COMMISSION DE L'ÉTHIQUE DE LA SCIENCE ET DE LA TECHNOLOGIE

AVIS

FOR THE ETHICAL MANAGEMENT OF GMOS

Summary, recommendations, and cautionary notes

Québec

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1200, route de l'Église
3e étage, bureau 3.45
Sainte-Foy (Québec)
G1V 4Z2

Production Support

Coordination
Diane Duquet

Meeting Secretary
Richard Blanchette

Research
Richard Blanchette and Diane Duquet, with contributions from Annick Poulin and Édith Tousignant

Writing
Diane Duquet, with contributions from Richard Blanchette, Édith Deleury, Georges Legault and Thérèse Leroux

Summary
André Lemelin and Diane Duquet

Technical Support

Documentation
Monique Blouin

Secretariat
Lauraine Bérard

Communication and Publishing Supervision
Cécile Plourde

Éditing
Renée Dolbec

Cover Design
Bleu Outremer

Design and Layout
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List of working committee members

Édith Deleury, Chair
Faculty of Law
Université Laval
CEST member

André Beauchamp
CEST Chair

Sabin Boily
President, Groupe Minutia (nanotechnology)
CEST member

Georges-Auguste Legault
Faculty of Letters and Human Sciences
Université de Sherbrooke

Thérèse Leroux
Faculty of Law
Université de Montréal

Dr Thomas Maniatis
McGill University Health Centre
McGill University
CEST member

Jorge Passalacqua
Adviser
Office de protection du consommateur

Jean-Guy Parent
Conseil des recherches en pêche et en agroalimentaire du Québec
Ministère de l'Agriculture, des Pêcheries et de l'Alimentation du Québec

Marie-Hélène Parizeau
Faculty of Philosophy
Université Laval

François Pothier
Faculty of Agricultural and Food Sciences
Université Laval
CEST member

Lawrence Smith
Faculty of Veterinary Medicine
Université de Montréal

From the CEST secretariat:

Diane Duquet, CEST Coordinator

Richard Blanchette, Scientific Adviser

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The Commission de l'éthique de la science et de la technologie (CEST) has produced an ethical assessment of genetically modified organisms (GMOs) in follow-up to an earlier Conseil de la science et de la technologie position statement on GMO issues in Québec. Unlike the Council, however, the Commission did not limit itself to genetically modified plants, but also examined microorganisms and transgenic animals. This choice was primarily motivated by its desire to consider the process of transgenesis per se, and not just the products that are the outcome.

The Commission's ethical assessment dealt with the risks and concerns associated with genetically modified products as well as the potential human and social implications of the transgenesis process.

GMOs and transgenesis

A *genetically modified organism* (GMO) is a living organism whose genetic material has been altered through genetic engineering, either to accentuate or add certain characteristics considered to be desirable, or attenuate—or even eliminate—characteristics considered undesirable. GMOs may be used in human or animal food or in silviculture and horticulture; as bioreactors to produce molecules for food, pharmaceutical, or industrial applications; or to create animal models used to study human diseases or perform basic research on complex biological mechanisms.

GMOs are produced by transgenesis, the alteration of an organism's genome. This may consist of removing, moving, or modifying an existing gene or inserting a new gene in order to produce the desired characteristics. In the latter case, it is even possible to cross the species barrier.

Since the advent of agriculture, humans have relied on selection to improve the genetic makeup of plants and animals, crossbreeding individuals bearing sought-after characteristics until the desired results are achieved. Scientific advances made it possible to provoke mutations using chemical substances or ionizing radiation, but the results remained highly unpredictable, and were often negative (instability, sterility).

Unlike earlier methods, transgenesis allows genes to be inserted from any species of plant, animal, or microorganism. In addition, it enables scientists to introduce simple but carefully targeted modifications that produce only the desired characteristic. Used for the first time on microorganisms in 1973, transgenesis makes it easier to work with microorganisms and can be used to increase production of a molecule or colonize a specific environment. Since 1982, it has emerged as an effective replacement for classic methods of animal selection, but has also been used to produce drugs and biomaterials (in the milk of certain mammals), pigs whose organs could be used for human transplants, etc. Used on plants since 1983, it can enhance species diversification, creating plants that secrete biodegradable plastic or a vaccine, for example, or fish with a gene that enhances their resistance to cold.

GMO research is conducted in private labs, universities, and public sector institutions and has attracted the attention of multinationals, well-established local firms, and startups alike. Certain efforts have received funding from multinationals, bioventures (public or private venture capital enterprises), and government programs designed to foster both R&D and related economic spinoffs. This makes it very difficult, if not impossible, to trace an accurate portrait of GMO research in Québec and Canada, identify subjects of research, and determine levels of public and private funding. This situation must change if we are to accurately appraise how research affects GMOs and measure its impact on the development of transgenic products and the assessment of health and environmental risks.

GMO applications: hopes and fears

Microorganisms

GMOs already have numerous applications. Genetic manipulation of microorganisms has considerable potential for research. Examples include modifying yeast to produce proteins for industrial or therapeutic use, or

to create metabolites and precursors for chemistry. GMOs could also provide a more reliable and affordable way to produce drugs (insulin, growth hormones, vaccines) as well as play a role in protecting the environment. In industry, for example, enzymes derived from transgenic organisms are being used to make detergents, transgenic bacteria are helping produce a biodegradable polymer used in fabric manufacturing, and other enzymes are being developed to decontaminate polluted soil.

