A Primer For Scientists

Ethical Issues of Environmental Biotechnology Research

Marc Saner

Institute On Governance
Institut sur la gouvernance

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Foreword and Acknowledgments

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For further information, please contact:

Marc Saner
Institute On Governance
122 Clarence Street
Ottawa, Ontario
K1N 5P6 Canada
tel: (613) 562-0090
fax: (613) 562-0097
info@iog.ca
www.iog.ca

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Preface

Biotechnology has been identified by the Canadian government, academia and industry as an important priority for research. Environment Canada has sponsored numerous biotechnology applications. The department invested in the Strategic Technology Application of Genomics in the Environment (STAGE) program. The objectives of the STAGE program are to enhance Environment Canada's capacity and understanding of the applications of genomics; explore the potential for responsible application of these advances in fulfilling departmental priorities and improved decision making; and to prepare the department to participate effectively in rapidly evolving genomics initiatives.

Biotechnology is growing at such a rapid pace that research and technologies are being developed before ethical issues can be fully addressed. Biotechnology, has also been under scrutiny by the public due to both safety and ethical concerns. Within the government infrastructure the capacity to address these issues is still limited, although there is a growing commitment to take ethical issues seriously. For example, government-wide initiatives to implement frameworks for the use of advice on science and technology, integrated risk management and the interpretation of the "precautionary principle" all touch on values and ethics.

Of particular importance is the *Values and Ethics Initiative* which was initiated by a task force chaired by the late John Tait. It addresses, as does this primer, issues at the workplace – an approach which supports the view that ethics is everybody's business.

For a number of reasons, scientists should think pro-actively about ethical issues in biotechnological research:

- Because it provides a component of the wise management of financial resources: The development of methods and products which have a very high probability of being socially and ethically acceptable should be given preference over others because they have a higher chance to succeed in the market place.

- Because it is necessary for effective communication: In applied science scientists are expected to defend scientific methodology and underlying values throughout the research process. In an increasingly transparent and scrutinized process scientists frequently may find themselves required to communicate to a broad audience (without having much time for preparation).

- Because conducting applied science entails responsibilities: Scientists have an obligation to reflect on the values held by the broad public because it is a "stakeholder." Furthermore, much research is directly or indirectly supported by public funds and emerging products may affect the welfare of the public and the environment.

In this primer the reader will be taken through an approximate research chronology and confronted with questions and insights. Here are some examples:

- *Funding and planning of research*
  How does one justify a project from a moral point of view? Where do we locate moral limits and why?
- *Research ethics*
  Why exactly should one care about animal welfare? Should one also care about other life-forms?
- *Regulatory ethics*
  What is meant if risk assessments are called "value-laden"? Where do the loyalties of government scientists lie?
- *Release and follow-up*
  How do we distinguish ethical from technical issues? Does in-depth technical knowledge and understanding entail special duties?
- *Non-action*
  Can we avoid dealing with ethics? Should precaution go both ways?

Ethics pervades all these activities and so does the "teaching" of ethics contained in this primer. As a consequence, issues addressed in one section of this primer (or, for that matter, in one section of your organization) will be applicable to others.

In this short primer you will find, hopefully, motivation, insight and tools to address ethical issues within your own research workplace. This primer is part of Environment Canada's Genomics, Ethics, Environment, Law and Society Initiative (GELS).

"Ethics"

Ethicists try to avoid defining "ethics" because conceptualizing "ethics" is precisely one of the important subject matters of the discipline. In other words, philosophy (including ethics) is, unlike science, very often self-reflective. Throughout the first section of this primer different conceptualizations of ethics will become clearer. The following quote by Princeton ethicist Peter Singer provides a good introduction:

> "What is ethics? The word itself is sometimes used to refer to the set of rules, principles, or ways of thinking that guide, or claim authority to guide, the actions of a particular group; and sometimes it stands for the systematic study of reasoning about how we ought to act. In the first of these senses, we may ask about the sexual ethics of the people of the Trobriand Islands, or speak about the way in which medical ethics in The Netherlands has come to accept voluntary euthanasia. In the second sense, 'ethics' is the name of a field of study, and often taught in university departments of philosophy. The context usually makes clear which sense is intended ... Some writers use the term 'morality' for the first, descriptive, sense in which I am using 'ethics'. They would talk of the morality of the Trobriand islanders when they want to describe what the islanders take to be right or wrong. They would reserve 'ethics' (or sometimes 'moral philosophy') for the field of study or the subject taught in departments of philosophy. I have not adopted this usage. Both 'ethics' and 'morality' have their roots in a word for 'customs', the former being a derivative of the Greek term from which we get 'ethos', and the latter from the Latin root that gives us 'mores', a word still used sometimes to describe the customs of people." [Peter Singer, ed., *Oxford Readers: Ethics*, Oxford and New York: Oxford University Press, 1994, pp. 4-5.]

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1. Introduction

1.1 Objectives, Approach and Limitations

The objective of this primer is to provide clear, concise and practical guidance on how to approach ethical issues pertinent to research on environmental biotechnology.

In chronological order, it covers the entire research process from the proposal stage, through laboratory and field research and also addresses issues relevant to the regulation and field use of products.

The primary audience are government scientists, managers and regulators. This primer has been written by a scientist (and ethicist) for scientists.

The goals are to motivate, foster and facilitate systematic ethical dialogue within government and to improve your abilities to communicate ethical issues to stakeholders.

Note that this primer is not a code of ethics in which you can hope to find what is permissible and what is not. Instead, it is an introductory learning tool which improves the understanding of this strange beast called "ethics." The focus here is to present and justify valid questions that you should consider rather than to prescribe limitations on your thought and actions.

This will foster your understanding of where some seemingly outlandish criticisms come from - what are the arguments for "animal rights" or why would somebody be worried about the "domination of nature"? It will simultaneously aid in protecting you from incurring ethical risk (the risk of being

accused of ethical misconduct), enable you to work in a responsible way and also to communicate your research goals and achievements in an effective way.

