option consommateurs
l'association des consommateurs du québec

Consumer Involvement in the Regulation of Genetically Modified Foods and Crops in Canada

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For: Office of Consumer Affairs, Industry Canada

2004

OPTION CONSOMMATEURS

MISSION

Option consommateurs is a nonprofit association whose mission is to defend and promote consumers' rights by assisting them both individually and collectively, by providing them with information, and by advocating on their behalf to decision-makers.

HISTORY

The association has existed since 1983. In 1999, it merged with the Association des consommateurs du Québec (ACQ), an organization with a 50-year history and a mission similar to that of Option consommateurs.

PRINCIPAL ACTIVITIES

Option consommateurs's staff of 20 are grouped into four departments: the Budgeting Department, the Legal Affairs Department, the Media Relations Department, and the Research and Representation Department. Over the years, Option consommateurs has developed expertise in the areas of financial services, health, agri-food, energy, travel, access to justice, trade practices, indebtedness, and protection of privacy. Each year, we reach 7,000–10,000 consumers directly and many more through our extensive media coverage. We participate in working groups and sit on boards of directors, carry out large-scale projects with important partners, and produce research reports, policy papers, buyer's guides, and a consumer information and action magazine called *Consommation*.

MEMBERSHIP

Option consommateurs pursues a variety of activities aimed at making change, including research, class-action lawsuits, and lobbying of public- and private-sector bodies. You can help us do more for you by becoming a member of Option consommateurs at www.option-consommateurs.org.

ACKNOWLEDGMENTS

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EXECUTIVE SUMMARY

The Canadian regulatory process for foods and crops derived from genetic engineering (GM foods and crops) has its strengths and its weaknesses. Like those of the United States, the European Union countries, Australia and New Zealand, it stands to be improved in terms of transparency, information, and public participation. Indeed, consumers and their representatives are expressing a lack of confidence in the government and deep concerns on this subject. Such sentiments were noted, for example, in a series of focus groups commissioned by our organization.

One concern relates to the absence of information and tools to facilitate understanding of the issues; another is the paucity of opportunities for public participation in the Canadian regulatory process. Few of the participants could accurately describe this process or identify the bodies responsible. Many felt frustrated at their inability to grasp the issues surrounding GMO approvals. In short, consumers need tools and information to bring them up to speed on these issues. GMOs are increasingly pervasive in our fields and on our plates and the need for appropriate regulation has become critical, yet consumers and citizens have no say in the matter at this time. They must be given direct or indirect opportunities to influence decisions. This goal could be furthered, for example, by holding more public debates and requiring the regulatory authorities to publish all the studies in their possession.

One cannot believe otherwise than that the authorities regulating GM foods and crops are making informed decisions and that they possess all the information necessary to justify them. Why should Canadian consumers be any less privileged? For example, when a submission to approve a new GMO is filed, consumers must be informed of the locations of the corresponding field trials and the municipalities concerned. The final decision document should describe the measures taken to limit any harmful effects and to handle GM crop residues as well as the plan to control any such effects and the

emergency action plan. In general, any public information and participation process should strive for transparency, public education, and awareness raising.

According to our focus group participants, public participation should also take place indirectly through representation on committees. Apart from direct consumer involvement during the two 60-day public comment periods and the holding of public hearings, citizens should have representatives, e.g. consumer and environmental groups, who can devote time and resources for this purpose. These should be systematically informed by means of an e-mail distribution list whenever submissions are filed.

Although the priority concerns of consumers relate to health and the environment, ethical and socioeconomic issues surrounding GMOs are of considerable interest to them. Therefore, while a committee of scientific experts is certainly a necessary part of the regulatory process, advisory committees on these two sets of issues must also be included. The work of the committee on socioeconomic issues would encompass important non-scientific issues related to GM product approvals such as the utility of the GMO to agriculture and society versus its potential hazards, the impacts of the patentability of seeds and species (intellectual property rights over seed), impacts of the decision on consumers' and animals' quality of life, integrity and knowledge of the food source, impacts on farming, environmental impacts, consumers' freedom of choice, farmers' freedom of choice, impacts on agro-industry, impacts on employment, sustainability of communities, impacts on the trade practices of other countries, and promotion of or impediment to sustainable development.

The committee on ethical issues would assess culinary and dietary values, the value, role, and benefits of agriculture in our society, diversity, and farmer independence.

These structures and mechanisms should not be ad hoc but rather prescribed by law in the form of amendments to the existing laws. The timing appears favourable, with several health and food laws including the *Food and Drugs Act* under review as part of Health Canada's legislative renewal process.

In general, consumers prefer a regulatory approach based on the precautionary principle rather than substantial equivalence. This is consistent with their wish to be informed of the presence of GMOs in food by means of mandatory labeling requirements.

Our 21 recommendations are constructive, realistic and readily applicable. They are in keeping with the work being carried out by Health Canada, CFIA, and Environment Canada in recent years, notably through pilot projects, to improve information and public participation in the regulatory process.

RECOMMENDATIONS

Transparency and public information

Recommendation 1

Option consommateurs recommends that Health Canada, CFIA, and Environment Canada pursue efforts on their respective websites to clarify the information on the organization and roles of the GMO regulatory authorities.