Genetic modification of microorganisms is undoubtedly the least controversial form of genetic engineering with regard to the risks involved, notably because of the strict controls in the pharmaceutical sector. Microorganisms do not seem to pose any significant allergy or toxicity hazard and show little danger of propagating in the environment. However, we cannot affirm that the release of GMOs into the environment is entirely risk-free.

Plants

In plant transgenesis research, much of the current focus is on basic research, an important tool for advancing our understanding of plant biology. From an agronomic perspective, characteristics developed in transgenic plants (resistance to herbicides, insecticides, viruses, etc.) will mainly benefit farmers, although researchers are also trying to improve the nutritional and flavor characteristics of certain products.

As for the risks associated with GM plants, the latest studies have yet to find any demonstrable scientific evidence of health risks (toxicity, allergenicity). From an environmental standpoint, however, threats to biodiversity, contamination of crops and wild plants, the development of pathogen resistance, and plant toxicity for animals are all potential risks that cannot be overlooked. Should any of them prove to be founded, nature could irreversibly evolve along a new path or change in ways that are difficult to reverse.

Animals

Although numerous animals have been subject to genetic manipulation, very few have been developed—and none commercialized—either as a food source or for therapeutic purposes. However, animal models such as transgenic mice do help us better understand human genetic disorders with a view to developing treatments. In pharmaceutical applications, GM animals are used to produce drugs (and the molecules that go into their fabrication) at lesser cost and in greater quantity. Animal milk, blood, and semen are widely used for this purpose. In agriculture, certain species could be genetically engineered to allow for reductions in herd size without affecting total output. In industrial applications, certain animals could be used as bioreactors to produce biomaterials, a well-known example being the transgenic goat that produces spider silk in its milk. Efforts are also being made to breed a GM pig whose waste contains less phosphorous.

As for the health risks associated with transgenic animals, sources consulted indicate they are on par with those identified for transgenic plants. The main environmental risk is accidental release into the environment, with the exception of transgenic insects, which are purposefully designed to compete with their wild counterparts in the natural environment.

The commercial and economic situation

The Commission has identified four main groups likely to have an economic interest in transgenesis and GMO commercialization: the agrifood and pharmaceutical industries, farmers, governments, and universities. For the time being, industry has been the main beneficiary of GMO research.

In the agrifood sector, the first transgenic commercial crops were introduced in 1995. By 2002, 58.7 million hectares were planted in transgenic crops, 99% of them in just four countries: the United States (39 million ha), Argentina (13.5 million), Canada (3.5 million), and China (2.1 million). The main transgenic crops are soy (63%), corn (21%), cotton (12%), and canola (5%). The big seed corporations who have developed this market also sell the fertilizers, pesticides, and herbicides specially designed for these GM varieties.

In Québec, transgenic crops were valued at approximately $84 million in 2001. Small farms seem to adopt transgenic varieties more readily, apparently because they save time and fuel and require less handling and fewer applications of pesticides and herbicides. Québec and Ontario farmers who planted transgenic corn and soy recorded better yields between 2000 and 2002. But opinions vary widely on how much farmers actually stand to gain from these crops.

Biotechnology firms are increasingly turning their attention to the fast-growing international pharmaceuticals market. Fully 60% of new drugs developed today are genetically engineered. In Québec, nearly 70% of biotech firms are actively involved in the health sector, particularly in the fields of biotherapeutics (22% of companies) and genomics (13%).

The regulatory context

In Canada, the federal government plays a central role in protecting public health through Health Canada and the Canadian Food Inspection Agency (CFIA). The provinces may adopt even more stringent laws in this area if they wish.

Under the *Food and Drugs Act*, Health Canada is responsible for food safety and approving the commercial sale of drugs destined for human use in Canada. Health Canada sets standards and policies for the production of new foods (including GM foods), and has the authority to authorize the sale of transgenic products for human consumption. If there are no health risks involved in consuming products containing the new food, Health Canada will not oppose its commercial release.

CFIA is responsible for issues related to livestock feed and the environment under the *Feeds Act*, the *Seeds Act*, the *Plant Protection Act*, the *Fertilizers Act*, and the *Health of Animals Act*. It ensures that animal feed is safe, effective, and properly labeled. It also has the authority to approve field trials of transgenic plants intended for large-scale farming and to issue import permits for new types of plants, whatever their end use.

In Québec, the *Food Products Act* covers both health and environmental matters. Under this law, the government may prescribe rules "respecting the sale of a product, the production, preservation, handling, preparation, conditioning, processing, transportation or stamping of a product or the storing of a product with intent to sell it." The main authorities responsible for administering the act are Ministère de l'Agriculture, des Pêcheries et de l'Alimentation and Ministère de l'Environnement, along with their partners from Filière agroalimentaire du Québec. In 1996, Québec also introduced a strategy and action plan to implement the UN Convention on Biological Diversity. Furthermore, Québec's government was the first in Canada to support the Carthagena Protocol on Biosafety.