Although this primer will increase your ability to anticipate, understand, debate and communicate ethical issues it is necessarily only a first step in a continuing learning project. Note also that ethics always remains "open," meaning that even if one arrives at best practices, codes and principles, one has not completed the project. Even though no final answer can be given, however, it may be quite easy to distinguish a strong argument from a weak one.

The focus of this primer is issues pertinent to environmental biotechnology research. You will find here only cursory reference to general issues in professional ethics (such as fraud or plagiarism) and workplace ethics (such as harassment or discrimination).

1.2 Why Ethics?

The preface states three good reasons for which one may choose to deal with ethics. What it does not express, however, is the pervasiveness of ethics. In very simple terms ethics come in three forms:

- Values (attitudes, intentions, "virtue")
- Rules (principles, codes, laws, "the right")
- Goals (mission and vision, "the good")

In other words, our attitudes, the rules we choose (or are forced to follow) and the goals we set all have something to do with ethics. Even if we think and act in a perfectly straightforward and reasonable way, we still are using an ethics framework! Just because something saves human lives does not mean it is free of ethics - all it means is that the justification may be simple.

As scientists, we are accustomed to dealing with obstacles in our research. Aside from the obvious difficulty of finding novel facts and creating inventions, there are economic constraints, administrative hurdles, legal limitations and, increasingly, ethical obstacles.

Being neither professional fund-raisers, nor administrators, nor legal experts, nor ethicists, our immediate instinct is to partition and delegate. I believe, however, that this conception of "ethics as an external hurdle" is the biggest obstacle when it comes avoiding ethical blunders. Ethics is not a hurdle like a registration requirement or the need to file grant applications. Instead ethics permeates everything we do. As a consequence, it is not possible to "simply do science and leave ethics to the experts."

In ethics there are seldom straight answers to straight questions. This text is somewhat the opposite of what one may hope: it gives complex answers to seemingly simple questions. Consider this: even in pure science finding the best question (and hypothesis) is often the most important part. Similarly, an intelligent debate over ethics requires an understanding of the complexity and an ability to formulate and respect good questions.

Still, "answers" there are. They come in the form of good arguments and form a small set of defensible values, rules and goals - a pluralistic answer to a complex non-empirical question. This is irritating if one wants a single answer (monism) but it is

better than living with "anything goes" (relativism).

Your cost-benefit analysis could be summarized as follows. On the cost side you have the time required to attack more than two millennia worth of literature, the problem of different approaches across the globe and a lack of final answers.

On the benefits side, you have the ability to avoid ethical risk, to broaden your understanding and communication skills and to address Socrates's claim that "the unexamined life is not worth living."

1.3 Three Positions in Environmental Ethics

Environmental ethics has been called "a triangular affair." The triangle is composed of the moral consideration of (1) only humans, (2) animals or (3) ecosystems. The first is often called "anthropocentrism" and is atomistic in that individuals are the focal point. The final is often called "ecocentrism" and is holistic in that entire ecosystems, even abiotic components, are considered in moral deliberations on what is good and right. Between the extremes is the ethical framework of the animal welfare movement which is non-anthropocentric in that the well-being of non-humans is considered but which is still atomistic in that individuals, and not systems, are the unit of consideration.

However, additional theories have been proposed and it is possible, for example, to formulate reasoned arguments to support duties towards lower animals and plants (the "biocentric" position). Further, spiritual elements have been included in the discussion of the interconnection between, e.g., aboriginal culture or Buddhism, and environmentalism. Furthermore, political elements have been included in the discussion between the ethical frameworks of feminism or Marxism, and environmentalism. I will refer to these occasionally, but will centre the following discussion around the corners of the environmental ethics triangle.

From the perspective of an Environment Canada employee we have to take note of the Department's mission to "make sustainable development a reality." The Brundtland Commission did not leave any doubt that its concept of sustainable development is anthropocentric. However, the Government of Canada has also committed itself to an ecocentric position in the Canadian Biodiversity Strategy. As a consequence it is desirable not to commit too strictly to a single position in environmental ethics.

A contemporary environmental ethicist, Bryan Norton, has worked extensively on the problem of unifying different positions. He developed an approach that he calls "weak anthropocentrism." It combines positions (1) and (3) of the environmental ethics triangle in that it supplements traditional anthropocentrism with a holistic element – an additional focus on ecosystems. Within weak anthropocentrism, it is postulated that while we must focus on the protection and conservation of entire systems, we do it ultimately for our own sake. This leads to a convergence between diverging positions and is a versatile approach in this context, although it may not give animal welfare as much attention as required (to protect oneself from ethical risk and to act responsibly).

2. Ethical Issues That Scientists Should Consider

2.1 Ethical Issues in the Planning and Funding of Research

It is a special feature of biotech research that the method itself is a subject of ethical debate. Independent of the features of the ultimate product (be that knowledge or a commercial product) you have to be ready to defend the methods used in its production. As you know, some of the methods have become hot topics and it is important to understand at the planning and funding stage what is going on.

Understanding the ethical debate requires that you acknowledge at least three things. First, legality and adherence to standard procedures of review may not suffice to protect you from ethical risk (see also sidebar). Biotechnology has become such a powerful tool, and is progressing so rapidly, that your responsibilities go further than ever. Second, the idea of a moral limit to certain scientific procedures and goals cannot be brushed aside easily. An example for a moral limit would be that *on principle* we do not force humans to participate in experimentation (even if we had capital punishment and they were criminals on death row). Setting such limits is not straightforward and selecting their location becomes a major issue in the debate over biotechnology. Third, the use of biotechnology may have international effects starting from ownership issues over the source material to the potentially high mobility of products.

Proactive Ethics – The issues listed here need to be taken seriously during the development of a research goal and plan. It is rather poor communication to state: "I am going to develop artificial life within the next 3 years so you better have an ethical debate about it." This does not show any sense of social responsibility, because the onus is on others, and it does not make sense to advocate research that, perhaps, should be prohibited on moral grounds. Instead, what you should consider doing is to propose a moral argument in favour of this research and put it to test before applying for the funds or starting the research. For example, is this research driven by curiosity alone and is this sufficient? At the very least, take on some of the responsibility. From a non-scientist's perspective it would be very encouraging to read in the media that scientists actually reflect on these issues.

