Food Security and Biotechnology in Africa

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MODULE 5

ETHICS AND WORLD VIEWS IN RELATION TO BIOTECHNOLOGY

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Module 5; Unit 4: Case Studies of the Influence of Ethical Concerns in the Use / Adoption of Biotechnology

Lecture 1: The meaning and characteristics of case methods of Learning (40 minutes Lecture)

Learning Outcomes

Students are expected to understand

- **the meaning of case method or learning**
- **the basic concepts of case method of learning**
- **the characteristics of case method of learning**
  - **be in a position to raise cases and examples for case based learning and interrogate such cases in an ethically compliant learning environment**
- **It also seeks to challenge students to engage the issues being discussed and participate in the deliberative process**

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The case study method is a way to introduce students to real-life situations in a way that requires them to think about the issues presented from a variety of different viewpoints, and ultimately to challenge their own views. This often involves role-playing activities in which students are asked to adopt and defend a view other than the one they personally hold. As the case is carried out in the classroom setting, students must adapt their position in light of critiques and counter arguments given by other members of the class. A case study activity often ends with an opportunity for students to discuss their own personal views on the issue presented, and how these views may have changed over the course of the activity. The case study method is a useful alternative to the lecture method. Whereas the lecture method concentrates primarily on conveying information in a one-way format, case studies give students an opportunity actively to take part in the learning process.

Lecture usually involves a passive audience whose participation only extends as far as listening and taking notes. This is useful when the objective is to summarize or present a general overview of a concept, but it falls short in that it does not help students to develop their own critical thinking skills. Lecture has long been the standard method of communicating information in the university setting. While it has been strongly criticized for its lack of significant student participation and its tendency to lose the audience's interest, many teachers continue to employ this method simply because they have not found any satisfactory alternative. This is not to say that lecture is without significant merits. Under some circumstances it may be the most appropriate method to convey information in an academic setting. However, it is often highly desirable to supplement lectures with alternative active learning techniques. The case study method is an especially effective way to accomplish this.

Active learning techniques allow students to participate in ways that lectures do not, by requiring them to engage their critical thinking, problem solving, and content evaluation skills as well as to develop their writing and public speaking abilities. Put simply, active learning is carried out through "instructional activities involving students in doing things and thinking about what they are doing." Whereas a class solely conducted through lectures will simply ask students to regurgitate information, or at best, personally to reflect on what has been presented, active learning involves the entire class in challenging, arguing for, defending, and shaping ideas. It is now well known that different students have quite different learning styles: some students learn best by reading, others by listening, and still others by roleplaying. Active learning techniques are particularly important since they have the potential to engage many more learning styles than just lecture alone.

It is also important to note how case study activities differ from formal debate. While the two involve some similar elements, they are actually quite different both in practice and in their objectives. Formal debate is adversarial; the point is to attack the opponent's claim in such a way that the audience is convinced of your point. In the context of debate, students may assume that there is a single correct viewpoint, and that any opposing views should simply be rejected. The adversarial process may encourage participants to adopt a combative rather than a deliberative attitude toward the subject matter. In other words, the object is simply to win. This goal replaces or takes precedence over thoughtful deliberation and respectful

consideration of the views of others. On the other hand a case study—a **"structured controversy"**—aims to help students to understand controversial issues in their full complexity with appreciation for a variety of different points of view and the reasons supporting them. In the case study method, participants use their differing viewpoints constructively. It has been argued that structured controversy in the classroom "results in greater student mastery and retention of the material and a greater ability to generalize the principles learned." This requires and exercises four major skills:

1) The ability to research; specifically to collect and analyze data in order to provide evidence in support of a position.
2) The ability to evaluate and criticize opposing viewpoints, and to respond to similar criticisms of one's own view.
3) The ability fairly to consider an issue from both sides.
4) The ability to synthesize information from both views in order to arrive at a compromise consistent with both positions.

While it may be a relatively minor point, it is important to note that the word "both"—indicating an assumption that there are two and only two sides to an issue—is highly misleading. In most complex controversies there are usually many different views and positions that need to be understood and appreciated. This is especially important when classes address complex issues involving moral *and* legal concerns. Because of this, in many cases it may be impossible to fulfil this fourth requirement. With a two-sided issue it is obvious that a collaborative effort to arrive at a conclusion involving some elements of both parties' interests is desirable. But some of the best cases will involve complicated and even ambiguous factors. They will not be as 'black and white' as suggested above. For this reason, it is suggested that a less stringent version of point four that requires one's concluding opinion to be informed by a fair consideration of all sides and an understanding of each viewpoint.

Sometimes an interest group represented in a case study may represent an *unethical* view that should be rejected altogether. At other times the seemingly "right" group will profess an illegal (or otherwise unenforceable) viewpoint thus negating many of its recommendations. While compromise may be a worthwhile objective in theory, in many real-life cases it is an unrealistic goal.

Characteristics of Good cases/ Making a good case

First, a case must generate excitement. This is important for a variety of reasons. Excitement and controversy can increase student participation and enhance retention of the material. If a case has a sense of immediacy and touches on current events or issues that personally affect the lives of the students, it will entice them to participate. Appealing to their personal interest will also help students to reason from the particulars of the case to more general, overriding principles, as they discover how the issue under consideration relates to their previously held views on the subject. This is especially important in role-playing case studies; students must "forget" that they are completing a classroom activity and really become involved in the interest group they are representing. The more interest-arousing and exciting the case is, the greater the chance of this happening. This will typically require that a case should be based

on relatively recent events and up-to-date on laws and scientific discoveries. However, a case must be more than just a fun distraction from lecture.

A good case must also provoke conflict and controversy. One criterion cited as a litmus test for a good case is whether reasonable people could disagree on the facts and the outcome of the case. The best cases will require a great deal of effort to defend because the opposing positions will be supported by powerful reasons and central interests. **In such a case, an appropriate conclusion will typically require incorporation of the good reasons that different interest groups bring to the table.** Finally, a good case will force the participants to make a decision. Not every case can be resolved, and for some the outcome will already have been determined in litigation (the result of litigation/ or rather a court decision or precedent in one country need not have effect or be binding in another. Court decisions are binding only in jurisdictions where they apply). But it is important that students should be able to arrive at a reasoned judgment after in-depth consideration. For example, a case about *in vitro* fertilization (IVF) will be less decision-forcing than one about genetic technologies that could allow parents effectively to "manufacture" their children by selecting their traits, such as physical appearance or athletic ability. Even though IVF is controversial, students who initially feel that it is morally problematic may decide that formulating an informed stance against it would not be worthwhile since it is both legal and commonly practiced.

Case study participants may feel less urgency to make a decision about an issue if they know that it has already been popularly resolved, or if there is no reason to believe that continued criticism would have any impact. It seems likely that IVF will continue to be available in the foreseeable future for those who want to take advantage of it. Because of this, students may think that there is no reason to argue about it, and may get less out of a case study activity focused on an issue like IVF. A case on other genetic technologies like the one listed above is likely to be more decision-forcing. This is because students are likely to feel that their viewpoints matter more, and that coming to a personal conclusion on the subject is more urgently crucial. They may be more likely to feel that critical examination of the practice may be influential either in the outcome of the case at hand or in other related cases. This distinction is worth mentioning because case studies involving issues that have already been legislated or otherwise resolved can still be decision forcing. They often have important implications for related cases, or for interest groups that are affected by the judgment. Because of this, an issue may still make a good case study even if the controversial issues involved have been resolved in court or in the court of public opinion. It is beneficial that case study participants challenge the views they bring in and the conclusions they arrive at through the course of the activity. It is also important that the participant completes the case study activity with a deeper understanding of the issues, even if it leaves them in a state of suspended judgment. It may be enough for a case study activity to goad students out of complacent dogmatism, even if it does not force them to arrive at a conclusion about the issue under consideration. A decision forcing case must encourage students to evaluate and analyze views different from their own, and different from the status quo, rather than force them to come to a literal decision on the issue.

One concern about the case study method is that it might encourage a dogmatic attitude of "lawyerly adversarialism" instead of truth-seeking. It must be kept in mind that the point of a case study is not for students to learn how to attack other students' positions, or even to "win" an argument. At first students my feel that it is futile to discuss differing viewpoints if it is never ultimately decided which one is the best; they should be reminded that the goal of the case study is to learn how to engage meaningfully with others and to explore the multiple sides of complex issues. In some cases it will be apparent that certain views are definitely illegal or immoral, but students should be encouraged to consider well-reasoned ways to respond to these views, rather than simply to point out their flaws. It may seem as though one view presented in a case study is clearly superior to others, depending on the demographic and ideological backgrounds of the class, but it is important that students understand even the most righteous or obvious positions still need to be backed up by solid evidence. Even if this goal of the case study activity is explained to the students, there is still the possibility that they will interpret discussion as debate, or that they will personally feel compelled to argue and attack views in stark contrast to their own. At this point it becomes the teacher's responsibility to make sure that this behaviour is avoided. This can be done in a variety of ways. First, the facilitator of a case study activity should take note of whether certain side of an issue are being underrepresented, or are not being given legitimate consideration. This is one instance where the teacher's moral obligation to bring in marginalized voices comes to play. He or she should ask probing questions not only to direct the course of discussion and appropriately frame the issue, but also to make sure that problems with the strongest views are explored, and that minority views get due consideration. Since many case studies will be on highly controversial moral topics, it is nearly inevitable that some students will become deeply engaged in very intense, even heated discussion. This should not be avoided since again, avoiding moral conflict only stifles rather than eliminates it. Instead, it is important that students learn appropriate ways to respond to those with whom they strongly disagree. It is the responsibility of the teacher to ensure that in cases like this the dialogue remains discursive rather than adversarial. Students' comments should directly respond to the evidence and arguments provided by the person or people with which they are engaged in discussion, rather than simply list reasons for why his or her view is superior.

