



Towards an Ethics Management System For Biotechnology

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the Interdepartmental Working Group
on Ethics and Public Confidence in Biotechnology
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The views expressed in this report are the views of the author and do not necessarily reflect those of the Institute On Governance or its Board of Directors.

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List of Organizations and Acronyms

CBAC	Canadian Biotechnology Advisory Committee (www.cbac-cccb.ca)
CCAC	Canadian Council on Animal Care (www.ccac.ca)
CIHR	Canadian Institutes of Health Research (www.cihr-irsc.gc.ca)
COMEST	World Commission on the Ethics of Scientific Knowledge and Technology (www.unesco.org/ethics/comest/)
FAO	Food and Agriculture Organization of the United Nations (www.fao.org)
–	Genome Canada (www.genomecanada.ca)
HUGO	The Human Genome Organization (www.hugo-international.org/hugo/)
IBC	International Bioethics Committee (www.unesco.org/ibc/index.html)
ISO	International Organization of Standardization (www.iso.ch)
NRC	National Research Council of Canada (www.nrc.ca)
NSERC	Natural Sciences and Engineering Research Council of Canada (www.nserc.ca)
OECD	Organization for Economic Cooperation and Development (www.oecd.org)
SETAC	Society of Environmental Toxicology and Chemistry (www.setac.org)
SSHRC	Social Sciences and Humanities Research Council of Canada (www.sshrc.ca)
UNESCO	United Nations Educational, Scientific & Cultural Organization (www.unesco.org)
UNEP	United Nations Environment Programme (www.unep.org)
WTO	World Trade Organization (www.wto.org)



Introduction

Increasingly, government officials are asked to take ethical considerations into account during regulatory decision-making – and especially in the case of biotech products. It is also clear, however, that ethical issues arise throughout the planning, production, and use of biotech products (i.e., the entire product life cycle) rather than just during the regulatory step. In this paper it is argued that the ethical issues should be considered throughout the product life cycle for two reasons.

First, the scope and role of ethics in regulatory decision-making can only be characterized in its given context. This context is most proximately defined by the ethical issues arising before and after the regulatory step. Understanding this context helps to avoid duplication and conflicts arising from a poor separation of duties or poor harmonization of concepts and standards. Further, if fundamental ethical debates that should take place early on are deferred to the regulatory step then proponents of products are faced with an inefficient and, arguably, unfair system. It is certainly not the intention of regulators to “invite” product submissions that are unacceptable on moral grounds – such a fundamental objection would make product safety and efficacy data irrelevant. In a nutshell, ethical decision-making in the regulatory context is also informed by pre- and post-regulatory considerations.

Second, the Federal Government is not only a regulator. It also plays a role in shaping outcomes throughout other steps in the product life cycle. For example, at the very beginning of the product life cycle (or, arguably, even before the product life cycle starts) it can shape the conditions for innovations through funding priorities and patenting regulations. Towards the end of the life cycle the government may re-evaluate products that are already on the market. Not everything is (or should be) under the influence of government, of course. Very important ethical decisions are also made by industry and by consumers. But governments, and the Federal Government in particular, function as partners in the development of value systems, ethical standards and defensible goals. Therefore, to solely focus on the regulatory role of the Federal Government is not warranted.

As a consequence, it is desirable to develop a framework for determining where in the life cycle ethical issues may arise and may be addressed. This discussion paper is a first attempt at developing such a framework, to identify the life cycle stage at which various ethical issues could be addressed, and the sectors who could have a role in addressing these issues.¹

¹ As opposed to simply describing who currently plays a role.



Conceptions of ‘ethics’ and approaches to ethical analysis are varied. It is, therefore, a good idea to disclose the basic concepts and approaches used in this paper – the following is a very brief summary. I am using a broad conception of ethics that is based on the differentiation of “is” from “ought” – the differentiation of statements describing empirical observations from other (value-laden) statements. This conception is broad because all statements that are not purely descriptive of empirical “facts” have to do with ethics.² I am also using an analytical and discourse-based (investigative) rather than a prescriptive (judgmental) approach to the practice of applied ethics.