"What's the Problem? - It is Legal!"

Legality provides very little defence in ethics. On the one hand, racism and sexism are legal in some nations and have been legal in our past – so what? On the other hand, a parking ticket always indicates illegality but not necessarily unethical behaviour.

As a consequence, the legality of the patenting of food plants does not prevent criticism from some political and ethical frameworks which entail that certain goods such as air, water and food should never fall under patent control. Some more spiritual ethical frameworks entail that the very idea of owning nature is indefensible.

Never mind the details of these arguments - the commentary specified in the title of this sidebar does not carry much weight in an ethical debate.

Moral Limits – This is perhaps the most important topic in this primer. Would you agree that scientific progress should have a limit? At this point I am not thinking about pragmatics - yes, it is perhaps impossible to stop science internationally. The question is: do you believe we *should* prohibit certain scientific programs (e.g., eugenics) on moral grounds even if there could be tangible benefits from them?

You may not be willing to go so far as to use the word "prohibition" but even then you have to acknowledge that we are already using moral limits in our society. We are using concepts such as "human dignity" or "intrinsic value of biodiversity" in international agreements which we have ratified. These concepts are metaphysical - science does not give us any guidance on their exact nature or justification. Still, we commit ourselves to them and this begs the question how to interpret these moral prescriptions.

Important here is that these concepts can support absolutism that can then be used to establish moral limits which prohibit certain means no matter what the ends are.

A number of topics in the biotechnology ethics debate are related to the question of setting an arbitrary moral limit. Should we patent people - why not? Should we patent animals? If we patent animals but not humans, could we at least patent non-sentient humans (e.g. coma patients)? Do you have "intrinsic value" and "dignity," and, thus, are you more than just an instrument for society to use? Why exactly does this apply to you and not to an ape? Can we own or licence air - why not? Can we own or licence genes - what does this mean? Should we agree that it is permissible to insert up to 1000 human genes into a pig but that the creation of a chimaera is off-limits - why? Does this have anything to do with the idea of "the natural"? Is not everything a slippery-slope?

The whole point here is to accept that it is very difficult to get rid of the idea of a moral limit because we already use the idea within the confines of our narrow anthropocentric outlooks (see, for example, the section "A Moral Imperative: Respect for Human Dignity" in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*).

So, what happens to this limit once one considers animals or even ecosystems in moral deliberations? Can you, as a scientist, explain why you and I have "dignity" and why a dog does not? Even more complex, why do we attribute dignity to absolutely <u>all</u> humans, including permanently and severely mentally handicapped humans, but not to <u>any</u> animals? Note that this is a question of logical consistency and is not driven by the "unscientific and emotional love for birds and bunnies."

I have to explain at this point that ethical issues are discussed here from a secular (non-religious) perspective. Philosophical ethics is based on reasoned arguments. In this view, the force of the argument is the measure of "rightness" rather then the nature of the source of the idea. The sacred texts used in world religions may provide such arguments but a simple reference to a sacred text will not do. For example, if we don't have good *arguments* against attributing dignity to animals then we lack good arguments against critics who want to prohibit certain biotechnologies involving animals.

I leave you here hanging with an unanswered question because the function of this primer is to stimulate thought and debate. There is, of course, also an abundance of literature on the subject and you can find some help on the topic in the Appendix.

I conclude this section with another difficult notion that has been used to suggest that biotechnology is morally impermissible. The idea of the "unnatural" is commonly stated in the context of genetic engineering although it is not commonly used in the context of traditional breeding. The concept of 'the natural' is difficult to elucidate. I believe, however, we can get at the idea by employing a related concept which is a little bit more tangible - the idea of "the domination of nature." This idea is a recurring theme in environmental ethics and you should understand its meaning. I will try to explain it in the following section.

Attitudes – Why is the Frankenstein theme so notorious in the biotech debate? Perhaps some people think about the harm done to the monster. I believe, however, that a central issue is Dr. Frankenstein himself because he pushes the limits of science and then finds out that he cannot control the consequences. (Note: A problem with attitudes is that, unlike actions, they are internal and difficult to assess.)

Now, the desire to dominate nature is an attitude which is given almost intrinsically in science and engineering. The whole point of these activities is that nature gives us all kinds of problems and we had better tackle them. At the same time, the domination of nature has been blamed for all kinds of severe problems. It has been argued that it leads to a lack of respect for nature and life, is a cause for environmental pollution and species extinction and is even at the root of a number of social problems.

A problem for us is that genetic engineering really is "the type specimen" of the domination of nature. We alter life in its most basic way with the goal of increasing our ability to control and manage the natural world.

Many or most uses of environmental biotechnology are, of course, not related to the creation of transgenics. Still, understanding the concept of the domination of nature is important to everybody who is being "accused" of doing biotechnology.

The cure for a blind rampant thirst to dominate nature is an attitude of respect. I believe most biologists are actually deeply respectful of nature *in a certain way* but it is worthwhile to step back and scrutinize one's own motives. The critical question here is: "Is there a softer, gentler, less invasive and persistent way to accomplish the same end and, if so, why don't I use it?" Pausing for a moment and trying to understand the viewpoint of critics goes a long way towards avoiding ethical risk and living up to one's responsibilities.

Independence – This is a much debated issue where scientists and science-critics may actually agree: bias is undesirable. Because bias is so highly undesirable, it should already be considered at the proposal stage. Independence, some would argue, is important in this context.

Over the last few decades cooperation between the private sector, public sector and academic researchers has intensified. This entails the danger that experimental design and measurements and interpretations of data become biased in subtle or not so subtle ways. The issue here is not overt conflicts of interest, but the borderline cases where affected researchers *believe* they remain unbiased and outside observers suspect the opposite.

A different take on the independence topic is the question of how far academic freedom (and your personal liberty) should go and to what extent it should be constrained by societal goal setting.

These two issues are not at all unique to biotechnology but I have to flag them here both as ethical issues and as ingredients of the biotech debate.