Again, it is important for the teacher to stress that the object of a case study activity is to learn about the different sides of an issue, not to win one's case. This should be encouraged by allowing students a time after the activity is completed to share ideas and express their personal views on the subject. They should also be asked to respond to the actual outcome of the case, where relevant, and to consider implications that this case may have for other related cases. In most situations the facilitator should avoid legislating any sort of conclusion, even in cases where the role-play activity calls for students to represent interest groups petitioning some sort of governing body. This will help students to realize that all views deserve and require reasoned consideration, which is one of the most important goals of a case study activity.

Case studies do not merely call for a restatement of one's own values, or of the facts in the interest group readings. Instead, they should involve thoughtful consideration of the issues, and of one's own views in light of the information presented during the course of the activity.

Students may come to the activity with certain advocacy roles which they are not compelled to abandon. Therefore after such an activity, students' views may not have changed with regard to the values at stake. It is a real possibility that no compromise will be reached and that students will still hold competing views. This is not wrong, or even undesirable, and it does not necessarily imply the promotion of moral relativism. First, in complex ethical cases, true compromise is an unrealistic ideal. There will always be moral conflict in public discourse, so the important point is that students are trained to properly engage with and respond to competing ethical viewpoints. Even if each participant in a case study begins with differing views on the topic and these views are not changed throughout the course of the activity, progress has still been made as long as they have learned how their previously held views relate to other equally well-formulated views. They should also understand and be able to respond to common objections of their view. Furthermore, although it is true that everyone is entitled to their own opinion, this does not mean that every opinion is equally right, or that every opinion is equally able to stand up to criticism. Second, viewed in the broader context of a course curriculum, a case study activity and the associated discussion of moral views is only one part of a greater objective. In a course with the substantive goal of delving deeply into philosophical issues and ethical theories, or in one aimed at how to best conduct scientific research, a case study provides an excellent opportunity to begin to explore the variety of competing moral values associated with certain issues. But a case study activity should be prefaced and followed by an examination of the broader theoretical context as well as the fundamental facts particular to such issues. With general objectives like these in place for the course as a whole, the case study method allows participants to delve into the more subjective aspects of the moral issues at hand.

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Module 5 Unit 4: Ethical issues in the uptake of Biotechnology

Lecture 2: **Recap of framework for analysing ethical issues (20 minutes)**

Learning Outcomes

- **Framework for analysing ethical issues has been explored in UNIT 3 / Lecture 3 (for 2 hours).**
- **This lecture is intended to refresh output from that activity as it relates to**
  - **Consequentialism;**
  - **Deontology;**
  - **Virtue & African Moral Theory;**
    :as bases for analysing ethical issues raised in crop, animal and environmental biotechnology

This lecture is intended to refresh output from that activity as it relates to Consequentialism; Deontology; Virtue & African Moral Theory as bases for analysing ethical issues raised in crop, animal and environmental biotechnology

The issues at stake…

In respect plant biotech the issues relate to the technology being:

- Blasphemous
- Unnatural
- Disrespectful
- Unsafe and having
- Negative Socio-economic consequences

Similarly, in respect animal biotech the issues relate to the technology being:

- Blasphemous
- Unnatural
- Disrespectful
- Unsafe and having
- Negative Socio-economic consequences

…..and in the environment, the issues relate to:

- Escape of transgene to Wild-type plants/ horizontal gene transfer
- GM Plants with selective advantage --leading to super-weeds
- Crossing of species boundaries
- Herbicide /pesticide damage to dependent wildlife and non-target organisms
- Development of resistance in insect pests
- Increased use of herbicides and pesticides
- Loss of biodiversity (crop and wildlife) and genetic diversity
- Unpredictable gene expression and flow (‘genetic pollution’)
- Alteration in evolutionary pattern
- Loss of ecosystem in marginal lands/ conversion of such lands to agriculture
- Agricultural Intensification
- Contamination of soil and water

Response / approaches to handling bioethical issues
Effective discussion of the issues raised above can be best achieved by keeping eye on predominant concerns:

- Uncertainty/ precautionary principles
- Consent, labels and choices

These may then be discussed on the bases of methods in ethics as developed in unit 1c (approached as below)

Consequentialism, Deontology (Kantian ethics), Virtue (Aristotle's moral theory) and African Moral theory

Module 5 Unit 4: Ethical issues in the uptake of Biotechnology

Lecture 3: **Evolution of Ethical Debate associated with the emergence of genetic engineering (bioethics) (1h) (Case study 1)**

Learning Outcomes

Students are expected to appreciate the evolution of bioethical debate (from medical ethics to bioethics) in the light of developments in biotechnology

Bioethics
(Refer to the first lecture and definitions for introduction to concepts)
Defined "as the systematic study of human conduct in the area of life sciences and healthcare, insofar as this conduct is examined in the light of moral values and principles"

- the concept of bioethics as a field of applied ethics encompasses three main areas
  - Medical ethics
  - Animal Ethics
  - Environmental ethics

These also correspond to the main areas of concerns related to the practice of biotechnology

- They are complexly interwoven in the context of biological commonality

- Bioethics provides a disciplinary framework for the whole array of moral questions and issues surrounding the life sciences concerning human beings, animals, and nature.

Early History

- History of bioethics & bioethical debates are rooted in Hippocratic writings (500 BC)
- Centred around doctor-patience relationships (beneficence / non- maleficence /confidentiality/ non exploitation of patient).
  - Early bioethics was synonymous with medical ethics; centred around the physician who made the decisions in the patient's best interest,

- The medical knowledge of the physician needed to be guided by ethical principles
- In some cultures he was also a priest who offered sacrifices

Evolution of Bioethical debates

- Issues around Nazi medical experiment
- Medical ethics in WW II
- Other unethical medical researches/ experimentation & matters related to (lack of) informed consent of participants introduced new challenges in bioethics.
    - Nuremberg trial & the Nuremberg code followed the discovery of Nazi human experimentations-
        - advent of informed consent in matters of medical experimentation
    - Information related to medical research in which subjects did not know they had been recruited emerged- early bioethics debate; the Belmont Report in US & Helsinki Declaration
    - Early sustained writings in bioethics and the influx of other disciplines into this new field resulted in rapid expansion leading to the emergence of bioethics as a distinct field
    - This was supported by the establishment of the earliest centres of bioethics

Advances in medical sciences: – ICU, life support facilities, dialysis, definition of life & death, organ transplantation etc.

- Medical decision making & ethical debate gets more intense and complex.
- Earliest medical selection committees emerged to decide who received what (dialysis, transplant or other limited resource) in parts of US.
- Life support, end of life / beginning of life debate increased the complexity of the dilemma
- Contraception /abortion debate; euthanasia / assisted suicide weighed in and religion became very important in the debate
- Economics of health care access also became important in bioethics debate
- Non medically qualified / the general public became interested & involved in making decisions that impacted medical practice, medical research and ethics.

Discovery of the double helix, advances in molecular biology and genetic engineering, advent / rapid growth in biotech raised the challenges further.

- The discovery of the code of life increased potential and power of biology
- Human genome project & its implications; stem cell research; control of life at basic or genetic level, “playing God” confidentiality and medical selections, etc.
- Genetic diagnosis and the possibility of genetic discrimination; what level of disclosure can be accepted?
- What about prenatal diagnosis and possibility of genetic selection and custom made children?
    - The ethical challenges related mostly to medical biotechnology

- Genetically modified organisms and foods; new pesticides, herbicides, species, long term consequences, loss of bio- and genetic diversity, gene pollution, transgenesis etc.
- Increased agricultural productivity, profits and patenting of life forms; big biotech industries and profit motives; subsistence agriculture and under developed nations, etc.
- Animal and environmental ethics
    - The genetic altering of foods and living products may have long term harmful consequences for animals and organism concerned, for the environment as a whole and for humans who consume or are exposed to these products-
        - suppose these potential consequences manifest over a time-scale beyond regulatory monitoring? What are the implications?
- There is a debate relating to the level of disclosure necessary both in medical and food application of this new technology

Recap: What is Ethics? (Taken from G. Tordjman (2013) Issues in Bioethics Course in Humanities, Dawson College, Canada)

Before explaining what **bioethics** is, let's look again at the term **ethics**. Ethics deals with questions of right and wrong, good or bad and our moral obligations to others as well as ourselves. Sometimes words, like morality, morals, values and others have been used as synonyms for ethics. Writers specializing in these matters make distinctions between these words but we will deal with these later.