I further differentiate three perspectives in ethics. They are closely related to the main traditions in the history of ethics although I use here everyday language. The three perspectives are outlined in **Table 1** – all three are significant to an ethical analysis. I will use some of the various terms contained in this table in the remainder of this text.

Table 1: Three Ethical Perspectives Cast in Everyday Language

(1) Focus on <u>motives</u> (character, attitudes, intentions, values)	
Focus on <u>actions</u>	(2) Focus on <u>consistency</u> (formalistic, universalistic, legalistic, principles, standards, rules and means)
	(3) Focus on <u>flexibility</u> (contextual, utility, case-specific, outcomes, consequences, goal and ends)

² A third category – statements of pure logical reasoning and mathematics – are not covered by this simple classification. In the given context, there is no need to add this category.



What Is A “Life Cycle Assessment”?

The theory and practice of life cycle assessments (LCA) is well developed in the environmental evaluation field. In a nutshell, a life cycle assessment would ideally measure and manage all environmental effects of a product from “cradle” to “grave” – from its production to its exit from the marketplace.³ A key player in the LCA debate is the International Organization of Standardization (ISO) who is developing an Environmental Management System (ISO 14000 series).⁴ Other important players are the Society of Environmental Toxicology and Chemistry (SETAC) that provided early thinking on the issue, and the United Nations Environment Programme (UNEP) that has now entered a partnership with SETAC called “The Life Cycle Initiative.”

Before relating the concept developed by ISO, SETAC and UNEP to the problem at hand, it is useful to illustrate the justification for the current interest in LCAs. The following quote by Klaus Toepfer, current Executive Director of UNEP, provides a clear rationale (underlines and numbers are added):

"Consumers are increasingly interested in the world behind the product⁽¹⁾ they buy. Life cycle thinking⁽²⁾ implies that everyone in the whole chain of a product's life cycle, from cradle to grave, has a responsibility⁽³⁾ and a role to play, taking into account all the relevant external effects. The impacts of all life cycle stages need to be considered comprehensively when taking informed decisions⁽⁴⁾ on production and consumption patterns, policies and management strategies."

A brief analysis of this statement reveals the close interrelationship between “life cycle thinking” and biotech ethics. Consider the four underlined and numbered fragments in the quote above:

- (1) The empirical observation that consumers want to know about “the world behind the product” refers to an increase in interest in the *process* that leads to *products* in the marketplace. For example, consumers are increasingly interested in knowing whether harm was done to either the environment or the welfare of animals during the production process.

³ The United States Environmental Protection Agency offers this useful primer: *LCA 101 – Introduction to LCA*: http://www.epa.gov/ORD/NRMRL/lcaccess/LCA101_printable.pdf

⁴ The ISO is following the success of its Quality Management System (ISO 9000 series of standards).



- (2) Characterizing life cycle assessment as “life cycle thinking” illustrates that a new kind of thinking or perspective is promoted here – we are not simply dealing with a toolkit.
- (3) The reference to “everyone involved has a responsibility” is a characterization of ethics as a pervasive, on-going activity. The responsibility for a product lies neither solely with the producer nor with the regulators – all parties involved are making important decisions and are, therefore, responsible. As a consequence, it would be desirable to compare and relate ethical debates that may emerge throughout the chronology of the production and use of a product (or method).
- (4) The view that informed decisions should be by definition comprehensive is very much an ethical position. University of British Columbia ethics professor Michael McDonald characterizes ethical decisions as decisions that are based on “all things considered.” Comprehensive (“holistic”) thinking has also been a mantra for environmentalists and it is, therefore, not a surprise that life cycle assessment is portrayed this way. However, one need not be an environmentalist to acknowledge that an inventory of all relevant standards and projected harms is a very useful basis for ethical debate. Therefore, the life cycle methodologies developed in the environmental context should be considered for their adaptability to non-environmental contexts.