At the international level, a number of organizations and treaties ensure food and environmental safety, including the Codex Alimentarius Commission, the World Trade Organization (WTO), the Convention on Biological Diversity, the Carthagena Protocol, and the International Harmonization Conference on therapeutic products.

Assessing risks

Approaches to risk assessment draw on different conceptions of GMOs, one based on method (the process), the other on results (the product). The process-based conception has led to the adoption of the precautionary principle characteristic of the European approach, whereas the product-based conception underlies the notion of substantial equivalence—assessing the equivalence of similar products—at the heart of the American and Canadian approach.

For the European Union, transgenic food products are different from normal food products. This led to a moratorium on the sale of GM foods in certain countries of the European Community in 1999. New regulations on labeling and traceability adopted by the European Parliament in July 2003 should pave the way to the lifting of the moratorium. These regulations will make it possible to trace GMOs and ensure that all products containing them are labeled appropriately. The minimum threshold for determining if products contain GMOs has been set at 0.9%. This threshold is 5% in Japan and Korea, as well as in Canada (note that labeling in Canada is voluntary).

In the United States and Canada, products deemed substantially equivalent to existing products are subject to normal regulatory approval. This is why both countries, unlike Europe, see no need for special GMO labeling requirements or for a traceability system that leads back to the producer (and ensures producer accountability for safety).

Health Canada safety evaluations are based on the principle of substantial equivalence, which is defined as a "comparison of molecular, compositional, and nutritional data for the modified organism to those of its traditional counterpart, where such exists." For environmental issues, all entities (businesses, researchers) wishing to test non-approved transgenic plants must apply for CFIA approval. Before authorizing trials in an

open environment, CFIA assesses the potential risk of the transgenic product for the environment.

Health Canada and CFIA share responsibility for food labeling policy. Currently, labeling of GMO's intended for human consumption is voluntary, except in certain cases where specific risks have been identified. A voluntary standard is under development by the Canadian Council of Grocery Distributors and the Canadian General Standards Board.

Canada currently has no GMO traceability system in place to help determine the identity, history, and source of products and potentially serve as a tool in implementing product recalls.

Although Québec has yet to introduce any labeling procedures, Filière agroalimentaire members adopted a position in favor of labeling in January 2000, albeit without indicating whether it should be compulsory or voluntary. As for traceability, Ministère de l'Agriculture, des Pêcheries et de l'Alimentation and Union des Producteurs agricoles have set up Agri-tracabilité Québec to help establish a traceability system for agricultural products. The system will first be implemented for cattle (and harmonized with the federal Cattle Identification Program), then extended to plants.

In a January 2003 discussion paper, the currently elected Québec Liberal Party announced its plans to modernize regulations and information available to consumers. It promised to "speed up implementation of compulsory traceability systems throughout the food chain"; "develop a compulsory labeling policy for all foods containing GMOs"; and "implement the necessary framework for the safe development of biotechnology, nutraceuticals, new reproductive technologies, transgenesis, etc." The Liberal Party also promised to "make information available to consumers about the impact of biotechnology on health and the environment" and "increase, in cooperation with the Canadian government, the availability of biofood research funding."

Initial observations

Scientific uncertainty. The overview of actual and apprehended GMO risks in the first chapter of the position statement clearly reveals the current gaps in scientific knowledge regarding the pleiotropic or unanticipated effects of GMOs and their long term impact on health and the environment. In addition, as described in Chapter 2, risk assessments carried out for the approval of GM products do not provide all necessary or desired guarantees of safety. In fact, scientific evaluation of GMOs that does not systematically take into account the values underlying risk assessment is in itself ethically problematic. In the Commission's view, current research and techniques for scientifically evaluating GMO safety do not allow for a complete assessment of GMO impacts on health and the environment.

Insufficient attention paid to process. Most of the documents consulted by the Commission made little distinction between genetically modified products and the process they derive from. Yet, as the differences between European and North American perspectives and laws on GMOs clearly show, the GMO conception underlying risk assessment practices is crucial to determining the approach and the regulations adopted. This led the Commission to establish a distinction between product and process that it views as fundamental to its ethical evaluation. But first, the Commission summarizes in Chapter 3 the approach it adopted for assessing and analyzing ethical issues related to GMOs

An ethical approach to evaluation

Numerous reports on GMOs have been produced by organizations worldwide. Most raise social and ethical concerns linked to the actual or apprehended risks associated with GMOs. In order to situate the challenges of assessing ethics in a democratic society, the Commission took a closer look at the approaches underlying these reports in order to identify the ethical issues raised by GMOs and the grounds on which to base its own ethical evaluation. In most of the reports, the opinion expressed refers to rights recognized by major international instruments and to commonly held principles and values in democratic societies.

The Commission has identified three dimensions to the challenge of evaluating ethics in democratic, pluralist Western societies. The first is the widespread notion that ethics are an exclusively private matter of no concern to the government decision-making process. The second is the existence of multiple ethical and moral points of view. The third lies in choosing, explaining, and operationalizing the principles and values framing an ethical evaluation.

Taking its lead from Denmark, the Science and Technology Ethics Commission believes that ethical debates must address social choices and refuses to confine ethics to the private sphere or to the simple matter of GMO acceptability among the public—i.e., an opinion poll. The Commission situates the framework of its reflection and ethical evaluation by reviewing the role of moral theory in assessing GMOs and clarifying the role that values and principles play. Ethical evaluation of GMOs may be informed by the moral obligations imposed upon us all by the very nature of consciousness itself (Kant), or by the values that legitimate our obligations, to the extent that these values are constitutive of human nature.

