merely restores the mosquito's original nature.

The ethical principle of nonmaleficence, do no harm, should guide our research activities and choices of technologies to develop. Concern over possible safety and environmental risks raised by biotechnology prompted WHO, the United Nations Environment Programme (UNEP), and the United Nations Industrial Development Organization (UNIDO) to identify and study these

safety issues. As a result, a UNIDO/UNEP/WHO/Food and Agriculture Organization (FAO) ad hoc Working Group was formed in 1990 to work out practical guidelines through a series of consultations with international experts and scientists from developing countries. In 1991, the UNIDO/UNEP/WHO/FAO Working Group on Biosafety issued the *Voluntary Code of Conduct for the Release of Organisms into the Environment*. UNDP and FAO generally support the development of genetic technology as long as benefits and risks of the organisms are considered. Countries need to strengthen their ability to establish committees to adequately address ethical, social, and scientific concerns.

The Scientists' Working Group on Biosafety of the Edmonds Institute in Washington D.C., United States, recommended that field trials of vectors genetically engineered to reduce disease should be small scale in terms of the area of dispersal of the vector:

> In the case of an anti-malaria or anti-dengue intervention, such a field trial could involve a single village or an isolated cluster of adjacent villages. No large-scale release should be attempted until the effectiveness is shown in the first trial.[43]

While participants in the United Nations system have reached consensus that we should proceed with the prudently selected use of GMOs, some groups within society continue to urge caution. Some countries have political regimes that do not accept GMOs, and in democracies, the attitude of the government depends in large part on a popular vote. Where two or more countries hold opposing opinions, another issue arises. While we should respect national sovereignty, GM vectors may spread beyond national borders.

The Cartagena Protocol on Biosafety was issued in January 2000, and effective September 2003, by the 1999 Conference of the Parties to the Convention on Biological Diversity (CBD) in Cartagena, Columbia. The objective of the Protocol to the CBD is to contribute to the safe transfer, handling, and use of living modified organisms (LMOs), plants, animals, and microbes, that cross international borders, and to avoid adverse effects on the conservation and sustainable use of biodiversity without unnecessarily disrupting world food trade. The Protocol provides countries the opportunity to obtain information before new biotech organisms are imported. It acknowledges each country's right to regulate bio-engineered organisms, subject to existing international obligations. It also creates a framework to help improve the capacity of developing countries to protect biodiversity. The Protocol also recommends risk assessment and risk management once agreement to import biotech organisms is reached, and capacity building in biotechnology research.

Many developing countries do not have the economic or scientific capacity needed to evaluate the products of modern biotechnology.[44] Based on the Cartagena Protocol recommendations, CBD members have established biosafety clearing houses that function as contact points in each member country, whence this information can be obtained without incurring prohibi-

tive monetary costs. We recommend that information about GM vectors should also be included in these clearing houses.

10. Conclusion

A variety of ethical issues are raised in response to the use of GM insects, but the most challenging may be how to ensure valid informed consent procedures for individuals and communities. Each community or society deserves the opportunity to reach consensus on how it values risk. We need a universal minimal standard of risk assessment applicable to disease vectors because diseases cross national and continental borders.

Before field release of transgenic insects, researchers must assess all associated scientific and social issues and develop safety precautions to address potential risks. They should minimize scientific and social risks through careful design of their research, relevant laboratory experience, and careful choice of the dispersal site. Even if no significant risks are recognized before study inception, a procedure for risk assessment should be set up so that new information can be gathered and interpreted. This procedure may involve establishing a specialized ethical review committee under the auspices of an international body such as TDR to offer advice to researchers on the ethics of projects.

Prior environmental, medical, and social studies should form the basis for site selection. Information should be exchanged as broadly as possible with community leaders and members of the local community. Mass media and existing educational institutions are two vehicles for information dissemination. Mechanisms to obtain individual and group consent need to be developed for public health interventions and in trials where researchers make changes to the environment that can affect members of the community.

One way to entice community involvement in field trials is to promise that the community will be first to enjoy any benefits derived from the research. To avoid intellectual property concerns being a barrier to implementing public health measures using GM vectors or pathogens, prior negotiation about intellectual property rights is preferable to confrontation.

Research data should be disseminated accurately and without bias to all stakeholders to benefit from global expertise and to encourage international consensus. We need an ongoing, active process of ethical analysis through a variety of forums. Researchers can allay most concerns by offering better information and education.

Ethically, we should identify core values that guide us as we research how to modify nature in the service of human needs. The ethical principle of beneficence demands action to eliminate hunger and disease. We must balance the need for technological advancement with our duty to protect and preserve the environment for future generations.

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