The importance of ethics should be clear since we make ethical judgments and decisions every day. Indeed, the ability to make ethical decisions has often been considered a key difference between humans and other animals. These decisions affect the people and the world around us, though it may be all too easy to ignore this at times. That is one reason it is important to examine ethics, including our own ethics. Since our ethical choices affect others this also tells us that ethics is largely a *social* matter, dealing with how we get along with others. But besides the impact our ethics has on others, ethics is important also because it is something that is key in defining who we are as individuals. As Daniel Maguire says

'Moral values are more basic than all other values, because moral values touch, not just on what we do or experience or have, but on what we "are." It is admittedly unfortunate if a person is not gifted with the values of wealth, gracefulness, beauty, education, and aesthetic sophistication. But it is a qualitative leap beyond the merely unfortunate if a person is a murderer, a liar, or a thief. Here the failure is at the level of what a person is and has to be as a person'

In short, our ethics tells us what kind of person we are. An ethics course is thus not just about learning what others have said or written but it is about learning about our own ethics and

becoming conscious about the decisions we make and this is what makes up a big part of the kind of person we are or want to be. But this is not a course that tells you *what* to think or what is right and wrong. Instead, it tries to help you find out about *how* to think about matters of right and wrong. What is right and wrong is up to you to decide. A requirement of ethics is that you provide good reasons for your actions and beliefs and for the values you have and that you are willing to question your beliefs. This is how we become more aware of and shape who we are.

THE GROWTH OF MEDICINE & THE BIRTH OF BIOETHICS

Beginnings

One of the most common methods of constructing bioethics' history is connecting its origin to particular technological developments, controversial issues, and landmark events. As a branch of philosophy (philosophical ethics), the origin of bioethics can be traced to the beginning of western philosophy in the 6th century BC in ancient Greece. Some thinkers at that time began to try to explain health and disease by the same means. The "father of medicine" in the West, **Hippocrates** (c. 460-377 BC) was one of the earliest to approach illness and health in this way. For example, he correctly interpreted epilepsy as a result of a brain anomaly rather than as possession by demons as had previously been thought. Medicine, as a science, began at this point. Hippocrates is also widely known for the famous **Hippocratic Oath** which is one of the earliest examples of a code of ethics for the medical profession. Hippocrates seemed to understand that doctors needed not just to have knowledge about their craft but also needed to have that knowledge guided by ethical principles. After all, anyone who had the power to heal also had the power to inflict harm. Thus was born the still influential Hippocratic Oath and at the same time, the field of bioethics.

However, there was little development of bioethics beyond the Hippocratic Oath until modern science and modern medicine began to make a serious impact on the lives of people. Bioethics rose when medical science began to make a substantial difference in the life span and the quality of life of the average person because along with these benefits were unforeseen drawbacks that we are now facing.

As important also were changes that had little to do with medical science and much more with political and economic battles. The beginning of modern bioethics owes much to events that happened during **World War II** (1939-45) and the period immediately after, sometimes described as the **Cold War** (especially 1950s to 70s). These events also have less to do with medical or scientific breakthroughs and much more with history, politics and economics. The notion of bioethics is commonly understood as a generic term for three main sub-disciplines: medical ethics, animal ethics, and environmental ethics. Each sub-discipline has its own particular area of bioethics, but there is a significant overlap of many issues, ethical approaches, concepts, and moral considerations. In addition, the field of bioethics presupposes at least some basic knowledge of important life sciences given that the three main areas of concern also correspond to the main areas of concern related to the practice of biotechnology. Hence bioethics has come to be defined "as the systematic study of human

conduct in the area of life sciences and healthcare, insofar as this conduct is examined in the light of moral values and principles"

Rapid developments in the natural sciences and technology (including biotechnology) have greatly facilitated better living conditions and increased the standard of living of people worldwide. On the other hand, there are undesirable consequences, such as nuclear waste, water and air pollution, the clearing of tropical forests, and large-scale livestock farming, as well as particular innovations such as gene technology and cloning, which have caused qualms and even fears concerning the future of humankind. Lacunae in legal systems, for example, regarding abortion and euthanasia, additionally are a cause of grave concern for many people. Furthermore, moral problems which stem from a concrete situation, for example, gene-manipulated food, have given rise to heated public debates and serious public concerns with regard to safety issues in the past. There was---and still is---a need for ethical guidance which is not satisfied simply by applying traditional ethical theories to the complex and novel problems of the twenty-first century.

Bioethics is concerned with a specific area of human conduct concerning the animate (for example, human beings and animals) and inanimate (for example, stones) natural world against the background of the life sciences and deals with the various problems that arise from this complex amalgam. Furthermore, bioethics is not only an inter-disciplinary field but also multidisciplinary since bioethicists come from various disciplines, each with its own distinctive set of assumptions.

History of Bioethics

The German theologian Fritz Jahr was the first to use the German term "Bio-Ethik" (which translates as "Bio-Ethics") in 1927 and forcefully argued, both for the establishment of a new academic discipline, and for the practice of a new, more civilized, ethical approach to issues concerning human beings and the environment. Jahr famously proclaimed his bioethical imperative: "Respect every living being, in principle, as an end in itself and treat it accordingly wherever it is possible". However, the cradle of the subject of bioethics as a course is the USA and this goes hand in hand with the origin of its institutionalization. At the beginning of this complex process, bioethics was seen as more or less identical with medical ethics. Animal ethics and environmental ethics are sub-disciplines which emerged at a later date. In the beginning, the great demand for medical ethics was grounded in reaction to some negative events, such as the research experiments on human subjects committed by the Nazis and the Tuskegee Syphilis Study.

At that time, bioethics was rather driven by urgent cases ("putting out fires") and did not consider systematic problems in healthcare such as the access to quality care. However, in reaction to these horrible events, the Nuremberg Code (1947) and the Declaration of Helsinki (1964) were created in order to provide researchers and physicians with ethical guidelines. In the case of the Tuskegee Syphilis Study, and other experiments in clinical research, it is clear however, that they were performed in the full knowledge of both sets of guidelines (and hence against the basic and most important idea of individual informed consent).

In particular, the idea of individual informed consent is due to the Prussian and German bureaucratic regulations of 1900/01 that appeal to the case of Dr. Albert Neisser in 1896 who publicly announced his concern about the possible dangers to the experimental subjects whom he vaccinated with an experimental immunizing serum. Additionally, the investigation of the death of 75 German children caused by the use of experimental tuberculosis vaccines in 1931 revealed that the mandatory informed consent was not obtained. The informed consent doctrine was thus originally a regulatory innovation created by Prussian bureaucrats; it was not an artefact of American legal or philosophical culture but of German bureaucratic culture. It was a German solution to problems created by the advances of German biomedical science.

Against this background the Institute of Society, Ethics, and the Life Sciences, later known as the Hastings Center, and the Joseph and Rose Kennedy Center for the Study of Human Reproduction and Bioethics were created in 1969 and 1971 respectively. They were the first two (academic) institutions to conduct research in medical ethics

Also, after **World War II** (1939-1945), more scientific advances had paved the way to modern medicine. Most important were the development of **antibiotics** such as **penicillin**, a major step in managing and eradicating bacterial infections like pneumonia, syphilis, gonorrhea, diphtheria, scarlet fever and tuberculosis. One disease, **smallpox**, which had killed millions of people throughout history, has been completely eradicated. A continuation of large-scale inoculation programs for diseases like polio have also all but eliminated many of the dreaded diseases of the past – at least in the rich countries.

In the 1960s the adoption of all kinds of life-saving machinery such as the **respirator**, the **kidney dialysis machine**, and, more recently, the adoption of various kinds of diagnostic scanning tools from the **CT scanner** to **ultrasound** to the latest computer-assisted **MRI** (Magnetic Resonance Imaging) systems have also made a profound impact on diagnosis and treatment of illness and disease. **Organ transplantation** and other techniques have prolonged the lives of many who would otherwise have died. Also important has been the continued development of **drugs** of all sorts. These have allowed people to manage illness, cope with pain, and otherwise lead more productive lives than they otherwise would. Again, however, most of the benefits of this discovery have gone to rich people or to people in the rich countries of the world. The ethical code that had traditionally supported the medical profession had to confront new questions, raised directly as a result of the extraordinary progress being made in the biomedical sciences: what is the definition of the death of a man? What are the limits for the use of resuscitation and for sustaining life? What are the consequences of organ transplants? What are the implications for interventions on new-born life and on the human genome? As a response to these questions, philosophers and theologians, jurists and sociologists, together with doctors and scientists, began to rethink and revise the old standards. Severe problems concerning the just distribution of health care resources emerged, for example, in access to kidney dialysis and intensive care units due to the consequences of scarcity, which caused much debate (concerning problems of resource allocation, for instance).Governments therefore instituted commissions to elaborate and recommend guide-lines and the tribunals began to hear and formulate ethical arguments in

line with their sentences encouraging legislators to approve laws regarding these matters. This, therefore, began the "bioethical movement" that brought about a drastic and profound revision of the centuries-old professional ethics that had governed the behaviour of doctors and their relationships with patients.

The Biotechnology Revolution

Most recently, a new wave of scientific advance in biology, genetics, and biological technology (**biotechnology)** has resulted in what has been called the **biological revolution or genetic revolution**. The manipulating of the genes of animals, plants and microorganisms, called **genetic engineering** or **recombinant DNA technology**, is at the heart of this revolution. Already this is promising and achieving new possibilities: genetic testing, prenatal diagnosis, gene therapy and more.