The precautionary principle is frequently confused with the notion of prevention. Whereas prevention means controlling proven risks, precaution involves limiting hypothetical risks. The precautionary principle is inspired by Hans Jonas' approach to morals inasmuch as it encourages states to take the necessary steps to prevent grave, irreversible damage and to protect the lives of present and future generations. The position of this philosopher is a benchmark given the frequent links made between his "principle of responsibility" and the precautionary principle. From a moral perspective, the precautionary principle is highly restrictive, with an obligation to act on potential risks as soon as they are identified.

The approach

Rather than adopt the precautionary *principle*, the Commission opted instead for a precautionary *approach*, which offers more flexibility in dealing with the scientific uncertainties of risk assessment. The Commission believes that this approach to risk management takes potential health and environmental impacts into account—even in the absence of scientific certainty—but without hindering decision making. The approach is designed to seek a balance between technological innovation and risk management, and is weighted toward caution in the face of uncertainty. By purposefully adopting the notion of a cautionary *approach*, the Commission intends to ensure that economic value is also taken into consideration when risk management measures are adopted.

After discussing the matter, the Commission chose a valued-based evaluation of GMOs inspired by the development of applied ethics in North American democracies. The ethical evaluation can be divided into six steps: understanding the situation; ascertaining the risks; identifying and analyzing the consequences; pinpointing and clarifying the values at issue; characterizing value conflicts and value hierarchies; and developing a practical rationale to justify decisions and recommendations.

Ethical evaluation of genetically modified *products*

In analyzing GMO risks and concerns, the Commission selected four values as the basis for its ethical assessment of issues related to GMO products: human health, the environment, the economy, and public trust in the government organizations responsible for managing GMO issues.

Health is a core value in all economically advanced Western nations. According to current scientific knowledge and evaluation methods, there is no real health risk in consuming GMO or GMO-derived products. However, these methods do not allow us to predict unanticipated effects or cumulative long term effects of transgenic products—or any other new product for that matter. Furthermore, the Commission cannot understate the importance of ensuring the safety of GMO products used in animal feed, not only to protect animal health, but because these products end up in products destined for human consumption. Overall then, the Commission believes that the current state of uncertainty is sufficient to warrant a precautionary approach.

Quality of the environment is another value of constantly increasing importance. There is a strong ethical impulse to take the environment into account in decision making, no matter what system of representation citizens live under. The power to directly modify life can be seen as a risk not only for humankind, but for the very future of life on earth, which explains the stiff resistance to GMOs in certain quarters.

GMO production helps stimulate *economic growth* in industrialized countries. For the time being, GMO products benefit a select few (notably biotech industries), but with time, their benefits could also extent to governments, and even consumers. For the Commission, the economy is important. It recognizes that any tightening of GMO approval and marketing regulations will affect the cost of GMO products and that those costs

may well be passed on to farmers and consumers. In the Commission's eyes, health and the environment must take precedence over economic value, but not overshadow it entirely.

Severe criticisms have been leveled at the Canadian evaluation and approval process. The public has expressed reservations about government agencies and their expert advisers, and has concerns about the safety of measures put in place to protect public health and the environment. Criticisms of current control and monitoring mechanisms raise questions about the independence of the federal government's regulatory role in agricultural technology vis-à-vis its role as a technology promoter, particularly with regard to CFIA. These are issues of transparency and legitimacy in decision-making that could, at worst, provoke widespread public doubts about the independence of the experts responsible for assessing GMO risks. This is why the Commission has also selected *public trust* as a value, alongside health, the environment, and the economy.

As part of its ethical evaluation of genetically modified *products*, the Commission has formulated seven recommendations. These recommendations draw on the identification of value conflicts related to specific aspects of the GMO question. They also derive from the Commission's decision to give precedence to certain values over others in decisions likely to affect the public or certain segments of the public. The recommendations formulated by the Commission follow upon each other in an increasingly specific graduated progression.

Recommandation no. 1

The Commission believes that it is crucial to reinforce public confidence in the bodies responsible for public safety and environmental protection. The public must be certain that there is no interference between government agency roles as biotechnology promoters and biotechnology control bodies, that health and environmental protection are not contingent to the anticipated economic spinoffs of biotechnology development, and that society is not treated as a vast laboratory.

The Commission recommends

that in order to assure the public that health and environmental protection are its main priorities, the Government of Québec take the necessary steps to ensure that Government of Canada regulatory requirements for the approval, control, and long term monitoring of GMOs—no matter what their area of application—are more stringent than existing standards for new products.

Recommandation no. 2

Considering that caution is an appropriate attitude in the face of legitimate public fears and concerns, to what extent should such requirements be reinforced? In the Commission's view, new food products need not be subject to the same standards of approval as drugs and other therapeutic products. However, uncertainties must be taken into account and government must act as if GMOs could pose a serious potential danger. The Commission therefore believes that rigorous scientific evaluation is sufficient to protect human health and the environment. It also deems that current evaluation methods that treat new products and transgenic products the same way cannot adequately take into account the apprehended risks and *potential* effects of GMOs on health and the environment. By stopping short of a call for the same level of evaluation standards as for drug approvals, the Commission seeks to mitigate the economic impact while at the same time reinforcing public and environmental safety.