Exploitation – The term "biopiracy" has been coined to express the idea that the use of biotechnology can entail an exploitation of aboriginal knowledge and peoples (nationally and internationally) who can perhaps claim an ownership of the genotypes in their territory.

A trick to foster the understanding of this issue is to "universalize." In ethics we sometimes refer to the concept of the "veil of ignorance." Imagine that when you put the veil in front of you, you lose the ability to know if you are negatively or positively affected.

Take for example the invention of PCR and the role of the Yellowstone Park as the place where the source organisms were found. Put on the veil of ignorance and imagine you may be the president of the Yellowstone Field Naturalist Club who did a lot of volunteer work. Would you consider it fair that some of the money made from this invention would be fed back into the park? (None did, in reality.) Assume the identities of other stakeholders and try to figure out what you mean when you say "fair."

Justification - So, how should you go about justifying your research on moral grounds? Working in the environmental field, you have a unique opportunity to address the ethical debate surrounding modern biotechnology (see sidebar).

Within the environmental ethics triangle you have three options to locate the focus of your justification. The benefits could be directly applicable to humans, sentient animals or the environment itself. It is of course also possible to argue that a benefit to animals and ecosystems entails an indirect benefit to humans who wish to use them or simply care for them.

As always, the goal is to find a convergence among the three options and to give preference to projects that can satisfy all three. If you go beyond the justification of ends, but also discuss the choice of your means from an ethical perspective, then you have gone a long way in taking on your responsibilities regarding the special ethical issues within environmental biotechnology.

At this point I will move on to the next step in the research chronology and discuss some issues in research ethics. I note, that the overlap between the different chapters is very significant and that it is necessary to consider this primer in its entirety. Still, I hope that this partitioning makes the subject matter a bit easier to digest.

A Moral Argument in Support of Environmental Biotechnology

Environmental biotechnology is uniquely privileged among the various uses of biotech because it can be supported with a very strong moral argument. Within the mission of Environment Canada it is meaningful to accept the core prescriptions of Aldo Leopold's land ethic: "A thing is right when it tends to preserve the integrity, stability and beauty of the biotic community."

A number of uses of biotechnology in environmental conservation and protection can satisfy Leopold's maxim. Ths would aid in obtaining support from environmentalist circles.

Detection methods such as micro-arrays, forensic techniques such as genetic fingerprinting of whale meat and perhaps even bioremediation techniques are examples that can be fairly easily supported from an environmental ethics viewpoint. This would help the global biotech debate because it would become more diversified and better informed.

2.2 Research Ethics

Scientific research is an important topic in applied ethics and there are a number of books dedicated to the topic. Further, it is also possible to identify values and standards that go along with professionalism in the public service (e.g., integrity, excellence, and transparency). Information on the specific ethical issues raised by environmental biotechnology is very scarce, however. I introduce this section with a short catalogue of ethical issues in general research and then discuss some important specific issues from the viewpoints of the three positions in the environmental ethics triangle.

A Research Ethics Catalogue – I want here very quickly remind you of ethical issues in research that are not specific to research in environmental biotechnology. At the level of attitudes and values it is commonly stated that scientists ought to adhere to high professional standards of honesty, carefulness, openness, mutual respect, respect for test subjects and social responsibility.

At the level of rules, actions and goals, all of the following are commonly discussed in research ethics: issues of misconduct such as harassment and unjust recruitment, issues in the sharing and preserving of resources, gender issues, bias and fraud, authorship, plagiarism and intellectual property issues and conflicts of interest. This is by no means a complete catalogue but shall suffice to remind you of the kind of broad workplace and professional ethics issues that may arise. Further guidance can be obtained from professional codes of conduct and from the books on research ethics listed in the Appendix.

The Involvement of Humans - In environmental biotechnology humans are not expected to be subjects of research. As a consequence, the (otherwise central) Tri-Council Policy Statement *Ethical Conduct for Research Involving Humans* will not often need to be consulted. However, the issue of a human donor of either genetic material, or cultural or personal information may arise. This is tightly connected to the difficult concept of ownership. For conflict to arise, it *may* matter if a profit is being derived from such use. Key questions are: (1) Are you treating humans as means rather than ends? (2) Did you obtain informed consent from the people involved?

There is no space here to delve into this issue but it needs to be clearly flagged as a major ethical risk and responsibility (see previous section under "Exploitation" for further information).

Another issue from an anthropocentric point of view is the direct harm to humans that your research may cause. This issue, however, is rather one of common-sense and is not specific to environmental biotechnology. As a consequence, I will not discuss it further.

Animal Experimentation – One problem with modern biotechnology is that is has lead to a worldwide increase in the number of test animals used in research. In this section I am no longer referring to the idea that such animals may have "dignity" (whatever that means). Instead, here I look at harm. There is little doubt that animals may experience pain and suffering in research laboratories – they are being harmed. What are the issues?

Once one gets away from the metaphysical ideas of dignity and "soul" it gets harder to neglect the harm done to animals. Utilitarians, for example, conceive of ethics as bringing the greatest good to the greatest number in an egalitarian manner. The British philosopher who first developed this idea stated already more than 200

years ago that the ability to be harmed is the key when it comes to selecting the entities that should be considered – this includes some animals, the so-called "sentient" animals. Simply put, if the good world is a world where happiness is maximized then everybody who is capable of being happy or unhappy must be considered.

What is important here is that mixing and matching ethical approaches rarely leads to a consistent, logically defensible position. It is very difficult to adhere to the idea of rights and, at the same time, think and act like a utilitarian. There is a fundamental tension between approaches to ethics which rely on rules and limits, and approaches (such as utilitarianism) which rely on goals.

Minimizing harm overall, however, does not only extend to the laboratory. For example, if you are doing animal research with the goal of improving the situation of wild individuals of the same species in nature then your situation is ethically much more defensible than if you are using animals to satisfy spurious human needs (infamous example: Draize-test used to assess a new shampoo).

I don't need to dwell on this further as this issue is not specific to environmental biotechnology. Important questions that you should consider are: (1) What are you doing to minimize pain and suffering of your research animals? (2) Do you really understand the arguments of animals welfare activists? Considering these two questions, I argue, is key in taking on your responsibilities and avoiding ethical risk.