But the power of genetic manipulation extends far beyond medicine and human health or disease. The biotechnology industry seeks to multiply the production of all types of animals and crops and increase the milk, meat and dairy from the animals we raise through **genetically modified organisms** (**GMOs**) and **genetically modified foods** (**GMFs**). New kinds of pesticides and herbicides and even new *species* have been created in the continued effort to improve productivity and increase profits. **Cloning** of animals, including humans, is only one example of the continuing spectacular advance not just in our ability to control disease but to control life itself – all life – at the most basic, genetic level.

The **genetic altering of foods and living products** may have long term harmful consequences for the animals and organisms concerned, for the environment as a whole and for humans who consume or are exposed to these products. At the same time, the commercial development of genetic "products" has led to the **patenting** of certain genetic lines and even whole organisms in the United States, raising the issue of whether owning the rights to living things is morally acceptable. The **diagnosis of genetic diseases** in adults presents us with the painful dilemma of whether we *should* inform people that they have these conditions, especially when no effective treatment exists. Widespread knowledge of our genetic makeup may increase the likelihood of a new form of **genetic discrimination** where employers, for example, refuse to hire us because of presumed genetic vulnerabilities to certain diseases and presumed genetic suitability for certain kinds of jobs. Diagnosis of the genetic conditions of the unborn (**prenatal diagnosis**) raises new questions about **selective abortion**, **sex-selection**, disability and the value or quality of life. Stem cell and fetal tissue research have also poured new fuel on the age-old abortion debate. The **genetic engineering** techniques used in biotechnology may also soon allow us to **alter the genetic makeup of human beings**. The same gene therapy techniques scientists use to replace genes responsible for genetic diseases by normally functioning ones may allow us to genetically "custom make" our children to have features and traits we consider desirable. This "playing of God" as some people call it, or the replacing of nature by human will might be one of the most serious and disturbing long term consequences of the new genetic technology. In this case, we are increasingly forced to ask what makes us human and what is freedom if someone else is able to design us as he/she desires? It would appear that for every advance there are serious harmful or potentially harmful "side effects", to say the least. This should make clear why ethical knowledge and debate are so urgently needed today.

Bioethics Movement

The United States of America was the cradle for the birth of this movement where bioethics moved initially from a situation of alarm to a state of deep concern with respect to scientific progress and of a society that paradoxically seemed to undermine the capacity for the survival of humankind. The discoveries in those years, and in those immediately following, announced in the field of genetic engineering the frightening possibility to create biological weapons and to alter the same statute of the diverse forms of life, of species and individuals, favouring a movement of "catastrophic" ideas and fears.

The idea that animals have a moral status and should be protected is based in modern moral philosophy, most notably utilitarianism, on the one hand, and the animal rights movement in the eighteenth and nineteenth centuries in Europe. On the other hand, Aristotle, Thomas Aquinas and Kant had a lasting (negative) effect on the way people thought about animals and their moral status. According to Aristotle (400 B.C.E.), animals do not have a moral status and hence human beings cannot treat them unjustly. According to Thomas Aquinas (thirteenth century), who shaped the Christian view on the moral status of animals for several hundred years, animals have no moral status and human beings are allowed to use them for their own comfort since everything is made by God and subjected to the rule of human beings. Kant (eighteenth century) famously argued that animals have no moral status but one should treat them appropriately since cruelty against animals might have a negative effect on our behaviour towards our fellow humans, that is, the brutalization of human behaviour.

The idea of protecting nature/the environment is a contemporary thought that particularly evolved by virtue of public concern about the rapid technological developments in the twentieth century and the extreme dangers to the whole globe posed by these developments, for example, nuclear waste, water and air pollution, the clearing of tropical forests, and global warming. Clearly, the environment is one of the key issues of our time and is another example of how technological change brings with it unforeseen problems and controversies. The point is, however, that a concern for bioethical issues is much older than the name of the phenomenon itself and the academic discipline. As we can see, almost all medical and technological breakthrough come with unforeseen and unintended, sometimes harmful effects. Today we also need to include the harmful effect not just on people but on the environment and on other animals and plants.

Ethical Principles in Bioethics

- Autonomy
- Rights
- Justice
- Equality
- Beneficence
- Confidentiality
- Non-maleficence
- Respect for human life
- Accountability

Irrespective of the ethical theory used as basis for addressing bioethical dilemmas, these principles will play key roles in the decisions that will be made.

Brief Explanation of some bioethics principles
(Taken from D.R.J. Macer (1995) Biotechnology and Bioethics in *Modern Biotechnology: Legal, Economic and Social Dimensions, Biotechnology,* Volume 12, ed. D. Brauer (Weinheim, Germany: VCH, 1995))

Autonomy
All people are different. This is easy to see, and is **also true of the choices that we make**. We may decide to play tennis, or golf, or chess, read a book, or watch television. These are all personal choices. In a democratic society we recognise that we have a duty to let people make their own choices. Above the challenges of new technologies, and increasing knowledge, the challenge of **respecting people as equal persons with their own set of values** is a challenge for all. This is also expressed in the language of rights, by **recognising the right of individuals to make choices**. This right to make choices extends to what to eat, right to know what is on offer etc.

Rights
Legal rights are claims that would be currently backed by the law if the case went to court, while human rights are critical to maintaining human dignity but may not have yet attained legal recognition. The recognition of human rights has changed the situation in many countries, and many countries in the world have signed the U.N. Declaration of Human Rights, or one of the regional versions of this. This can be applied to many situations, for example, we all have a right to be involved in decisions about our country, the freedom of religion, or speech, to raise a family, to share in the benefits arising from scientific advances, and a right to a reasonable future. Respect for personal rights should change the nature of relationships between people in power and people without power from being characterised by authoritarianism or paternalism to becoming a partnership.
Ethics is not the same as law. Ethics is a higher pursuit, doing more than the law requires. The law is needed to protect people and to set a minimum standard, but you cannot determine good moral behaviour by settling cases in a court of law. The solution is to have more careful and moral physicians, companies, and politicians, and the replacement of monetary balance sheets by ethical values, as the primary motive of decision-making.

Beneficence
One of the underlying philosophical ideas of society is to pursue progress. The most cited justification for this is the pursuit of improved medicines and health. It has often been assumed that it is better to attempt to do good than to try not to do harm. A failure to attempt to do good, working for people's best interests is taken to be a sin of omission. Beneficence is the impetus for further research into ways of improving health and agriculture, and for protecting the environment. Beneficence supports the concept of experimentation, if it is performed to lead to possible benefits.
The term beneficence suggests more than actions of mercy, for which charity would be a better term. The principle of beneficence asserts an obligation to help others further their important and legitimate interests. It means that if you see someone drowning, providing you can swim, you have to try to help them by jumping in the water with them. It also includes the weighing of risks, to avoid doing harm. Governments have a duty to offer their citizens the opportunity to use new technology, providing it does not violate other fundamental ethical principles. Just what the definition of fundamental ethical principles is may be culturally and

religiously dependent, especially in the way that they are balanced when opposing principles conflict. Although different cultures vary, they all share some concept of beneficence and do no harm.
Beneficence also asserts an obligation upon those who possess life-saving technology, in medicine or agriculture, to share their technology with others who need it. This is relevant to biotech companies also, who may hold patent rights on particular processes, beneficence would assert that they must share it with others, even if they cannot pay for it. This may mean that companies share developments with developing countries, or give new drugs to individuals too poor to purchase them.

Do No Harm (non-maleficence)

The laws of society generally attempt to penalise people who do harm, even if the motive was to do good. There needs to be a balance between these two principles and it is very relevant to areas of science and technology, where we can expect both benefits and risks. Importantly, we must balance risks versus benefits of different and often alternative technologies then apply these comparisons to our own behaviour, as well as in determining government policy.
Do no harm is a very broad term, but is the basis for the principles of justice and confidentiality, and philantropy. It can also be expressed as respect for human life and integrity. This feature is found in the Hippocratic tradition and all other traditions of medical and general ethics. To do no harm is expressed more at an individual level, whereas justice is the expression of this concept at a societal level. Do no harm has been called the principle of non-maleficence.
Biotechnology and genetic engineering are providing many benefits, but there are also many risks. It is also unclear who will really benefit the most. It is important to see these benefits and risks in an international way because the world is becoming smaller and ever more interdependent. All people of the world can benefit if it is used well, through medicines, and more environmentally sustainable agriculture.
However, biotechnological inventions that allow industrialised countries to become self-sufficient in many products will change the international trade balances and prosperity of people in developing and industrialised countries. If developing countries cannot export products because of product substitution the result may be political instability and war. This may in the end become the biggest risk. For example, the use of enzymic conversion of corn starch into high fructose corn syrup causes serious damage to the economies of sugar exporting nations, and may already have caused political instability there. We need to remember national and international issues.
Although we will continue to enjoy the many benefits to humanity, and we may hope for environmental benefits, the price of the new technology is that it may make us think about our decisions more than in the past. International food safety and environmental standards should be speedily developed to ensure that all people of the world share their protection, and no country becomes a testing ground for new applications.