The Commission recommends[1]

that the Government of Québec take steps to ensure that the Government of Canada subject GMO approvals to scientific evaluation that takes into account not only the foreseeable risks, but also the *potential* effects of these organisms on human and animal health and the environment.

Recommandation no. 3

The Commission considers that scientific evaluations required under the existing new product approval process—including transgenic products—do not adequately account for the special nature of GMO-derived products. It also believes current methods have

1. This recommendation is inspired by the first part of Royal Society of Canada Recommendation 7.1.

limitations that could potentially impact on health and the environment. In keeping with the cautionary approach adopted for the evaluation, the Commission believes that regulatory measures must not be based solely on levels of certainty or science's current ability to measure risk, and that it is advisable to specify the requirements of such an approach.

The Commission recommends[2]

that the Government of Québec take action with the Government of Canada to ensure that when scientific arguments exist suggesting a product may have undesirable effects on the environment or human or animal health, regulatory bodies like CFIA and Health Canada apply the same rules for real and proven risks to assess the potential and apprehended risks—even if available tests do not allow these risks to be identified with high levels of certainty or to be accurately measured.

Recommandation no. 4

In the Commission's view, approval requirements for transgenic products must take into account both scientific and cultural considerations, and must therefore be based not only on facts, but on criteria of public acceptability. This requires an interdisciplinary approach. Furthermore, considering that transparency is a crucial democratic value for public governance and that it represents a non-paternalistic approach to dealing with the public, the Commission believes that findings that lead to the approval of transgenic products must be in the public domain.

The Commission recommends

that the Government of Québec intervene with the Government of Canada

a) to ensure that the assessment of transgenic products for environmental and human and animal health risks is conducted in open consultation with a Commission made up of independent experts from the natural and social sciences[3] and, where appropriate, members of the public; and

b) to ensure that the expert Commission, in the interests of transparency, makes its work public and readily available.

Recommandation no. 5

There are two possible approaches to establishing the burden of proof for GMO approval. Under the first, the government is responsible for proving that a product represents too great a risk to be approved. Under the second, businesses are responsible for proving that their products have passed all regulation testing and meet all regulatory standards. The Commission believes that the second approach is the right one. Given that companies are the first to benefit economically from transgenesis, it is not the government's role to assume the onus of proof at public expense. The principle of good governance must apply and to this effect, the government must possess all the information it needs to ensure that product evaluations meet regulatory requirements and to make the information public.

The Commission recommends

a) that biotechnology companies be required—at their own expense—to demonstrate that evaluations of their transgenic products comply with regulation procedures and to provide all necessary proof of the findings obtained; and

b) that all data from regulation product approval testing be made readily available to the public, including previous test results from products that did not lead to product approval.

Recommandation no. 6

For evaluations based on the principle of substantial equivalence, equivalence must not be assumed, but proven; otherwise, the appearance of new toxins will go unnoticed. This requires monitoring of transgenic products, especially periodic testing for short, medium, and long term effects on health and the environment. Health Canada has already taken steps in this direction. Also crucial is the ability to trace the origin of these products in the event of a safety or environmental incident. In the Commission's view, a traceability system is essential. Members of the Commission members are aware of the associated costs, but the measure is in keeping with the precautionary approach they

2. This recommendation follows upon Royal Society of Canada Recommendation 8.3.

3. This part of the recommendation is inspired by recommendations 7.2 and 7.3 of the Royal Society of Canada report.

recommend. Moreover, a traceability system could soon prove indispensable in international trade. However, system costs should be borne by the biotechnology firms that produce GMOs.

The Commission recommends

that the Government of Québec require that all organizations concerned implement GMO traceability mechanisms in order to

a) enable authorities to quickly trace the origin of genetically modified products in the event of safety or environmental problems; and

b) provide for regular assessment of the short, medium, and long term effects of GMOs on the environment and human and animal health.

Recommandation no. 7

In light of research efforts to reduce the uncertainty surrounding the impact of transgenic products, the Commission is in favor of implementing a research monitoring process and continuous auditing of approval, control, and monitoring measures under the supervision of a multidisciplinary group of experts. The Commission is concerned about the possible effects of transgenesis on biodiversity, effects that range from the potential extinction of certain plants and animals to the introduction of new species with the potential to disturb or transform ecosystems. It believes that Québec should set up a biodiversity observatory to track developments and react effectively to problems as they arise.

The Commission recommends

a) that the Government of Québec take steps to have the Government of Canada implement a mechanism to continuously audit GMO approval processes and procedures in open consultation with the expert community;

b) that Canadian and Québec grant agencies, along with other organizations in a position to fund research (certain sectoral departments and organizations like Genome Canada and Génome Québec, for example), establish research programs to ensure that GMO assessments are based on the latest knowledge in the field; and

c) that the Québec government set up a biodiversity observatory to monitor, among other things, the impact of transgenesis on plant and animal biodiversity.