Biodiversity and Ecosystems – I state here the obvious: living material has an inherent propensity for mobility and propagation (persistence) which is a factor in laboratory and greenhouse research. The consequence, risk to biodiversity and ecosystems may arise even from indoor use of transgenic and non-indigenous life forms. Quarantine facilities may be required and their limitations should not be downplayed. In a nutshell, a full environmental risk assessment may be required at the research stage.

I discuss this issue further below under "The Ethics of Environmental Release."

"Our Animals Are Fine - We Follow CCAC Standards"

If you are using animals in research then it is your responsibility to understand the role, standards and procedures of the Canadian Council for Animal Care (CCAC). Without taking away from the important work CCAC is doing I want to ask now if your responsibilities end here.

One important point of consideration is that the largest animal welfare NGO in Canada, People for the Ethical Treatment of Animals (PETA) is not welcome at CCAC when new guidelines are being developed. There is a simple reason for that. PETA wants us to stop using animals in research while CCAC is in the business of legitimizing animal research that follows its standards of minimizing pain and suffering. As a consequence, the two groups are so far apart that a dialogue seems impossible.

What is noteworthy here is the possibility that established ethical procedures may give you *a false sense of security regarding ethical risk.* It may also stop you from thinking further about the issue. If animal research is your job, is it not reasonable to expect you to fully understand the arguments of the largest NGO addressing this issue in Canada and to be able to argue your own case without simply referring to CCAC?

2.3 Ethics of Regulatory Assessments

A number of scientists in the Federal Government of Canada are employed as regulators and assessors of environmental risk. However, even if you are a research scientist you may have to deal with the regulatory system.

Regulation is the place where many ethical decision are made. Regulators directly interfere with research when research permits are required for an activity. Regulators also define the data requirements and quality and safety standards that registrants of products must comply with.

Sometimes, ethical issues are simply perceived to be "another regulatory hurdle" between research and marketing. In this primer, however, I have tried to emphasize that ethics is pervasive rather than one of many hurdles that are currently put into the path of scientists.

Another take on ethics in regulation comes from the study of the objectivity of regulatory assessments. Regulators have a difficult task because they are not producing original research, receive data of varying quality and have to deal with data gaps and a lack of standardization in the choice of standards and endpoints in risk assessment.

Judging the quality of submitted data cannot be free of risk. Each submitted study must be either judged acceptable, incomplete or unacceptable. Professional judgment used in these decisions is affected by the willingness of risk assessors to take risk and by judgement about what is important and what is not. Because of this limitation, risk assessments are considered "value-laden."

One way to deal with this issue is to establish a more defined gap between facts and values ("is" and "ought") by making the value judgments explicit and subject to standardization and management.

As a research scientist you have the responsibility to facilitate this process by refraining from spinning issues in your submissions. Regulators must also be transparent about value-judgments. The goal is objectivity as far it can be achieved within risk assessment. For example, just because a product has been developed within government should not entail automatic registration (an important question related to this context is discussed in the sidebar).

Where Does Your Loyalty Lie?

Government scientist serve a least four masters: the public, the administration, the scientific community, and themselves. Fortunately, all parties value sound science positively and it is often possible to serve everybody simultaneously.

Particularly in regulation, however, tension may arise if a scientist is dissatisfied with a decision that was made by managers based on the scientist's results. Recently, a number of government scientists in different departments have "blown the whistle" in this context. As a consequence, the issues of loyalty and professionalism have become ongoing concerns within the Federal Government of Canada.

Scientists are well advised to discuss and reflect on this issue before problems arise. A clearer understanding of expectations from various stakeholders is thus achieved and early detection is the best basis to address issues.

2.4 Ethics of Environmental Release and Follow-Up

Once a product has been approved and released the ethical issues (if any) will be closely related to actual consequences – the beneficial and harmful effects of a product. A particular concern with biotechnology is its reproducing products that are intrinsically "infinitely" persistent (and mobile).

In agriculture, the contamination of organic farms or apiculture with off-site transgenic pollen has become an important issue. Think about this in the sense of "trespassing." Related to this are movements across national borders. A product may be registered in one nation but not the other.

You may argue that following government guidelines will be sufficient to address this issue but here I have to remind you that your special knowledge of the organism also gives you special responsibility. Very few people will understand the risks better than you. That makes you the bearer of ethical risk because you will be at least partly blamed if things go wrong.

Granted, invasive species are scarce, and granted, it often takes decades for escapees to reveal their full invasive potential. On the other hand, a new persistent pest, weed, or contaminant, can be a very costly, long term, and international problem.

It is again helpful to universalize. From behind the veil of ignorance, what should one decide in this constellation where beneficiaries and risk-bearers are not the same individuals?

At this level, technical issues of risk, ethical issues and broad political issues become intertwined (see also sidebar). Questions that arise are: Who is at risk? Who is liable? Can risk-bearers successfully sue the responsible parties and do the responsible parties have sufficient means to repair the damage? Who is controlling vital resources and is the constellation compliant with a concept of social justice? Has the risk been evaluated broadly, including the risk to the environment itself and including the risk to social justice and stability?

I don't think it is the job of scientist as professionals, to address these broad issues in detail. I would argue, however, that it is the responsibility of all citizens to think about the world we want to inhabit and leave behind. To this end, broad (sometimes bold or idealistic) political ideas have to be evaluated and debated.

Ethical vs. Technical Issues

In public debate it happens frequently that the so-called ethical issues discussed are really technical issues.

For example, if everybody agrees that feeding the world is the supreme goal then the question of the use of food biotechnology is a technical issue. Either it works better than the alternatives or it does not. Just because predictions are highly uncertain does not render an issue "ethical."

However, somebody may argue that in absence of any information we have to rely on fundamental principles and value systems. These may then fall into the domain of ethics but it is rare that one has no information that facilitates the choice of means towards a common end.

If somebody goes so far as to maintain that the means in question are impermissible no matter how suitable they are to achieve a desirable end then they are using a moral argument as discussed earlier under "Moral Limit."