Relating life cycle thinking to the issue of biotechnology ethics is best done by combining concepts from both ISO⁵ and UNEP/SETAC⁶ and by looking beyond a narrow definition of LCA. An important clarification is necessary here. In ISO’s terms, LCA is only one component of the life cycle thinking that guides its environmental management system. Other standards for “design for environment,” labels, communication, performance evaluation and audit can be considered before or after LCAs are conducted. Similarly, the conceptual chart used by UNEP puts “society’s needs” and “exploration” before the actual product-specific cradle to grave assessment.

This is important in the biotech ethics context because some of the most important issues have to do with the activities that take place before any product has been developed – they have to do with ideas, attitudes of researchers, goals and planned use of methods. To avoid any confusion, it would be best to

⁵ See <http://www.iso.ch/iso/en/prods-services/otherpubs/iso14000/index.html> for a chart of the ISO 14000 model.

⁶ The Life cycle Initiative is described at <http://www.uneptie.org/pc/sustain/lca/lca.htm>



use the broad term “life cycle thinking” rather than the more narrow term “life cycle assessment” when addressing the full breadth of ethical issues associated with biotechnology.

Table 2 below, shows the life cycle chronologies using the terminologies of both ISO and UNEP in the first two columns. Comparing these two columns illustrates that the language used is fairly different although the approach is very similar. In the third column, the life cycle stages identified by ISO and UNEP are applied to biotechnology ethics from a government perspective. Nine different steps can be distinguished in the biotechnology ethics context. They will be discussed in detail further below. The fourth column shows the different groups that are decision-makers at that point in the chronology.

Please note that using these concepts in the biotechnology ethics context should be by no means interpreted as a proposal to adopt the business practices of the ISO or other organizations named in this paper. One should also note that the choice of the different steps and, especially, the choice of the so-called “key players” is in itself an ethical issue. I made an effort to take a balanced approach to the identification of different steps, but understand the list of “key players” as examples only. I put some emphasis on large international and government-related Canadian organizations but remain mostly non-specific when it comes to the players representing industry, environment and animal welfare, international development, patients and consumers, etc. The choice of appropriate partners and external advice is a very complex issue that requires careful planning and justification.



Table 2: Life Cycle Thinking Applied to Biotechnology Ethics

ISO 14000 Model	UNEP LCA Concept	Concepts Applied to Biotech Ethics (From a Government Perspective)	Who
Design for environment (ISO 14062)	Need	(1) Framework setting, proposal, funding, communication	Indu Acad Gov Publ
	Explore		
<u>Life cycle assessment</u> (ISO 14040 series) 1. Goal and scope definition 2. Inventory analysis (inputs and outputs) 3. Impact assessment	Extract (<u>Cradle</u>)	(2) Early research and patenting	Gov Publ
	Refine		
	Manufacture	(3) Product design, development and testing	
	-	(4) Product assessment, regulation, registration, communication	Gov
Labels, declarations (ISO 14020 series)	Use (recycle, reuse)	(5) Market launch (incl. labels and communication)	Indu Gov
		(6) Market surveillance, enforcement, communication, user education	Indu Gov Publ
Communication (ISO 14063)	-	(7) Product re-evaluation	Gov Indu
	Return (<u>Grave</u>)	-	-
Performance evaluation (ISO 14030 series)	-	(8) Evaluate performance of ethics evaluation	Gov Indu
Audit (ISO 19011)	-	(9) Improve governance of ethics evaluation	Indu

Acronyms and Abbreviations:

ISO = International Organization of Standardization
 ISO 14000 = ISO's Environmental Management System
 UNEP = United Nations Environment Programme
 LCA = Life Cycle Assessment
 Who = Who is principally conducting these activities

Indu = Industries
 Acad = Academe
 Gov = Governments
 Publ = Public



A Product-Based Life Cycle Overview

The life cycle overview in this section presents selected ethical issues as they arise in the context of biotechnology. The Government of Canada may neither need nor want to consider all of these issues – the purpose here is to lay them out to facilitate planning of priorities and raise awareness of the role of other organizations or individuals involved in the process.