Ethical evaluation of the GMO process

In its ethical evaluation of the process of transgenesis, the Commission addresses the potential impacts of transgenesis on society and the population. The many applications of transgenesis as a technology raise numerous value-related ethical issues. In this light, the Commission decided to stress the value of community, from the perspective of a pluralistic and democratic society that promotes the respect and autonomy of all citizens, no matter what their culture, convictions, or beliefs. Relations with those different from ourselves are a key issue in ethics. The challenge of living in a community is to build a stable social environment. Like all values, it is an ideal never fully achieved, but made possible by tolerance. Establishing a relationship with others assumes that we recognize their independence, which is the very basis of our ability to make individual and group decisions. This gives rise to the need for clear, accurate, and objective information, an ethical imperative for the provision of free and informed consent.

Ethical evaluation of GMOs must identify the context GMO products are used in order to determine their potential impact on our social organization and collective and individual welfare. People are at the center of Commission preoccupations. We all "experience" GMOs even if we do not consume them, which is reason enough to intervene at the ethical level to ensure that decision makers' choices are also informed by human values as related to community. The Commission looked at ethical issues raised by GMOs in relation to agricultural production on the one hand, and to the symbolic and spiritual representations of various groups making up Québec society on the other. It concluded its reflection by addressing the question of freedom of choice and the public's role in decision making.

The Commission formulated only two recommendations regarding the process of transgenesis. Given the complexity and scope of the ethical considerations and concerns engendered by such a process, the Commission preferred to alert political authorities to the human and social aspects to be considered in any GMO-related decision. As a result, it focused on formulating cautions that draw the attention of decision makers to aspects of the GMO question that are less well covered, and perhaps less well known or recognized.

Local and international agricultural production

For a long time, and increasingly so, farms have benefited from scientific and technical progress. Farmers and livestock producers have adapted their lifestyles and taken advantage of these advances to complement their traditional knowledge. The Commission examined the potential impact of GMOs on the farm lifestyle, especially the following aspects: farmer independence, coexistence of different crops and growing practices, and, briefly, the fate of the developing countries. It found that GMOs are just one aspect of a debate on the future of Québec agriculture that has yet to be held, particularly regarding the preferred mode of production, the type of food to be produced, and the most appropriate technology. The GMO controversy highlights the need for a debate on the relationship between genetics, farming communities, and society as a whole.

Once a way of life, farming is now a way to earn a living. The idyllic picture of farm life, with the farmer as his own master, still survives, but is gradually being supplanted by a vision of the farmer as small businessman who juggles with the constraints of managing a business and is no longer independent. With the advent of the GMO industry and controls on transgenic crops, that independence is likely to shrink even further, if not disappear entirely. Producers are increasingly dependent on their suppliers, who decide which seeds are the most profitable to genetically engineer, protect them with patents, prohibit farmers from reusing them, and sell them for a healthy profit. As for government agencies, they impose rules designed to limit pollen propagation, prevent contamination of related species in the vicinity, and provide shelter to insect pests. Perhaps production gains will make up for a certain loss of independence, but the Commission obviously cannot reach any conclusions in this regard.

FIRST COMMISSION CAUTIONARY NOTE

The Commission would like to draw attention to the risk of dependency for farmers growing transgenic crops. Farmers should be well informed before switching to transgenic varieties and should be fully aware that until proven otherwise or until biotechnology evolves further, transgenic crop profitability remains uncertain.

Freedom of choice for farmers is another issue almost never addressed in GMO documentation. There is public demand for fresh produce from small-scale farms that focus on quality and flavor and avoid chemical pesticides. However, due to the risk of contamination, transgenic crops make poor bedfellows for conventional and organic crops. As a result, the farmers who plant GMO crops could end up imposing their choice on fellow producers without their consent and to their detriment, limiting consumer choice in the process.

SECOND COMMISSION CAUTIONARY NOTE

To what extent do GMO crops hinder community by limiting the freedom of farmers and indirectly imposing a monolithic approach to agriculture? At present, the Commission believes that GMO crops encroach upon the right of farmers to choose the style of farming and type of crops most suitable to them. More than ever, GMOs illustrate the old maxim that one's freedom ends where the freedom of others begins. Government has a social responsibility it cannot ignore if it wishes to promote GMOs while maintaining crop diversity and varied growing practices.

When the issue of GMO crops is raised, the future of the developing countries is one of the topics sparking the most heated debate—debate in which the voices of those directly concerned too often take a back seat. This issue being much too complex to deal with in a few lines, the Commission only highlights certain key aspects. On the one hand, the Commission recognizes that GMOs could potentially benefit countries afflicted by drought, soil salinity, and crop destruction by insect pests, as well as widespread dietary deficiencies. Should genetic engineering fulfill its promise, transgenic crops could conceivably improve public health and crop productivity and increase farmer incomes. On the other hand, the introduction of transgenic crops could also have major social impacts in these countries. GM crops tend to promote intensive agriculture, whereas developing nations have to focus on subsistence-oriented agriculture to meet the needs of their populations. Already, the trend toward export crops has come at the detriment of local food supplies. Another aspect deserving consideration is the issue of environmental protection and monitoring in situations where farmers lack training and there are no monitoring agencies present. Lastly, the issue of patent protection takes on added importance in countries where the cost of purchasing GMO inputs is prohibitive, given people's limited capacity to pay.