Justice

Those who claim that individual autonomy comes above societal interests need to remember that the reason for protecting society is because it involves many human lives, which must all be respected. Individual freedom is limited by respect for the autonomy of all other individuals in society and the world. People's well-being should be promoted, and their values and choices respected, but equally, which places limits on the pursuit of individual autonomy. We also need to consider interests of future generations which places limits on this generation's autonomy. We also need to apply this principle globally, as no single

country should pursue policies which harm people of any country. The key principle arising from the high value of human life is respect for autonomy of each individual human being. This means they should have the freedom to decide major issues regarding their life, and is behind the idea of human rights. This idea is found in many religions also. Part of autonomy is some freedom to decide what to do, as long as it does not harm others. Internationally, the area of biotechnology patent policy should be examined in light of public opinion and the principle of justice. Shared genetic resources should not be able to be owned by any one individual or company. At the same time, some patent protection for specific applications involving biotechnology need to be protected to encourage further research, and to make the results of such research immediately open for further scientific research.

Confidentiality

The emphasis on confidentiality is very important. Personal information should be private. There may be some exceptions when criminal activity is involved or when third parties are at direct risk of avoidable harm. It is very difficult to develop good criteria for exceptions, and they will remain rare. We must be careful when using computer databanks that contain personal information, and if they cannot be kept confidential, the information should not be entered to such a bank.

A feature of the ethical use of new genetics is the privacy of genetic information. This is one of the residual features of the existing medical tradition that needs to be reinforced. It is not only because of respect for people's autonomy, but it is also needed to retain trust with people. If we break a person's confidences, then we cannot be trusted. If medical insurance companies try to take only low risk clients by pre-screening the applicants, there should be the right to refuse such questions. This is the only way to ensure proper and just health care. We need to protect individuals from discrimination that may come in an imperfect world, one that does not hold justice as its pinnacle.

Animal Rights

These above principles apply to human interactions with other humans. However, we also interact with animals, and the environment. The moral status of animals, and decisions about whether it is ethical for humans to use them, depends on several key internal attributes of animals; the ability to think, the ability to be aware of family members, the ability to feel pain (at different levels), and the state of being alive. All will recognise, inflicting pain is bad so if we do use animals we should avoid pain. If we believe that we evolved from animals we should think that some of the attributes that we believe humans have, which confer moral value on humans, may also be present in some animals. Although we cannot draw black and white lines, we could say that because some primates or whales and dolphins appear to possess similar brain features, similar family behaviour and grief over the loss of family members to humans, they possess higher moral status than animals that do not exhibit these. Therefore, if we can achieve the same end by using animals that are more "primitive" than these, such as other mammals, or animals more primitive than mammals, then we should use the animals at the lowest evolutionary level suitable for such an experiment, or for food production (which is by far the greatest use of animals). If we take this line of reasoning further, we conclude that we should use animal cells rather than whole animals, or use plants or microorganisms for experiments, or for testing the safety of food.

Animals are being used for genetic engineering, for use as models of human disease, for use in the production of useful substances such as proteins for medical use, and in the more traditional uses in agriculture. Some of these uses, such as the production of mutations in strains of animal to study human disease will have human benefit, but are more ethically challenging because some of these strains may feel pain.

Environmental Ethics

Humans also have interactions with the environment, and in fact depend upon the health of the environment for life. The easiest way to argue for the protection of the environment is to appeal to the human dependence upon it. There are also human benefits that come from products we find in nature; from a variety of species we obtain food, clothing, housing, fuel and medicine. The variety of uses also supports the preservation of the diversity of living organisms, biodiversity. The ecosystem is delicately balanced, and the danger of introducing new organisms into the environment if that may upset this balance is another key issue raised by genetic engineering. However, we have been using agricultural selection for thousands of years, so the introduction and selection of improved and useful microorganisms, plants and animals is nothing new, and what we need is to learn from mistakes of the past.

The above arguments should convince people of the value of the environment, and that is a first stage. However, it appeals to our sense of values based on human utility. There is a further way to argue for the protection of nature and the environment, and it is a more worthy paradigm. It is that nature has value for itself because, it is there. We should not damage other species, unless it is absolutely necessary for the survival of human beings (not the luxury of human life). Nature has life, thus it has some value. Another paradigm for looking at the world is a religious view, that God made the world so the world has value, and we are stewards of the planet, not owners. This paradigm can make people live in a better way than if they look at the world only with the paradigm of human benefit.

There needs to be examination of the view of nature that different people have, so that we can find what the commonly acceptable limits to modification of nature, plant and animal varieties, and human beings are. In the modern world any new science can easily spread, so researchers are accountable to all peoples of the world. There will be future possible applications of technology which are against "common morality", yet there is little research on what is acceptable. We need to know what these perceived limits of changing nature are, before we grossly change the characters of individual organisms, or make irreversible changes to the ecosystem and human society.

Microorganisms are generally placed at the lowest end of the "scale" of ethical status, because the only internal character they have is the state of being alive. External factors from a human aesthetic viewpoint mean that the only argument usually applied to them is human utility. Biodiversity may have some value in itself, though it is yet to be defined in non-religious terms. If we want to preserve biodiversity, it is essential that we separate parts of nature on land and ocean as nature reserves or parks, away from the parts of nature which are agricultural areas. However, while we separate these areas physically we should not separate them psychologically as areas which we can abuse and areas which we protect. This applies both in terms of sustainable environmental protection and animal rights. In fact, agricultural biodiversity is of direct human utility, and we should attempt to stop its continued loss.

Ethical Theories as applied to Bioethics

(Taken from “Bioethics- Internet Encyclopaedia of Ethics”)

Deontological Approaches

Deontological approaches such as provided by Kant (1785) are commonly characterized by applying usually strict moral rules or norms to concrete cases. Religious approaches, such as those of the Catholic Church, and non-religious deontological approaches, such as Kantian-oriented theories, are prime examples of applying moral rules. In Kantian-oriented approaches, -at least, in the original version---moral status is assigned according to “rationality” and not according to “membership of the human species”. Other Neo-Kantian

deontological approaches, however, might emphasize "human dignity" and hence run into serious troubles with regard to the objection of speciesism as well. In other words, there is a fundamental disagreement inherent in the notion of human dignity---roughly, the idea that there is something special about human beings---and the ascription of moral status to non-human nature such as animals and plants.

Kantian-oriented deontological approaches (or Kantianism) generally adhere to the basic Kantian ideas of respect for persons and human dignity; both central ideas are rooted in the human being's capacity to act autonomously. Kantianism has been adopted in order to provide a justification for strict truth telling in medical contexts, bedside rationing, and medical experiments. This development can be seen as a counter-movement against previous malpractice. The former practice consisted in not telling the truth to the patient in order either not to cause additional harm or not to undermine the goals of the medical experiments (for example, the Tuskegee Syphilis Study). In the late 20th century, this has changed by virtue of acknowledging the patient's right to be told the truth about his or her health condition. Yhis also applies to the patient's involvement in research studies - including research with placebos- in order to enable the patient to make adequate autonomous decisions (individual informed consent). The second formula of Kant's Categorical Imperative---"Act in such a way that you treat humanity, whether in your own person or in the person of any other, never merely as a means to an end, but always at the same time as an end" -has been successfully used in different medical contexts in order to avoid abuses. In particular, it is nowadays used to avoid abuses in research experiments on human subjects. Additionally, deontological approaches have been used in the fields of animal ethics and environmental ethics

Genuine religious approaches are problematic by virtue of their strong commitment to religious presuppositions such as the existence of God as the ultimate source of morality or the absolute sacredness of the human life. In modern---or rather secular---societies, this line of reasoning cannot be taken as a universal starting point to justify moral norms for religious and non-religious people alike in medical contexts on issues such as abortion, euthanasia, the use of contraceptives, and genetic enhancement. Despite the reasonableness of Kantian-oriented deontological approaches in cases concerning truth telling and in the context of medical exploitation, they particularly suffer from using moral norms too general and abstract to be applied without difficulty or stiltedness to concrete cases. The upshot is that deontological approaches are less effective at providing adequate guidance since their application is too complex and possibly misleading.

Consequentialism (Mill's Utilitarianism)

One of the most prominent and influential ways of ethical reasoning and decision making in the field of bioethics is based on utilitarianism. In the late twentieth century, utilitarian approaches were so influential that many people outside academia believed that all bioethicists were utilitarians. Utilitarianism, in fact, contains a wide range of different approaches, but one can distinguish four important core elements that all utilitarian approaches have in common:

1. *The consequence principle*: The consequences of a given action are the measure of its moral quality.

2. *The utility principle*: The moral rightness and wrongness of actions are determined by the greatest possible utility for the greatest possible number of all sentient beings.
3. *The hedonistic principle*: The consequences of a given action are evaluated with reference to a particular value. This particular prime value can be as follows: (1) Promoting pleasure, or (2) avoiding pain, or (3) satisfaction of interests or considered preferences, or (4) satisfaction of some objective criteria of well-being, and so forth.
4. *The universal principle*: Maximize the total utility for all sentient beings affected.