2.5 The Ethics of Non-Action

Considering this lengthy list of potential ethical issues one may be inclined to side with one of two extreme approaches: (a) not addressing the issues or (b) avoiding environmental biotechnology.

Not facing the ethical issues would be misguided. It has been shown many times how this can later lead to inflated problems – we cannot avoid our obligation to deal with them. Avoiding the development of environmental biotechnology does not solve the problem either. Considering our very real problems with pollution, climate change, and species preservation, non-action is not an option. We need to remind critics that alternative actions may also give rise to similarly complex ethical issues. A good way to explain this is that the precautionary principle (which has now been written into the Canadian Environmental Protection Act) can always be applied in two ways: (1) to prevent action or (2) to prevent non-action. In some cases, lack of action could easily result in the harm that the precautionary principle is designed to prevent.

This translates into the ethical debate which may very well come to the conclusion that we have a moral obligation to pursue certain environmental biotechnologies (see, for example, the sidebar "A Moral Argument ..."). In the evaluation of such projects one has to be cautious about both unwise risk taking through action and unwise risk taking through inaction.

A careful evaluation of both science and ethics can help. For example, Don Doering of the World Resources Institute has argued that the emergence of "truly green" products will be fostered if ethical, social and environmental considerations are brought into the front-end of genetic engineering product design. You can find his "Design-for-environment Principles for Genetic Engineering" at: www.wri.org/wri/meb/biotech_design.pdf.

Such pro-active thinking also provides the best judgment to balance the "ethics of non-action" with the "ethics of action" before major resources have been allocated. Always remember, you are involved in *applied* science - science for a purpose. It cannot be stripped of responsibilities either way, if you choose to pursue or if you choose to avoid a research activity.

Are You Ready?

Now that we are at the end of the listing of issues in this primer, it is time to ask yourself if you are ready to justify your attitudes and actions in your field of responsibility. What are the attitudes, rules and goals surrounding your research and how do you support them?

Do you have a good understanding of the harm you may cause in a very broad sense? That this does not only include overt risk to health and the environment but also less tangible harm such as conflicts with the value-systems of aboriginals, people in developing countries, people with different beliefs? Are you considering harm to non-humans and future generations and, if not, why not? Have you evaluated where your loyalties must lie? Finally, are you prepared to communicate your arguments to non-scientists?

Don't forget: ethical issues are pervasive and cannot be delegated to specialists. Justifying your personal ethics to yourself neither protects you from ethical risk nor assures that you are living up to your responsibilities.

3. How To Proceed From Here

3.1 Dialogue

We are all able to listen and express ourselves to some extent but most of us wish we could improve upon these two skills.

Progress requires respect for diverging positions and a willingness to learn the concepts, language and arguments required. In the ethics debate over environmental biotechnology we need to learn the factual and the ethical issues and to consider the following principles.

Principles of Ethical Dialogue

1. Diversity – If we can reach common ethical solutions based on diverse moral values, then diversity is an advantage, not a problem.

- While human cultures contain many diverse ethical outlooks, there is more overlap than disagreement among the codes of conduct that they prescribe.
- Diversity in basic principles can be a resource when we face novel problems that our usual moral outlooks cannot solve. Thus some Western ethicists, finding no adequate conception of respect for nature in their own traditions, began searching for it in Asian or Aboriginal cultural and philosophical sources.
- A discussion from which some moral outlooks were arbitrarily excluded would be slanted and unfair. In principle, then, every moral voice needs to be heard. However, it does not follow that every moral outlook has to be accepted, as applied in every issue or case.

2. Fallibility – Since different moral outlooks sometimes lead to different conclusions, clearly we can't all be right in all cases.

- On the contrary, every moral outlook is fallible. Life is complex enough that, given any general moral outlook, there will be some cases where applying it will lead us to the wrong conclusions.
- For the same reason, ethics is not a field in which "anything goes". On the contrary, it is possible for anyone to make ethical mistakes.
- Yet if it is possible to make mistakes, then ethical questions must have some right answers (with which the wrong answers disagree) no matter how difficult it may be to know what they are.
- Consequently, ethics is not a popularity contest. The right answer may not be the one that is believed by the greatest number of people. Rather, right answers need to pass certain tests, including the following two:

3. Consistency – If our moral outlook leads us to a particular judgment about a particular case, we must be willing to apply the same judgment to all comparable cases.

- Thus the "golden rule" directs us to treat others as we would have them treat us, or, negatively, to avoid treating others in ways that we would not have them treat us.
- Some version of this rule is expressed in all major ethical traditions, whether secular or religious.

4. Responsibility – A moral outlook is mistaken in cases where it leads us to conclusions that would clearly cause unnecessary harm.

- For example, a moral outlook telling us never to lie seems misapplied in cases where only lying to a murderer would save the victim's life.

- However, the difficulty, especially in environmental ethics, lies in defining "harm". Comparing varying harms to humans may be difficult enough, but weighing these against harms to ecosystems or against species is far more contentious. These are central issues in environmental ethics.

Phases of Ethical Dialogue

A full account of the ethical issues surrounding any particular policy or regulatory question has these phases:

1. Opening – Opening the dialogue involves surveying how all relevant moral outlooks apply to the question at hand, to see what conclusions can be drawn from them.

2. Analysis – Moving the dialogue towards closure involves assessing each outlook critically to detect:

- inconsistencies that may be involved in applying it to this case and other comparable cases;
- irresponsibility (causing unnecessary harm) in applying it to this case in particular;
- convergence of conclusions from applications that are not inconsistent or irresponsible.

3. Feed-back Loop - Complex debates will require more than one iteration of these phases to accommodate evolving moral positions and arguments.

4. Goal – One should set the humble goal of arriving at common solutions to problems rather than trying to convince other parties of one's own metaphysical world-view.

3.2 Shared Values and Principles

What You Can Do Yourself – Ideally, a dialogue does not only enrich the understanding of participants but also arrives at some common ground. This common ground may exist only within a small group of people and may be subject to periodic revision. Still, it is not a bad idea to actually write down common beliefs, attitudes, arguments, principles and visions. The content of a number of professional codes that can be found on the world wide web is based on a such an exercise (see Appendix). The production of such codes, best practices and vision statements can also draw on the help of internal policy analysts and external ethics consultants.