THIRD COMMISSION CAUTIONARY NOTE

For the Commission, it is clear that the developed countries must take the issue of transgenic crops in developing countries into account in decisions on food aid, international trade, and intellectual property. The Canadian Biotechnology Advisory Commission has already examined this issue and made a number of valuable recommendations.[4] The Québec Commission felt compelled to point out that these countries must have a voice in the debate on these issues.

Cultural and spiritual representations

The way in which we represent human beings and life itself has been irrevocably altered by scientific breakthroughs in biology. Humans share much of their genome with species considered as inferior. So what makes a person human? Many view transgenesis as a Trojan horse set to unleash a technological nightmare. Apocalyptic predictions about scientific progress are nothing new, of course, but how can we explain the public's reaction to GMOs? Recurring themes raised in public debate include questions about the legitimacy of transferring genes between species, and even kingdoms; man's abuse of power over nature; and the legitimacy of commodifying life. Could these changes impact on community or impose a monolithic vision of the world where the artificial is king? The Commission sought to understand the roots of these questions through the symbolic representations of Québec society. It examined representations of humankind's place in the universe, our responsibility toward nature, and the dietary laws imposed by various cultural and spiritual groups. It also reflected on the commodification of life.

The Commission looked at the three so-called religions of the book, Christianity, Judaism, and Islam. Each of these religions sets forth precepts to be followed during the course of one's earthly life in order to have access to the great beyond when one's time comes. Buddhism represents a different tradition with a less rigid framework. It was also considered by the Commission given that it is practiced in certain communities and is attracting growing numbers of Christians. Lastly, the Commission looked at the representations of our native peoples, whose presence in Québec is of significant historical importance.

The line of questioning was as follows: ***Is it legitimate for humans to interfere with nature? And if biotechnology imposes itself de facto, can diverse spiritual and culture representations continue to coexist in the spirit of community at the foundation of a pluralist society?***

In *Christianity*, sacredness resides within human beings, and it is they who instill creation with the potential for sacrality. However, this tradition has given rise to two opposing conceptions: on the one hand, humans are expected to dominate nature, and on the other, they are to preserve it to the best of their ability. *Judaism* admits the mastery of nature and human use of other species, but here as well, two traditions come into conflict: according to the first, humans have been given the power to build a better world, according to their best judgment; according to the second, the order of creation cannot be altered, because doing so would imply some imperfection in God's design. In short, there exists in Judaism an ethical dilemma between the praise of knowledge and the praise of caution. In the *Islamic* tradition, humans are recognized as enlightened caretakers of nature, with the sacred duty to protect it. They must strike a balance between their role as replacements for God invested with the responsibility of perpetuating his work, and their role as servants of God who must submit to forces of nature greater than themselves. In the *Buddhist* tradition, humans do not hold any special place within nature, and must therefore not enslave nature in satisfying their desires. The relationship with nature must be harmonious, which gives rise to an environmental ethic. In the *holistic native vision*, relations between the entities of the visible and invisible world are characterized by reciprocity and interdependence. Altering nature is viewed as an irresponsible act. And any attempt to manipulate the genetic material of living organisms is considered to be a form of biocolonialism and a violation of their identity.

This schematic overview shows that the representations of life associated with transgenesis could well come into conflict with prevailing symbolic, cultural, and spiritual representations in Québec society and spark anti-GMO sentiment within the population.

The issue of dietary laws is especially relevant to the GMO debate due to possible transfer of genetic material between species and kingdoms. This runs counter to the notion of food "purity" required by certain religions. A no-label policy for GMO foods could force believers to violate their religious precepts in matters of food.

4. Especially recommendations 8.2 and 8.3

Although *Christianity* does not have dietary laws, the question is particularly complex in the *Jewish tradition*, where it is important to know what is in the food you eat. Whether DNA is food has yet to be determined. In the *Islamic tradition*, dietary law is very important, and specifies foods that are lawful, forbidden, or questionable. There are two divergent currents of thought regarding transgenic foods—that of the Sunni and Shiite authorities in the Middle East, and that of Western Islam. Under *Buddhism*, eating meat is largely forbidden, except in certain schools of thought. As for the *native tradition*, food prohibitions derive from the imperatives of hunting and center around the key notions of sharing and reciprocity. At this time, no particular opinion about eating GMO foods prevails.

The nature of modern food complicates matters greatly for certain believers wishing to respect their traditions. Things are complicated even further by the arrival on the market of barely detectable GMOs that people may consume without their knowledge due to a lack of proper labeling. In a pluralist, democratic society, these are aspects that should be taken into consideration in the ethical debate on freedom of choice.

The expression "commodification" of life refers to any conception that reduces life to its physical and chemical components and views vital processes as simple physical processes. Aware of the important issues this conception raises, the Commission has selected four that should be the subject of in-depth multidisciplinary research:

Coexistence of cultural diversity– If GMOs come into widespread use in agriculture, we run the risk of developing a monolithic conception of food, and even a monolithic vision of the world, with one kind of producer and one kind of product, thereby depriving consumers of their freedom of choice.

Cultural destruction– When Western culture came into contact with native culture, it left it deeply scared; the integration of biotechnology and the commodification of nature appear to run counter to efforts to revitalize native culture.