Utilitarian approaches in bioethics have been less concerned with public welfare than other vital aspects, such as: (1) debunking the traditional religious views on the sacredness of human beings, the prohibition of abortion, infanticide, and euthanasia; (2) stressing the importance of non-rational sentient animals (animal ethics) and the preservation of nature (environmental ethics) against anthropocentric approaches such as Kantianism and religious approaches; (3) arguing against the use of human rights and human dignity in bioethical discourses; (4) maximizing the patient's well-being or best interests in medicine. In this context, utilitarians claim that one should focus on the patient avoiding pain and suffering, and therefore one should, for example, allow terminally ill patients to obtain physician-assisted suicide. Furthermore, the religious idea that human life is sacred and hence must be protected from the moment of conception is rejected by utilitarians who believe that religious claims are unsubstantiated and incompatible with the requirements of a modern, secular nation-state (for example, research on human embryos and genetic enhancement should be made possible). In addition, abortion and infanticide in cases where the baby has a severe disability should be possible depending on the circumstances of the particular case and by appealing to the idea of personhood. For instance, one should not be allowed to kill a human being or sentient animal if one can detect in that being rationality and self-consciousness---the core elements of personhood according. To treat sentient animals with interests differently than human beings is speciesism which is comparable to sexism and racism and must be avoided. Moral judgements, according to utilitarians, should always be impartial and universal. Additionally human beings must consider the equal interests of human beings and animals alike.

The general idea to always maximize the patient's well-being according to a rather simplistic idea of calculating and comparing the pleasures and pains of all affected persons seems questionable to many people since they do not think that the outcome of these calculations necessarily leads to morally right or wrong actions. Furthermore, the claim that the killing of an innocent being in the case of a fetus with a (severe) disability might be the best possible outcome in some situations---by adhering to "the good life" doctrine---seems to undermine some important values of living together (compassion, care, responsibility for the weak, justice). In addition, the idea that minority groups such as people with (severe) disabilities and patients in a permanent vegetative state can be legitimately sacrificed in some cases has led to a rather bad reputation for utilitarian approaches. Utilitarians are also at odds with approaches in bioethics that appeal to human dignity and human rights.

Virtue Ethics

Virtue ethics or moral ethics has deeply influenced the ethical reasoning and decision making in the field of bioethics, particularly in medical ethics. The general idea of virtue ethical

approaches in bioethics is that one should act in accordance with what the virtuous agent would have chosen. In more detail, an action is morally right if it is done by adhering to the ethical virtues in order to promote human flourishing and well-being; the action is morally good if the person in question acts on the basis of the right motive as well as his or her action is based on a firm and good character or disposition. That means an action that is morally right (for instance, to help the needy) but performed according to the wrong motive (such as to gain honour and reputation) is not morally good. The right action and the right motive must both come together in virtue ethics.

Generally speaking, virtue ethical approaches put a lot of weight on the particular agent. For example, the virtuous physician in medical ethics should not only be a well trained and conscientious professional---one who shows compassion towards his or her patients, is helpful and honest, and keeps his or her promises---but also should be strongly inclined to promote the patient's well-being even at his or her own expense. The virtuous agent in bioethics knows how to deal with complex cases, shows a greater sensitivity than proponents of deontological and utilitarian approaches, and acts virtuously not only by complying with moral norms but also "going the extra mile" to perform supererogatory actions. Virtue ethical approaches have been applied in medical ethics as well as in the field of environmental and animal ethics.

African Moral Theology

This evolving field of ethical discuss may be taken on case specific bases based on the environment of application.

Examples may be drawn from traditional agriculture and traditional medicine to engage with students on how African moral theology can be deployed to solve moral dilemmas that arise from the applications of biotechnology in securing African food security.

Module 5 Unit 4: Ethical issues in the uptake of Biotechnology

Lectures 4-7 (1 hour for each case study): **Case Studies 1-4: Uptake of Biotechnology in 1. America (1h); 2. Europe (1h); 3. Asia (1h) and 4. Africa (1h)**

- Evolution of agro-biotechnology in America, Europe, Asia and Africa
- Uptake of agro-biotechnology in America, Europe, Asia and Africa and the impact of regulatory framework
- State of agro-biotechnology in America, Europe, Asia and Africa

Learning Outcomes

Students are expected to appreciate the evolution of biotechnology related to food production in: 1). United States of America. 2). Europe; 3). Asia; and 4). Africa; and how the regulatory framework has influenced uptake of the technology by farmers and consumers in these different environments.

The same policy classifications apply and the Table developed by Paarlberg (2000) should be used interrogate the classifications and their impact on adoption by each continent/ country

The foundation for these lectures is:

Paarlberg, R.L. (2000) Governing the GM Crop Revolution: Policy Choices for Developing Countries; *Food, Agriculture, and the Environment Discussion Paper 33:* International Food Pol icy Research Institute; 2033 K Street, N.W. Washing ton, D.C. 20006 U.S.A.

Students are encouraged to download and read this material in full (44 pages)

UPTAKE OF BIOTECHNOLOGY AROUND THEW WORLD

The material presented here represents the bedrock of the lecture for lectures 4-7. The process is discussed in detail in the lecture and presented in grid form in the power-point material.

The genetic modification (GM) of plants and animals has been the foundation of all modern agriculture. For 10,000 years human societies have modified natural species through crude practices such as seed se lection and controlled breeding. The power of these practices was enhanced dramatically in the 20th century by breakthroughs in basic genetic science, leading eventually to modern hybrid seed varieties for important food crops such as maize and, by mid- century, to high-yielding "Green Revolution" seed varieties for wheat and rice.

In 1953 science moved toward a deeper understanding of the molecular foundation of plant and animal genetics with the discovery of the double helical structure of the DNA molecules that are the critical constituents of genes. The modification of species could now be undertaken at the molecular level through engineered gene transfers. In 1973 scientists began engineering recombination of DNA molecules by moving specific genes carrying desired traits from a source organism into the DNA of a living target organism. That genetic trans formation technique which has been called genetic engineering but is now commonly known

simply as GM—seemed to promise not only greater range and speed for genetic modification pro cesses but also greater control over the outcome.

Commercial applications of GM techniques in agriculture were nonetheless expensive to develop and slow to be commercialized. The modern commercial GM crop revolution did not begin until 1995–96. At that point a number of new GM corn, cotton, and soy bean varieties, engineered to resist pests and viruses or to tolerate broad- spectrum herbicides, won approval from regulators and were released commercially in a number of countries, led by the United States. In some countries the new crops spread quickly. By 1999 roughly half the U.S. soy bean crop and one- third of the U.S. corn crop was grown from GM seed. Farmers were attracted to these new varieties because they required less management or till age and less pesticide or herbicide spraying.

The planting of GM crops spread rapidly between 1996 and 1999, but only in three countries: Argentina, Canada, and the United States. Together, these three countries accounted for 99 per cent of all GM crop acre age in 1999 (James 2000). One reason for this confinement of GM crop acre age was commercial: the private companies that developed GM crops initially de -signed them for use by wealthier farmers in temperate- zone countries with the purchasing power and commercial seed- buying habits to support the new products. Poor subsistence farmers in tropical countries were less at tractive as commercial customers, so developing- country subsistence crops such as cassava, millet, and cowpeas were not among the first crops trans -formed with GM techniques.

Conscious policy choice has now become a second reason for the restricted spread of GM crops. While some governments have taken a permissive regulatory attitude toward new GM crop technologies, other governments have taken a more cautious view. The U.S. government led the way with a per missive approach, screening GM crop technologies for food safety and biosafety risks using essentially the same methods employed for conventional crops, then al lowing private markets for GM crops to operate without any new labelling or segregation restrictions. Argentina and Canada followed a similar pol icy path. Governments in Europe and Japan initially did the same but then quickly became more cautious as anxieties or opposition grew among domestic consumers, environmental organizations, and anti-globalization advocacy groups. In Europe, where "green" parties are strong and where a "mad cow dis ease" crisis in 1996 sensitized the media to food safety issues, the GM crop revolution en countered strong social resistance.

Responding to demands from consumers, green party leaders, organic farmers, environmental organizations, and international seed company critics, governments in Europe began imposing separate labelling requirements on GM foods in 1997. In 1998 the European Union (EU) then blocked the registration of any new varieties of GM crops. This had the effect of halting the import into the EU of any bulk commodities from Argentina, Canada, or the United States that might contain GM varieties unregistered in Europe. Private food companies and retailers in Europe, hoping to stay ahead of the back lash against GM foods and crops, began voluntarily removing GM products from the shelf or reducing their use of GM ingredients.

European governments and food companies explained they were taking these measures on a "precautionary" basis. They had no scientific evidence that any GM foods or crops on the market were any less safe for human consumption or for the environment than the corresponding conventional foods and crops. Yet the novelty of the GM pro cess seemed to

suggest that conventional food safety and biosafety screening procedures were no longer adequate for judging possible risks. Pending greater certainty, governments in Europe began to block new applications of the technology and to re quire that consumers be informed when purchasing foods with GM content. Elements of this more cautious European pol icy approach to GM crops and foods spread to Japan and to the other industrial countries of East Asia and the Pacific in 1999 and 2000.

These divergent policies toward GM technologies in rich countries have now created a complicated problem of policy choice in the developing world. Should governments in the developing world follow the more per missive U.S. approach to ward GM crop technologies or the more pre cautionary EU approach? Developing- country officials have come under growing pressure from various donor agencies, international organizations, philanthropic foundations, private business firms, and non-governmental organizations (NGOs) to adopt either one set of polices or the other, to fall in line behind either Europe or the United States. The separate and distinct interests that some developing countries have in GM crop technologies risk being obscured in the pro cess.