The ethical issues discussed below do not exist in a vacuum and many of them are not unique to biotechnology. On the contrary, they are in most cases part of an on-going ethics dialogue over funding and research practices, animal welfare, health and environmental ethics, business practices, social justice, the public good, and so forth. However, biotechnology renders some traditional issues much more pressing (they differ in magnitude even if they do not differ in kind). Some biotechnology ethics issues can be considered novel and unique, yet, relevant analogies can be found in other contexts. Therefore, broadening the view can be very helpful and facilitate not only strategic planning, but also the practical task of dealing with selected priority issues (although the broader view may be bewildering at first). For example, consideration of the broader ethical issues leads to an awareness of other groups involved, such as professional associations, academics in related disciplines, research ethics boards working for industry, and so forth.

All nine steps identified above (**Table 2**) are illustrated below with examples (“key issues”), followed by a listing of groups or individuals who should be involved in the debate (“key players”).

(1) Framework setting, proposal, funding, communication

Introduction

Ethical issues arise before the “cradle” stage of a product especially in the case of biotechnology. One could even argue that *the most important* ethical issues arise during the formulation of ideas, goals, and research proposals. Issues may be specific to a planned research proposal or they may open the need to reflect on broader issues such as a re-evaluation of the framework within which funding is taking place. An example of the “broad” issue-type would be research using embryonic stem-cells. In such cases, it is important to analyze where the policy debates should take place (e.g., parliament, civil society, research communities, etc.). These debates will always touch on ethics, political philosophy,



and governance issues because they are debates over fundamental issues that entail broad and significant consequences.

In many instances, the ethical issues will be specific to a particular research project. The term “design for environment” used in the environmental context could be adapted here – product design would ideally conform to the idea of “ethical design” in that both the means and ends are ethically defensible based on a broad consideration of standards and predicted outcomes. Further, like in all other research, ethical issues may emerge during the funding stage. Governments are major contributors to research and have to make choices over research directions. The increased cooperation between industry and universities makes the funding issue more noteworthy than in the past. Finally, some research goals are so controversial (e.g., the “improvement” of the human species) that communication and ethical debate have to be considered as early as possible. This last point applies more to biotechnology than to most other research topics.

Some Key Issues

- How should researchers and society deal with projects that are described as “playing God” by some observers (implying a lack of social responsibility or the immoral attitude of researchers)? Is it sufficient for a researcher to announce “I will be able to create such-and-such (e.g., artificial life, cloned humans, etc.) within the next five years – society should have a debate about it”? How exactly should society deal with such issues? Related: Is there a moral limit (or intrinsic serious risk) that should lead us to prohibit the use of certain means (e.g., human reproductive cloning, human genes in food production) no matter the ends? And is it pragmatically possible to agree on and enforce such prohibitions internationally?
- Currently, research ethics boards in Canada base their operations on the Tri-Council Policy Statement *Ethical Conduct for Research Involving Humans*. Other committees deal with animal welfare issues (using the standards issued by the Canadian Council on Animal Care). These boards and committees do not have a mandate to engage in broad ethical debate. Should their mandate be broadened or should somebody else deal with these issues? Note that the governance of Research Ethics Boards has been identified as an important issue in the recent speech from the throne.
- The increase in partnerships between universities, governments and private industry has many benefits. However, it also comes with its own “costs” (or risks). Classic research ethics issues, such as threats to academic freedom, bias, falsification of data, or misrepresentation of results can



become more pressing in the very dynamic and potentially highly profitable field of biotechnology. Also, government–industry relationships can lead to a loss of public confidence in the stringency and neutrality of regulatory oversight.

- Some issues are so fundamentally important that the political level (and international level) should be engaged in issues arising at this early step. A lack of such engagement can also be considered an ethical (and political) issue worthy of attention. Similarly, the willingness and ability of governments to deal with issues very early on (e.g., the coming convergence between information technology, biotechnology and, perhaps, nanotechnology) should be evaluated from both a political and ethical perspective.
- The evaluation of the pros and cons of stakeholder consultations and input from expert committees has an important ethics component. The use of external input in government decision-making is not straightforward because of the following intrinsic dilemma: (a) if the advice from external bodies must be followed then they, arguably, may have too much power and may undermine democracy; (b) if the advice from external bodies may be ignored, how do you keep them motivated and how do you assure a just and defensible process? At the same time, there exists a clear need and desire to communicate important coming issues to the public.