I see the cost-benefit analysis as follows. On the up side we can note that things usually get much clearer once one writes them down. It is also easier to share views and to compare new ideas with the results of older debates. The transparency for outside stakeholders is enhanced. If produced among a group it can foster the sense of a real accomplishment and a sense of common ownership of an actual product. On the down side one makes the system more rigid, the perceived need to arrive at a product may make the dialogue less open and productive, one may plan to revise codes and then never do it (although you wish you would) and one makes oneself vulnerable to criticism from outside (although this may also be a good thing).

I would argue that all meetings are more efficient if one attempts to capture the content in writing. It helps to force participants to produce an argumentative thread and it best reveals semantic problems – these frequently point to the

core philosophical issues. Therefore, why not make your ethics discussions somewhat formal, no matter if you do them within a single lab or in a larger setting? If you then arrive at something resembling a code, you are still free to formalize and publish it or to keep it private. One piece of advice: the content should not be predominantly "we believe such-and-such" but, instead, "we argue such-and-such." It is easy to arrive at common beliefs among the like-minded but that does not prepare you well to deal with your full responsibilities and ethical risk.

If you come into the possession of a formal professional code then do not forget that some form of implementation, assessment of utility, and follow-up are required. It can be counter-productive to produce a document and then not use it. Even if it is being used, not being able to comment on its actual utility may be problematic. The worst use of ethics is its reduction to a mere public relations exercise.

This primer is focussed on environmental biotechnology and can only aid in the development of certain specific components of a professional code. I want to close by broadening the debate one last time. Consider the following three bits of information (subtitles) in your reflections on where to go now.

AAAS Pledge of Scientists – At the February 2001 meeting of the American Association for the Advancement of Science the workshop "To Pledge or Not to Pledge: An Oath for Scientists?" took place. This is taken from the description of this workshop (from www.aaas.org):

"The idea of taking an Oath in science surfaced most recently at the 1999 World Conference on Science in Budapest, where Sir Joseph Rotblat, 1995 Nobel Peace Prize laureate, proposed there be something like a Hippocratic Oath for science. A survey by AAAS identified an estimated 15-16 oaths for scientists or engineers proposed or currently being used. Proponents of such an Oath refer to its great symbolic value by reaffirming the importance of behaving ethically. It would encourage deeper reflection by scientists and engineers on the conduct and impact of their work, while creating a greater sense of accountability on their part. Opponents argue that an Oath would be too general to provide useful guidance. And, if mandatory, would be viewed more as an obstacle to overcome than a set of ideals to be embraced."

BIO Principles – The Biotechnology Industry Organization (BIO) represents biotechnology companies, academic institutions, U.S. state biotechnology centers and related organizations throughout the United States and in many other countries. They state:

"While biotechnology can greatly improve the quality of life, we recognize that this new technology should be approached with an appropriate mixture of enthusiasm, caution and humility. Biotechnology can provide useful tools for combating disease, hunger and environmental contamination, but it should not be viewed as a panacea or as miraculous. For example, life-saving medicines may have serious side effects, and, while our expanding knowledge of genetics can help create the next generation of medicines, it can also raise important ethical issues. With these considerations in mind, we have adopted the following statement of principles. While some of these principles are codified in government statutes and regulations, this statement is intended to provide guidance to our industry that goes beyond legal requirements." Find these principles at: www.bio.org/bioethics/principles.html.

Environment Canada's Code of Conduct - This documents is available on Environment Canada's Intranet at:

infolane.ncr.ec.gc.ca/val-eth/index_e.html

4. Appendix

4.1 Selected Introductory Literature

Research Ethics

Elliott, Deni and J.E. Stern (Eds.), 1997, *Research Ethics: A Reader* (Hanover: University Press of New England).

Gorman, Michael E., M.M. Mehalik and P.H. Werhane, 2000, *Ethical and Environmental Challenges to Engineering* (Englewood Cliffs, N.J.: Prentice Hall).

Resnik, David. B., 1998, *The Ethics of Science: An Introduction* (London: Routledge).

Schrader-Frechette, Kristin, 1994, *Ethics of Scientific Research* (Lanham, Maryland: Rowman and Littlefield*).*

Stern, Judy E. and D. Elliott, 1997, *The Ethics of Scientific Research: A Guidebook for Course Development* (Hanover: University Press of New England*).*

Environmental Ethics

Callicott, Baird J. (1980) "Animal liberation: A triangular affair," *Environmental Ethics* 2: 311-338.

Des Jardins, Joseph (1997) *Environmental Ethics: An Introduction to Environmental Philosophy*, second edition (Belmont, CA: Wadsworth Publishing Company).

Leopold, Aldo (1949) *A Sand County Almanac* (New York: Oxford University Press).

Norton, Bryan (1991) *Toward Unity Among Environmentalists* (New York: Oxford University Press).

Plumwood, Val (1993) *Feminism and the Mastery of Nature* (London: Routledge).

Regan, Tom (1983) *The Case for Animal Rights* (Berkeley: University of California Press).

Singer, Peter (1977) *Animal Liberation: A New Ethics for Our Treatment of Animals* (New York: Avon Books).

Stone, Christopher (1987) *Earth and Other Ethics: The Case for Moral Pluralism* (New York: Harper & Row).

VanDe Veer, Donald and Christine Pierce (1994) *The Environmental Ethics and Policy Book: Philosophy, Ecology, Economics* (Belmont, CA: Wadsworth).

Biotechnology Specific

Comstock, Gary (2000) *Vexing Nature: On the Ethical Case Against Agricultural Biotechnology* (Kluwer Academic Publishers).

Saner, Marc, Jay Drydyk and Campbell Wyndham (2000) *Ethical Issues in the Use of Environmental Biotechnology*, Report for Environment Canada under STAGE, 82 pp. (available from the same source as this primer).

Thompson, Paul B. (1997) *Food Biotechnology in Ethical Perspective* (New York: Chapman and Hall).