For example, poor tropical countries face a stronger agricultural production imperative than either Europe or the United States, suggesting that GM crops could eventually be of higher value to them, compared with some rich countries. Yet at the same time these developing countries tend to have a weaker scientific, technical, and regulatory capacity within their own borders, which could make the safe development and use of GM crops more difficult for their scientists and farmers. The private industry–driven U.S. approach may not be well suited to developing- country circumstances because of natural tensions between the commercial interests and property rights of private international firms on the one hand and the meagre financial resources and distinct technological needs of tropical- country farmers on the other. Yet the European approach may be equally in appropriate, given that so many farmers and consumers in poor countries are not yet as wealthy and well fed as Europeans. In addition, farmers in most poor countries face rural environmental protection challenges quite distinct from those caused or faced by agriculture in Europe or other rich countries.

Following is an analytic frame work for classifying some of the policy choices developing countries must now make with regard to GM crops and foods. Five policy choice settings are germane: (1) intellectual property rights (IPR), (2) biosafety, (3) food safety and consumer choice, (4) trade, and (5) public research investment. In some emerging economies some biotech policies are actually more cautious than those adopted in Europe. Farmers in most European countries may legally plant at least some GM crops if they wish to do so, and imports of some GM crops are permitted. Yet, as of late 2000, authorities in most emerging economies had not yet approved commercial planting of any GM crops or the routine commercial importation of GM commodities. This degree of caution is surprising, given the conspicuous unmet food production needs in some of these countries. The extreme caution is also surprising given the prevalence in some of these countries of precisely the crop- pest and crop- disease problems that GM crops have been designed to address. Also puzzling is the fact that all such countries have slowed the planting of GM crops primarily in the name of biological safety, which has not otherwise been a high policy priority. However, within the list of countries examined in the lectures, it is easy to discern how policy choices have enhanced or impeded the adoption of biotechnology in the agriculture of different developing and developed nations.

A major challenge and learning of the following four (4) lectures of 4 hours is therefore for the students to be able to explain the emergence of highly precautionary biosafety policies toward GM crops in some developing countries but not in others. It will be nice for the students to be able to build an understanding of how relationship between some Africa and Asian developing countries with Europe has encouraged the emergence of the precautionary principles (perhaps also to contrast this with how the relation between Philippines and the US has encourages permissive regulations and so enhanced adoption).

Classifying Policies towards GM Crops and Foods

Powerful new technologies require new policy choices. This section suggests one method of classifying the most important choices governments in the developing world must make regarding GM crops and foods. This classification scheme will then make it possible to examine and compare actual choices that have been made by a number of governments (particularly in the developing world) in the matter of governance of biotechnology goods and services.

Several ways of classifying policy choices regarding GM crops and foods come to mind: which institutions make these choices, what policy processes (democratic or otherwise) are used, and who in society benefits. This lecture attempts to classifies policy choices according to a more fundamental question: will they tend to promote use of the new technology or prevent its use? From among the gradients between promotion and prevention, four overall policy postures emerge. Policies that accelerate the spread of GM crop and food technologies within the borders of a nation can be termed "promotional." Policies that are neutral toward the new technology, in tending neither to speed nor to slow its spread, will herein be called "permissive." Policies intended to slow the spread of GM crops and foods for various reasons will be called "precautionary." Finally, policies that tend to block or ban entirely the spread of this new technology will be called "preventive." Governments can choose to be promotional, permissive, precautionary, or preventive toward GM crops in several distinct policy venues. Five important venues dominate:

- intellectual property rights (IPR) policy;
- biosafety policy;
- trade policy;
- food safety and consumer choice policy; and
- public research policy

In each of these settings, a separate set of choices regarding GM crops and foods will eventually have to be made.

Intellectual Property Rights Policy

During the Green Revolution of the 1960s and 1970s, governments in the developing world did not feel compelled to provide private companies or private plant breeders with exclusive intellectual property rights to the sale or use of new crop technologies. The new high-yielding crop varieties then being offered to developing-country farmers had been developed by breeders working for philanthropic or public research institutions. The new seeds were not developed and sold by private companies; instead they were given away through international assistance programs, distributed by non-profit NGOs, or sold at subsidized prices by government corporations.

So far in the GM crop revolution, it is private companies that have taken the lead. When public funding for international agricultural research faltered in the 1980s, the initiative in developing most new GM crops fell to private seed and biotechnology companies (James

2000; Enriquez and Goldberg 2000). These companies do not normally behave like public sector extension services. To recover their expensive private investments in the development of GM seeds, they seek exclusive rights to sell or to license the sale of those seeds to farmers.

Given the lead role of the private sector, developing countries wishing to promote GM crops might consider, at one extreme, a policy of offering the same generous IPR protections currently provided under U.S. patent and trade mark laws. Advocates of this kind of patent protection say it is one reason U.S.-based companies have become world leaders in the development of commercially applicable GM crop inventions.

A slightly less promotional option would be to extend to companies and GM crop developers the somewhat weaker IPR protection provided under the International Union for the Protection of New Varieties of Plants (UPOV). This "plant breeders' rights" approach is favoured over patent protection by most governments in Europe. UPOV strikes an important balance between the rights of plant breeders to capture commercial benefits from innovation and the rights of those same breeders to use protected genetic resources as an initial source of variation in the breeding process. Early forms of the UPOV convention also sought to protect the traditional privilege of farmers to replicate seeds of protected varieties for replanting on their own farms.

The most recent (1991) version of UPOV is the strongest, and nations following this approach will be considered here to have a permissive IPR policy toward GM crops. UPOV 1991 gives breeders IPR protection for 20–25 years, and prior authorization from the holder of these rights is necessary for any production, commercial marketing, offering in sale, or marketing of propagating material of the protected variety. The breeder earns royalty payments for the protected variety, and any one in fringing on those rights may be prosecuted. At the same time, breeders themselves may use protected varieties as an initial source of variation for the creation of new varieties and then market those *new* varieties without authorization from the original breeder. UPOV 1991 permits member states to protect plant varieties with patents as well as plant breeders' rights (PBR), and the United States follows this "double protection" option, but most European countries expressly forbid patenting of plant varieties and operate under UPOV only.

A weaker but coexisting version of the UPOV Convention dating back to 1978 will be classified here as a precautionary IPR policy toward GM crops. Under UPOV 1978, the balance was tilted less toward incentives to innovate or invest in new technologies and more toward options for poor farmers to use technologies that already existed. UPOV 1978 implicitly protected the privilege of farmers to use protected plant varieties for propagation purposes on their own holdings, the so called "farmers' privilege." This relatively weak UPOV 1978 standard is nonetheless sufficient to meet the minimum PBRs required under the trade-related intellectual property rights (TRIPS) agreement of the World Trade Organization (WTO), an international agreement that became binding for many developing countries beginning in January 2000.

At a preventive extreme, developing- country governments might decide to offer no IPR guarantees at all to private companies or commercial breeders for newly created varieties of plants or animals. Blocking the spread of GM crop technologies would not have to be the primary motive for taking this preventive IPR policy approach, but the preventive result could be the same.

Biosafety Policy

As indicated in Table a second policy venue in which developing- country governments must make choices regarding GM crops is the area of biological safety, or biosafety. A number of known hazards to the biological environment must be considered whenever a new plant variety (GM or otherwise) is introduced into a farming ecosystem. These include harmful competition with or direct damage to desirable species, unwanted gene flow (including transgene flow) into close relative species, unwanted resistance to herbicides among weeds or unwanted resistance to insecticides among pests, the creation of new strains of viral pathogens, and undesired losses in biodiversity. Environmental adovcates have worried that the risks of such biosafety hazards from novel GM crops might be greater than from conventional crops.

When choosing a biosafety policy toward GM crops, developing countries can again be promotional, permissive, precautionary, or preventive. Governments wishing to be fully promotional might either impose no biosafety screening at all for new GM crops or give routine approval to any new crop approved else-where. Commercial release of new GM seeds into the farming environment could then proceed as soon as the transgenic seeds were bred for the agronomic traits (such as color, yield, or cooking properties) desired by local farmers.

A per missive approach would be to test GM crops on a case- by- case basis for the same known biosafety risks that have long been associated with conventional crops. Under this approach GM crops would not be singled out because of their novel transgenic nature as inherently more dangerous; they would be screened for biosafety risks in the same manner that non-GM crops have long been screened for such risks. This is a permissive approach in the sense that it does not set a higher biosafety standard for GM than for non- GM crops. Yet it may not be a lax or a lenient approach if the biosafety standards being met are set sufficiently high. The U.S. government follows this permissive approach and claims that its standards for screening both GM and non- GM crops have so far been high enough to protect against any documented biodamage.

Most of the industrial nations beyond the United States, and many developing countries as well, are more inclined to view GM crops as sufficiently novel to require separate and more cautious biosafety consideration. This precautionary approach singles out GM crops for tighter biosafety regulation simply because of their novelty and the scientific uncertainties that are always associated with novelty. Under this approach, governments would slow down or hold back on the field testing or commercial release of GM crops not just to avoid biosafety risks that are known and have been demonstrated, but also to avoid some risks that may not yet be known or are still undemonstrated.