Some Key Players

- The Canadian Biotechnology Advisory Committee (CBAC)
- Funding agencies (e.g., NSERC, CIHR, SSHRC, Genome Canada)
- Universities, National Research Council, research groups in Government
- Professional associations (e.g., the American Association for the Advancement of Science)
- Research ethics boards (academic and industry), the Canadian Council on Animal Care
- Watchdog organizations (e.g., the Union of Concerned Scientists)
- Patient and consumer groups
- Environmental and international development groups
- Industry associations (e.g., BioteCanada, Biotech Industry Organization); corporations
- Parliament (ideally)
- International organizations (e.g., FAO, HUGO, COMEST, IBC)



(2) Early research and patenting

Introduction

In terms of risk, early research in the laboratory or in confined conditions may be just as important as later research or even full-blown industrial production in the biotech context. Some living agents are highly mobile and invasive. As a consequence, high risk research requires stringent oversight (and perhaps containment) early on. Ethical debates that hinge on outcomes should take place either at this step or sooner. Other research ethics issues, such as animal welfare, may also have to be addressed at this early step. Further, biological research is based on samples, and the ownership and control over these samples is an issue in both the health and environmental sectors. This issue of “bioprospecting” is closely tied to the benefits coming from patents. The biotechnology industry did not grow as soon as new methods became available. Instead, it started to grow once patents on DNA were granted. Because of this tight interrelationship, the standards of the Patent Office influence the direction of the industry (and, thus, the availability of future products) in a very important way – this also illustrates that the discreet steps in the life cycle presented here are interdependent and that they do overlap.

Some Key Issues

- High risk research poses its own ethical issues. Aside from the obvious case of biological weapons research, research into xenotransplantation and other methods that may cause the transmission of diseases from animals into the human population can be considered from an ethical viewpoint. The threat to biodiversity arising from certain environmental uses of biotechnology also falls in this category (e.g., genetically engineered fish has been discussed from this perspective). Stringently enforced containment procedures can mitigate these risks and defer associated issues to the next step (“Product Design, Development and Testing”).
- Biotechnology has led to an increase in the use of laboratory animals (e.g., for immunological methods). This is not a biotech specific ethical issue but, because of the scale, it should be considered. Further, biotechnology also allows the creation of animals that may suffer “by design.” Some research may increase the pressure to use species similar to ours – this should be viewed in the context of the international efforts to save the great apes.⁷
- The origin and use of living materials poses an array of ethical issues. Key topics are the practice of bioprospecting (searching for useful biological materials) and the ownership of human tissues. The

⁷ See <http://www.unep.org/grasp/> and <http://www.greatapeproject.org/>



prospecting for related traditional knowledge should also be considered. Related issues are the ethics of the breadth of patent claims, licencing schemes, farmer's privileges, and the idea of benefit sharing. Finally, the scope of what can be patented can be discussed from an ethical viewpoint (e.g., the moral reasons for the human exemption in the recent CBAC report).

Some Key Players

- Research groups and research ethics boards (especially for research involving human subjects)
- Canadian Council on Animal Care, International Fund for Animal Welfare
- Patent Office
- Owners or custodians of land (e.g., crown land, parks, aboriginal lands)
- International organizations (e.g., WTO, United Nations)
- NGOs engaged in health and environmental issues, and international development
- Patient and consumer groups
- Government bodies dealing with “innovation” and competitiveness of the Canadian industry

(3) Product design, development and testing

Introduction

This is the key stage for an environmental life cycle assessment. In a LCA, an inventory of inputs and outputs can be created and the impacts can then be estimated. In the biotech ethics context this step does not lead to radically different issues when compared to the previous step. In the context of large-scale industrial production (“bioproducts”) the issue of the efficacy of biotechnology products arises. Biotechnology may allow the use of materials currently considered “waste,” improve the efficiency of production, and produce outputs that are less harmful than alternatives. It is important that an ethical analysis does not exclude the consideration of benefits. Traditional LCA will go a long way in addressing these issues. However, it would be possible to broaden LCA measurements of inputs, outputs and impacts and include additional measurements on, for example, parameters relevant to health care and the economy.