Dehumanization of humankind– Transgenesis provides us with considerable power over life and the ability to transform living organisms. How far will we go in using these techniques on humans? When will we see eugenics and cloning?

Owning life– The issue of owning life permeates the entire biotechnology debate in light of a patent system designed to protect intellectual property and encourage R&D. The Commission does not deny the need for such mechanisms, but considers this to be a fundamental issue requiring profound reflection and debate.

FOURTH COMMISSION CAUTIONARY NOTE

In light of its views on the impact of transgenesis on cultural and spiritual representations, the Commission believes that society should develop a means of counterbalancing the current trend toward the commodification of life and averting a certain dehumanization.

The ability to exercise freedom of choice and contribute to decision making

The central mission of the CEST is to democratize science and technology. Through its reflections and work, the Commission puts people and the future of society at the forefront of its concerns. The very exercise of democracy requires access to information to make informed decisions. Yet information in circulation about GMOs seems to leave consumers with little opportunity to assess the arguments on the anticipated benefits of this technology and the health and environmental risks it may cause. The general public would also benefit from access to more specific information on the results of tests required for the approval and sale of transgenic products. The Commission reiterates the need for federal and provincial bodies to provide the population with all relevant information. We must avoid a situation where the choices of individual producers deprive society of the material means to live according to its values, just as we must avoid depriving producers of their freedom to choose. Lastly, the Commission notes that the government cannot impose risks upon the public, however small, without its knowledge.

Proper labeling is the only way to enable people to exercise their product preferences. Huge strides have been made in this area, with more and more products carrying nutrition information. From now on, GMO labeling must cover the issues of representations, dietary law, and concerns over potential health risks.

Recommandation no. 8

The Commission recommends

That the Government of Québec, alone or in cooperation with the Government of Canada, impose compulsory labeling on all transgenic products to allow consumers to exercise their freedom of choice in an informed manner.

In its position statement entitled *The Ethical Issues of Genetic Databases: Towards Democratic and Responsible Regulation* (2003)[5], the Commission devoted an entire chapter to the democratic management of ethical issues. Readers are invited to consult this previous document for a more detailed point of view. GMOs are a test case for public involvement in decision making. Food is part of our daily existence. Political decisions affecting food must therefore take the views of the entire population into account. Yet with few exceptions, opinion polls on biotechnology and GMOs always yield the same results, results reflecting personal perceptions more than informed opinions.

The Commission believes that political decisions regarding matters of food—GMOs obviously included—must take into account public views, expectations, and fears on the topic or on the impact of this new technology on health and the environment. The vast GMO consultation in the United Kingdom is a good example, and should serve as inspiration for decision-making authorities. Of course, public opinion must be based on objective information designed to meet the public's need to understand the ins and outs of the GMO controversy. In this opinion statement, the Commission sought to present the most comprehensive and objective information possible in order to provide a foundation for a rational, nonpartisan debate on the question. It is only on this condition that public debate will inspire public authorities and provide a basis for their decisions regarding GMOs.

Recommandation no. 9

The Commission recommends

that the Government of Québec, prior to making any decision regarding GMOs, hold an informed public debate on the issue—i.e., that it inform the public about the pros and cons of GMOs, government orientations on the matter, and the values it intends to promote in its policies—so that Québec's population can make known its views, expectations, and fears about GMOs.

In conclusion, the Commission hopes the government will pay careful attention to this position statement on GMO ethical issues, along with the other scientific, economic, and legal opinions it receives, in reaching decisions on GMO-related matters.

5. In French only : « Les enjeux éthiques des banques d'information génétique : pour un encadrement responsable et démocratique ». However, a « Position Statement : Summary and recommendations » is available in English and in Spanish on the Commission's website – http://www.ethique.gouv.qc.ca.

Members of the Commission de l'éthique de la science et de la technologie

Chair :

Mr. André Beauchamp
President
Enviro-Sage

Members :

Mr. Sabin Boily
Founding president
Groupe Minutia (nanotechnology)

Mr. Yves Boisvert[1]
Professor
École nationale d'administration publique (ÉNAP)

Mr. David Boucher
Graduate Student
Université du Québec à Rimouski

Ms Édith Deleury
Professor – Faculty of Law
Université Laval

Mr. Jean-Claude Guédon
Professor – Faculty of Arts and Science
Université de Montréal

Ms Michèle S. Jean
Chairperson of the UNESCO International Bioethics Committee
Program Development Consultant – Faculty of Higher Education
Université de Montréal

Dr Thomas Maniatis
McGill University Health Centre
McGill University

Ms Isabelle Montpetit
Science journalist
CBC – Radio-Canada

Ms Nicole O'Bomsawin
Director
Abenaki Museum of Odanak

Ms Johane Patenaude
Professor of Ethics – Faculty of Medicine
Université de Sherbrooke

Mr. François Pothier
Professor – Faculty of Agricultural and Food Sciences
Université Laval

Ms Louise Rozon
Director
Option consommateurs

Guest Members :

Ms Anne Marcoux[2]
Jurist
Conseil de la santé et du bien-être

Mr. Guy Turcotte
Associate Deputy Minister
Ministère des Relations avec les citoyens et de l'Immigration (Québec)

Coordinator :

Ms Diane Duquet

1. Until April 2003.
2. Until December 2002.