At an even more cautious extreme, a fully preventive approach to the biosafety of GM crops might be adopted. Under this approach, new GM crop varieties would not be screened for risks case by case; instead the presence of risk would be assumed without testing because of the novelty of the GM process alone, and permission to release GM crops into the environment would be denied.

Trade Policy

In the area of trade policy, the gradient from promotion to prevention is more difficult to describe because consumer and importer acceptance of GM crops in international commodity markets is uncertain and evolving. Assuming consumers and importers accept GM crops, a developing country hoping to pro mote those crops would plant them with confidence,

knowing they would cut production costs and increase export competitiveness. However, if consumers and importers increasingly reject GM crops, developing countries seeking export sales might be induced to ban GM crops internally so as to be able to offer bulk commodities to the world market with a "GM- free" label.

A promotional trade policy toward GM crops may be defined as one that (1) promotes planting of GM crops in hopes of reducing farm production costs, thus increasing price competitiveness, and (2) permits GM commodities, seeds, and plant materials to come into the country with little or no restraint. A permissive trade pol icy would neither promote nor prevent the planting of GM crops internally and might regulate imports, but in a way that draws no invidious distinction between GM and non-GM imports. A permissive policy would follow the WTO's science-based standards for sanitary and phytosanitary (SPS) trade restrictions.

A precautionary trade policy toward GM crops would impose a separate and more restrictive set of regulations on trans-boundary movements of GM plant materials and seeds. Such special regulations might take the form of additional testing or information-sharing requirements and procedures, labeling requirements, or prior notification requirements. One frame work for this precautionary approach is the advance informed assent (AIA) agreement incorporated into the Cartagena Protocol on Biosafety, negotiated in January 2000 within the Convention on Biological Diversity (CBD 1992, 2000).

If strict enough, precautionary import regulations might present such an in convenience to exporters as to block virtually all movements of GM materials, seeds, or commodities into the country. In that case, the policy would have to be classified as preventive rather than precautionary. Imposing an outright ban or an open-ended moratorium on imports of GM crops or material would be a more direct way of embracing a preventive policy approach. One emerging trade policy motive for a preventive approach toward GM crops has been the recent international consumer backlash against GM. If this backlash continues to strengthen, banning GM crops at home could be one way for developing countries to strengthen their attractiveness as a source of bulk commodities in the eyes of industrial- country importers in Europe or Japan.

Food Safety and Consumer Choice Policy

Issues of food safety and in formed consumer choice tend to dominate the public debate over GM crops in the industrial world while remaining less salient in most developing countries. Food safety is of course a serious problem in poor countries, but the principal dangers come more from already demonstrated hazards—such as unclean water, lack of refrigeration, and unsanitary conditions for food trans port, storage, marketing, and preparation—than from speculative hazards associated with the GM content of foods.

Nonetheless, a gradient of developing country policy choices toward GM foods, from promotional to preventive, can be drawn. At a promotional extreme, these governments might be reassured by the evidence developed so far through testing and actual consumption in the developed world and conclude that the food safety risks posed by the GM crops already on the market in rich countries are no greater than the risks posed by the non-GM equivalents of those crops (Nuffield Council on Bioethics 1999). Their policy response would be to require no new testing or labelling procedures for those already-approved GM crops. Only if a GM food were significantly different from its conventional counterpart for example, if the nutritional value were different or if it caused allergies would a label be required to indicate

that difference. Such an approach would mimic the promotional approach taken so far by the United States.

Following a slightly more heedful approach, governments might conclude that even if new risks specific to GM foods have not yet been demonstrated by scientists, consumers still have some right to know when they are consuming GM foods. Following this approach (classified here as permissive) governments might require food companies to designate foods as "GM" if more than a specified percentage of the content came from GM crops. To avoid placing an undue burden on companies and producers, fresh foods that do not currently require labelling and processed foods (such as hydrogenated vegetable oil) that cannot be tested physically for GM content3 might be excluded from such a regulation. Consumer choice policies in some EU countries have at times tried to follow this permissive model.

Under a still more precautionary approach, governments would require labelling for all GM foods, including fresh and processed foods. The only way to enforce such a requirement would be to require totally segregated or "identity-preserved" marketing channels for GM versus non-GM foods, all the way from the farmer's field to the consumer's plate. That would be a costly option for any nation growing, importing, or exporting GM foods, as it would require an expensive duplication of equipment and facilities in the food transport, storage, and processing sectors. Yet it would be the only way to give all consumers a fully informed choice.

A preventive approach in this area would ban all internal sales of GM foods. This approach might be taken as an ultra- precautionary step to protect domestic consumers against hypothetical or unknown risks. For countries not yet growing GM crops, a total ban might even have the attraction of being cheaper than the precautionary "fully informed choice" approach because it would avoid the need to segregate markets and duplicate food- handling infrastructures. This advantage, however, would be gained at the cost of eliminating all consumer choice. A softer preventive approach might be to require stigmatizing labels on all GM foods, describing them (even without any scientific evidence) as dangerous to consumers.

Public Research Investment Policy

Public investments in agricultural research have helped developing countries generate high rates of economic return from higher farm productivity growth. How to allocate these research investments across different crops or farming systems has always been a difficult policy problem for national agricultural research institutes, given the persistent scarcity of funds available for any kind of research activity in the developing world. With the emergence of transgenic crop technologies, national research institutes now face a new choice. Should they invest scarce treasury funds or scarce donor funding in this new technology? In those developing countries where private corporate involvement or investment in the farm and seed sector has not traditionally been welcomed or, conversely, has been hard to attract, the investment of treasury funds may be the only way to launch a GM crop revolution.

At a promotional extreme, then, governments might invest their own treasury funds in the actual development of their own GM crops. One motive might be to steer GM technology development toward the crops most critical to low-resource farm communities that tend to be "orphaned" by researchers in the profit- making private sector.

A slightly less promotional approach would not invest in the development of new GM crops but only in the transfer ("back crossing") of already developed GM crop traits into local crop varieties. That is, rather than trying to compete with the international companies and research centers that have already developed potentially useful GM crop applications, developing-country governments would seek agreements with those companies or institutes to permit the transfer of already-developed GM crop traits into local crop germplasm.

A more precautionary approach toward public sector research would allow back crossing of GM traits into local cultivars but would not spend any significant national treasury resources for that purpose. If donors or international agricultural research centers wanted to sponsor the introduction of desirable transgenes into local germplasm, and if they wanted to finance the associated up grade that might be needed in biosafety facilities or personnel training, that would be welcomed. But treasury funds would be reserved for more traditional agricultural research activities, perhaps including non-GM biotechnology research in areas like tissue culture or molecular marker-assisted breeding.

A preventive approach would make no investments at all- of either treasury funds or donor funds- in any transgenic technology development or adaptation work.

Summary

This classification scheme is not intended to favour one set of policy choices over another. Its purpose is only to suggest some useful dividing lines between choices, for classification purposes. Nor does this classification scheme imply that the best choice for one developing country will be the best for all others. Different developing-country governments might make different choices depending on their size, ecological endowment, research capacity, trade posture, or the distinctive agricultural and rural development challenges they face. In the IPR venue, for example, countries with large internal commercial seed markets may be able to attract significant private sector investments and technology transfers in the GM crop area even without the lure of a strong IPR policy. In the trade venue, countries that export bulk commodities to Europe or Japan may have reasons to become pre cautionary or even preventive toward GM crops. In biosafety, coun tries with rural environments that contain the wild relatives of GM crops may have more cause to worry about unwanted gene flow and may wish to select a more cautious biosafety policy as a result. In food safety, for those countries where most foods are sold in rural markets without any packaging or labelling, some of the consumer choice pol icy options listed here may be moot. And in public research, countries starting with small internal research capacities will naturally have fewer options to pursue a promotional public investment strategy, compared with countries starting with a strong capacity.

Nor does this scheme assume that a country making a cautious choice in one venue will necessarily make a cautious choice in all others. For example, a country might well make a precautionary or preventive IPR policy choice while at the same time making a promotional public research investment choice. This might be rational if the country wanted the technology to develop in the public rather than the private sector. Also countries making a precautionary or preventive choice to ward the planting of GM crops on biosafety or trade grounds might have no need to make a separate or equally precautionary choice in the area of consumer choice because there might be no GM foods on the local market.

How might developing countries be expected to make their choices overall? One might guess that most developing countries, compared with rich countries, would place less emphasis on

biosafety and perhaps more emphasis on enhanced farm productivity and commodity export promotion, since in the developing world environmental goals such as biodiversity protection are frequently subordinated to developmental goals such as increased food production and growth in foreign exchange earnings or rural in come. Developing countries with significant unsolved agricultural development problems or food security problems might thus be expected to take at least a permissive view of GM crop technologies in most venues, particularly biosafety.

For details of the analytic framework for classifying nations on the basis of the aforementioned policy choice settings PLEASE REFER TO

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This discussion paper also analyses Kenya, Brazil, India and China and compares these countries on bases of the policy choices and how those have affected uptake of biotechnology. The same approach may be adopted to compare analyse other African Countries on the bases of the existing biosafety laws and biotechnology and trade policies as may be available.

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