Key Issues and Players

- See Step (2). In the case of high-risk research (actual or perceived risk) a host of issues arises in the practice of clinical trials and environmental releases (e.g., concerning informed consent of all affected parties, disclosure of testing sites, evaluation of risks and benefits in the context of who are the risk bearers and beneficiaries, “not in my backyard” issues).
- In considering the results of traditional LCAs one may wish to broaden the framework to include additional parameters of interest. Cooperation with the LCA community would be important to ensure the practicality of such a project. It would also help to understand the ethical issues that arise during the design of an environmental LCA (e.g., the difficulty in justifying the choice of the framework within which measurements are taken).

(4) Product assessment, regulation, registration, communication

Introduction

Compared to many other products, the pressure on risk assessors, managers and communicators to consider non-scientific issues is elevated in the case of biotech regulation. The broad awareness of ethical issues often arises only when products reach the regulatory step, i.e., when the products are fully developed. This is unfortunate because it puts regulators in the uncomfortable position of having to deal with issues that should have been addressed much earlier (e.g., at the proposal step). Adding to the complexity of the situation is input coming from external sources such as ethics or science advisory committees. Finally, because of the potential mobility of many biotech products, regulation often requires international considerations. The “ethics management system” advocated in this paper would improve this situation because it would improve the ability of stakeholders to address issues pro-actively (at the step where the ethical issues arise).

Some Key Issues

- Regulators should make consistent, fair decisions. If biotech products are evaluated differently from other products then (a) biotechnology needs to be defined clearly and (b) the differential treatment must be justified and explained. Both are tricky. For example, does “biotechnology” include featherless chickens, hybrid super-rice and herbicide-resistant wheat, all of which have been developed without genetic engineering (this is very closely related to the so-called *process vs. product* debate)? There are many practical aspects to this issue, but an ethics debate inevitably



emerges alongside because the conception of “biotechnology” is value-laden. One should note here that regulatory science is highly applied because it serves a relatively narrow purpose (when compared to “pure science”). Purposes are defined by values. A good regulatory system is explicit about its built-in value judgments which does not take away from the claim that regulatory systems should be “science-based.” Making values explicit, allows for a better separation of (objective) observations and ethical or political judgments which is necessary for “sound science.”

- Biotechnology is widely expected to have profound impacts on the way we live and the way we see ourselves. One could argue, therefore, that considerations beyond physical risk should be part of the assessment and management of biotech products. Or, at least, biotech should be evaluated based on a very detailed assessment of the structure of beneficiaries and risk bearers. Related to this point is the conception and use of the precautionary approach / principle. How much precaution is appropriate and which conception of precaution can be best reconciled with “science” (and protected from inappropriate use in the international trade context)?
- It seems wise to base complex decisions on a very broad base (indeed, this is the idea stated above of ethical decisions being based on “all things considered”). As a consequence, regulators may want advice and input from science or ethics committees and from the public. This can lead to a host of ethics issues (already discussed under Step 1). A transparent process also demands that the public will need to be informed about approaches (e.g., about how conflicts-of-interest are dealt with) and about decisions (based on good practices of risk communication – the design of which has an ethics component). Further, international cooperation is advisable for products used in trade and products that may move across borders unintentionally – disagreements among nations will lead to political and ethical discussions.