Philosophy

Kiernan-Lewis, Del (2000) *Learning to Philosophize: A Primer* (Belmont, CA: Wadsworth).

Melchert, Norman (1995) *The Great Conversation: A Historical Introduction to Philosophy* (Mountain View, CA: Mayfield).

Government of Canada Reports Quoted

Government of Canada, 2000, *A Framework for Science and Technology Advice: Principles and Guidelines for the Effective Use of Science and Technology Advice in Government Decision Making,* Cat. No. C2-500/2000

Task Force on Public Service Values and Ethics (John Tait, Chair), 1996, 2000, *A Strong Foundation*, Canadian Centre for Management Development, Cat. No. SC94-72/1996

Treasury Board of Canada, 2001, *Integrated Risk Management Framework,* Cat. No. BT22-78/2001

Tri-Council Policy Statement, 1998, *Ethical Conduct for Research Involving Humans*, Cat. No. MR21-18/1998 E

4.2 Selected Internet Locations

Government of Canada

Canadian Biotechnology Strategy ▸ **http://biotech.gc.ca/engdoc/homepage.html**
Canadian Biotechnology Advisory Committee
▸ **http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwGeneratedInterE/Home**
Canadian Centre for Management Development
▸ **http://www.ccmd-ccg.gc.ca/main_e.html**
Genome Canada ▸ **http://www.genomecanada.ca**
Science and Technology Policy Papers ▸ **http://strategis.ic.gc.ca/SSG/te01167e.html**
Treasury Board Office of Values and Ethics ▸ **www.tbs-sct.gc.ca/veo-bve/home_e.asp**

Other Canadian Organizations and Resources

BIOTECanada's Code of Conduct ▸ **www.biotech.ca/EN/code.html**
Canadian Bioethics Society ▸ **www.bioethics.ca**
Canadian Council for Animal Care ▸ **www.ccac.ca**
Canadian Society for the Study of Practical Ethics ▸ **www.carleton.ca/csspe-sceea/**
Ethics Resources (Centre for Applied Ethics, UBC) ▸ **www.ethicsweb.ca/resources/**
Professional Codes:
▸ **www.ethicsweb.ca/resources/professional/codes-of-ethics.html**
Ethics Practitioners' Association of Canada ▸ **www.epac-apec.ca**
National Council on Ethics in Human Research ▸ **http://ncehr.medical.org**

Non-Canadian Organizations and Resources

Assoc. for Practical and Professional Ethics ▸ **www.indiana.edu/~appe/**
Biotechnology Industry Organization's Principles ▸ **www.bio.org/bioethics/principles.html**
Codes of Ethics Online (Illinois Institute of Technology)
▸ **www.iit.edu/departments.csep/PublicWWW/codes/**
Ethics Links (The Values Institute, University of San Diego) ▸ **http://ethics.acusd.edu/**
European Group on Ethics in Science and New Technologies
▸ **http://europa.eu.int/comm/european_group_ethics/index_en.htm**
Harvard resource ▸ **www.cid.harvard.edu/cidbiotech/links/htm**
International Society for Environmental Ethics ▸ **www.cep.unt.edu/ISEE.html**
Markkula Center for Applied Ethics ▸ **http://www.scu.edu/ethics/**
Nuffield Council on Bioethics (U.K.) ▸ **www.nuffieldbioethics.org/home/**
Online Ethics Center for Engineering and Science ▸ **www.onlineethics.org**
Office of Research Integrity (U.S.) ▸ **http://ori.dhhs.gov/**
UNESCO Ethics Program
▸**http://portal.unesco.org/shs.en/ev/php@URL_ID+1837&URL_DO=DO_TOPIC&URL_SECTION=201.html**
Union of Concerned Scientists ▸ **www.ucsusa.org**

4.3 Environmental Ethics Glossary

Animal welfare ethics: Non-anthropocentric ethics in which animals are given moral standing, i.e., their interests and welfare count in moral deliberations (the consideration of the pain of animals, or, in a more radical form, the "rights" of animals). See also "Sentience."

Anthropocentrism: The position that only humans should be considered in a moral context. The interests, welfare and fate of non-humans do not need to be considered (except if non-consideration would indirectly affect humans, e.g., the owners of pets). "Weak anthropocentrism" emphasises the importance of ecosystems for human well-being.

Biocentrism: A non-anthropocentric ethical theory giving support to the view that being alive is a sufficient criterion for moral standing: the interests of all life forms should be considered in moral deliberations.

Deep Ecology: A non-anthropocentric political and ethical movement and collection of ideas which emphasize the interconnectedness of humans with the ecosphere and which favours the equality of all life forms. Within this holistic way of thinking non-living matter is not excluded from moral deliberations.

Ecocentrism: Non-anthropocentric, represented by "Deep Ecology" and "Land Ethic."

Ecofeminism: A group of political and ethical theories which emphasize the linkages between the domination of woman and the domination of nature. A main idea is that the goals of feminism and those of environmental protection are inseparable.

Environmental Ethics Triangle: Three positions, (1) anthropocentrism, (2) animal welfare and (3) ecocentrism, are thought to represent three fundamentally different approaches to environmental ethics that are difficult to reconcile. Thinking of these three approaches simultaneously is facilitated by conceptualizing environmental ethics as a "triangular affair."

Ethical Monism, Pluralism, and Relativism: The view that ethical justifications may be based on one, several or many (any) ethical theories.

Land Ethic: A non-anthropocentric ethical viewpoint proposed by Aldo Leopold in the late 1940s. The key principle is that "A thing is right when it tends to preserve the integrity, stability and beauty of the biotic community." This holistic thinking does not exclude the abiotic environment from consideration.

Sentience: The ability to feel pain and to suffer. Animals are called "sentient" in the animal welfare context if we are just about as certain that they suffer as we are when we have to evaluate the suffering other humans (note: we do not usually take our clues from language in the case of humans). See also "Animal Welfare."

Social Ecology: A political and ethical theory which emphasizes the linkages between the domination of powerless humans and the domination of nature. A central idea is that the goals of social justice and those of environmental protection are inseparable. Typically opposed to deep ecology and intellectually close to Marxism or socialism.