Some Key Players

- Regulators (risk identifiers, assessors, managers, communicators), external advisors to regulators
- Regulatory experts in industry
- User groups (e.g., farmers or patients in need of products)
- International bodies involved in regulatory standards (e.g., OECD, ISO)
- International bodies involved in trade (e.g., WTO)
- For workplace issues (“whistle-blowers”): Integrity officers, ethics officers



(5) Market launch (incl. labels and communication)

Introduction

Not all products entering the consumer's market undergo the same regulatory oversight – the use pattern and product claims influence the regulatory approval required. Nor are all markets the same – for example, one can distinguish domestic and export markets, professional users (such as farmers and doctors) and non-professional consumers. An ethics management system should evaluate the government's role in setting standards to inform users and bystanders in a contextual manner, so that benefits are maximized and harm (and negligence) is minimized. Aside from maximizing overall utility, these standards should also pay attention to the needs of minorities and thus assist with implementing the ideals of fairness and equality.

Some Key Issues

- The labeling of biotech products as “biotech” or “genetically engineered” draws attention to the *process* by which the product was generated. Should “process” be emphasized? The debate over this question has an important ethics component because governments and vendors have to consider value-laden concepts such as precaution, differences in risk tolerance, and differences in the level of tolerance over what is morally acceptable – not to mention whether this last point is sufficient grounds to implement mandatory labeling.
- The need for information by importing nations can be discussed from an ethical viewpoint (e.g., the recent issue over food aid to southern Africa). Also, can “ethics” be sufficient ground for an import moratorium even if the product appears safe in terms of physical risk? This is a complex issue that intersects politics, economic and regulatory systems, cultural preferences, and trade interests.

Some Key Players

- Manufacturing, distribution and retail industries
- Government, diplomats
- Regulators (label claims)



(6) Market surveillance, enforcement, communication, user education

Introduction

Governments enforce standards (e.g., food quality, purity of pharmaceuticals) and sometimes also directly influence the market (e.g., tobacco control programs). When problems are discovered governments not only wish to communicate with industry but also with consumers. There are a number of ethical issues associated with these activities.

Some Key Issues

- How much government interference in the market is defensible? How does one balance the protection of consumers (including patients) with their right to retain autonomy? These issues need to be addressed when initiatives are started that are not strictly mandated (even in the case of a relatively non-intrusive “Informing Canadians About Biotechnology” campaign).
- The arrival of increasing numbers of genetic tests raises ethical issues over their potential misuse by doctors and patients and over potential misinformation by advertisers (e.g., how should a “Your Genome On a CD” product be advertised?).
- The banking of DNA raises privacy concerns. Governments have to think of these in two different ways: (a) what is appropriate for the government functioning as an employer and (b) what are appropriate policies for Canada (e.g., the insurance sector)?
- The advent of gene therapy and genetic counseling gives rise to a number of ethical and technical issues. For example, which forms of gene therapies are appropriate and which are not (e.g., designer babies)? How do we know whether genetic counseling works and what should we do if it does not work?
- Some products will create large financial gains. These products may have been produced, in part, from raw materials derived from specific people, populations or environments. The issue of benefit sharing will arise (see also under “Patents”). Also, some products may cause damage and the issue of liability arises. It would be beneficial if these financial issues were clarified earlier in the life cycle using “what if” scenarios – waiting for these issues to hit the courts is likely not the best way to address them.



Some Key Players

- Manufacturing, distribution and retail industries (and their associations)
- Enforcement bodies of governments
- Consumers and professional users (e.g., farmers, medical professionals)
- Consumer groups, watchdog organizations
- Policy makers

(7) Product re-evaluation

Introduction

The same issues listed under Step (4) also apply here, but additional data and new standards need to be taken into account. This section, however, does not only refer to formal re-evaluations by government regulators. Industry also monitors its products and may decide to re-evaluate label claims, use, user information, etc. Finally, consumer groups are “re-evaluating” products on an on-going basis.

Key Issues and Key Players

- See Step (4)
- Government and industry may want to cooperate on developing standards for industry instruments such as “Responsible Care”⁸ (both these words are ethical concepts) in the biotech context.
- Government and consumer groups may want to cooperate on early warning issues. Such an initiative would be compliant with the concept of “care” and would also give consumer groups and watchdog organizations some credit for their important work (something they may not fully get if they have to function as the critics of government).

⁸ Responsible Care® has been pioneered in 1985 by the Canadian Chemical Producers’ Association and is now supported internationally: <http://www.ccpa.ca/english/who/index.html>



(8) Evaluate performance of ‘ethics evaluation’

To some extent this paper is part of an ethics re-evaluation. It may be wise to explicitly schedule this re-evaluation step (re-evaluation of procedures and substantive issues, rather than re-evaluation of products), thus rendering the “ethics management system” iterative and self-reflective. This would express the desire to develop the best possible system within the given time and resource constraints. Such an evaluation can be done at different levels of consultation. If all indicators of the system indicate a smooth functioning process then consultations do not need to be as extensive as when problems abound.

The commitment to re-evaluate the substance and processes of an ethics management system entails two things. First, the re-evaluation has to be based on some data and, thus, indicators measuring the performance of the system should be put in place beforehand. Second, it is not easy for people to evaluate their own performance. External “audits” (or, at least, external advice) may be helpful in this context.

(9) Improve governance of ‘ethics evaluation’

Re-evaluation does little good if one does not act on it. Enacting change, however, requires a good understanding of the current pragmatic constraints and of the ultimate goals of government. This is the time to consider the very big picture (for example, if the speed of change is the issue then somebody has to seriously think about managing the speed of change). This is also the time to reflect on how pervasive and transformative biotechnology may be (e.g., do policies have to be reviewed at all levels?). Actual changes may, in the end, be very minor but they will be founded on a solid ethical justification.

Overarching and Outside Issues: Some issues cannot be squeezed into the product life cycle outlined above. They are truly overarching in that they have to be dealt with at several or all steps of the life cycle process. Characterizing the “appropriate amount of government control” is such an example. Further, some products are outside of the normal production and market stream. An example is biological warfare (e.g., the production of race-specific diseases using biotechnology) – not to imply that those are being produced in Canada. The overarching issues relate back to the very beginning of this list of 9 steps.



Life Cycle Thinking Applied to Policy Development

The previous chapter suggests that the product evaluation process is a good model to approach ethical issues surrounding biotechnology. One could also argue that the most important use of life-cycle thinking is to apply it directly to *policy*. This approach is somewhat removed from the origin of life cycle methodologies in the environmental field. It is, however, still a useful tool to stress the importance of completeness and “the big picture.”

In policy development one could at least characterize the following 6 steps:

1. Identification of the need for a policy change or new policy
2. Analysis of the key issues and identification of the “owners” of the issue (e.g., jurisdiction)
3. Identification of policy options and choice of instrument
4. Consultation and decision (may or may not require cabinet, may or may not require legislative change) and announcement
5. Implementation
6. Evaluation and revision

Within the product model discussed in the previous chapter, policies may exist in each of the 9 product life cycle steps listed. Therefore, one could consider the policy development cycle as “circles inside the bigger circle” – the latter representing the product cycle. The opposite view is also possible. Policy exists before research takes place, and the product life cycle could be pictured within a bigger policy development cycle. It is doubtful that this ambiguity requires discussion and consensus over the most meaningful concept. It seems likely, however, that the completeness and systematic thinking that emerges from “life cycle thinking” is of practical use. Further, the life cycle classification is relatively value-free because it is based on *chronology* rather than *priority*, leading to classification system that should minimize disagreements based on ideological divergence.



Next Steps

The life cycle overview presented here is a heuristic tool. It can be used for three purposes. First, it can be used to communicate what is meant by “life cycle thinking” and convince readers of the utility that lies in this approach. Second, it can be used as a basis for discussion to answer the question of “How does the Government of Canada (or a particular department) fit into the ethics activities that take place during the life cycle?” Third, it can be used to discuss the question “How should the Government of Canada influence (if at all) the activities beyond its immediate authority, in order to facilitate the emergence of the best possible ethics management system?” Hopefully, addressing these questions will help to (1) improve the network connections among players, (2) identify and address capacity gaps, and (3) ultimately increase the quality, coherence and completeness of ethical decision-making in the biotech context.