Recommendation 2

Option consommateurs recommends that the regulatory authorities publish all results of studies of GMO impacts on health and the environment in the government's possession.

Recommendation 3

Option consommateurs recommends that publications distributed by the regulatory authorities relate to regional, national, and international affairs.

Recommendation 4

Option consommateurs recommends that GMO submissions for approval be systematically published on receipt. Publication should take the same form as in the CropLife pilot project, i.e., posting of a notice on the CFIA website, but should also include publication in at least one large-circulation newspaper. The website should be updated whenever new relevant information is obtained.

Recommendation 5

Option consommateurs recommends that concerned stakeholders such as consumer associations and the main environmental groups be systematically informed of the filing of submissions and the corresponding decisions.

Recommendation 6

Option consommateurs recommends, pursuant to the *Access to Information Act* and as part of Health Canada's ongoing legislative renewal, that the regulatory

framework clearly specify a limited number of types of information that may be kept confidential and that it require proper justification for confidentiality requests.

Recommendation 7

Option consommateurs recommends that, in the context of submissions for approval to conduct field trials, the site(s) where GM plants are to be grown be disclosed.

Option consommateurs recommends that the competent authority inform the municipality where the release will take place, as well as the neighbouring municipalities, by sending them a copy of the submission.

Recommendation 8

Option consommateurs recommends that decision documents contain the following items: a description of the potential environmental and human health effects, a description of measures taken to limit harmful effects, a description of the plan to control the effects, a description of measures to handle GM crop residues, and a description of the emergency plan of action. Where field trials are concerned, the decision document should also include the sites where GM plants will be grown.

Public Comprehension of and Trust in the Regulatory Process

Recommendation 9

Option consommateurs recommends that the regulations distinguish between novel foods and GMOs so that the latter can be subjected to special assessment and treatment, acknowledging that they have special characteristics and often raise issues not raised by other novel foods.

Recommendation 10

In order to give consumers confidence in the GM food and crop regulatory process, Option consommateurs recommends that deregulation of approved products be rejected as a regulatory approach.

Recommendation 11

Option consommateurs recommends that stricter, more comprehensive post-approval surveillance be exercised so as to discern the long-term health and environmental impacts of trials and crops.

Public participation

Recommendation 12

Option consommateurs recommends that more numerous opportunities be offered to debate the issues surrounding GM foods so that Canadian consumers and their representatives can be better informed, hence better able to make informed food choices and provide judicious advice to the government.

Recommendation 13

Option consommateurs recommends that two opportunities for public involvement be added to the approval process. The first should take place upon receipt of a submission for approval and publication thereof, as in the current Health Canada/CFIA/CropLife pilot project. The second should take place between the committee's publication of the evaluation results and the final decision.

Recommendation 14

Option consommateurs recommends that the 60-day length of the first comment period be maintained as proposed in the CropLife pilot project. The length of the second comment period should also be 60 days. Public participation should also include the holding of public hearings.

Recommendation 15

Option consommateurs recommends, in the context of Health Canada's proposed pilot project, that independent external experts be appointed to participate in the scientific approval process.

Option consommateurs recommends that these scientists be free of financial and other conflicts of interest with the novel foods or PNTs assessed.

Recommendation 16

Option consommateurs recommends that public information and public participation be specifically provided for in amendments to existing laws in the context of Health Canada's ongoing legislative renewal.

Consideration of socioeconomic and ethical issues

Recommendation 17

Option consommateurs recommends that two advisory committees be created, one on ethical issues and the other on socioeconomic and general public interest issues.

Recommendation 18

Option consommateurs recommends that scientists who sit on the advisory committees be free of financial and other conflicts of interest with the novel foods or PNTs assessed.

Recommendation 19

Option consommateurs recommends that all the committees (the existing scientific committee backed by the advisory committee on ethical issues and the advisory committee on socioeconomic and general public interest issues) define a liability regime applicable in the event of genetic pollution or health harm.

Food labelling

Recommendation 20

Option consommateurs recommends that Canada urgently adopt regulations for mandatory labeling of GMOs in food as well as an adequate traceability system.

Recommendation 21

Option consommateurs recommends that labeling indicate not only the presence or absence of detectable GMOs in a product (product approach) but also the manufacturing process for the food product (process approach).

Our recommendations as to the model that would best meet Canada's public information and participation needs are summarized in Appendix 1.

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INTRODUCTION

Food is part and parcel of the human experience. Still today, in the twenty-first century and in the West, what we eat often defines who we are. Whatever we may pretend, food retains its strong cultural and religious dimension in our societies. People's emotional attachment to food can be so deep that it resembles something like love[1] — or its opposite.

Genetically engineered foods and crops, or genetically modified organisms (GMO), given the distrust they inspire in members of the public, are exemplary of this fraught relationship between people and food. While GMOs are among the advances made in two decades of biotechnology[2] to serve the needs of the agri-food industry, their legitimacy and the power they give human beings are being challenged. Moreover, the spread of these products comes within a context of market globalization, a phenomenon that has given indications of its weaknesses, inequities and risks. For example, a public health crisis arising anywhere in the world can find itself in Canada and on our plates within a matter of weeks.

And in fact, the world's public health crises have compromised trust in both public and private institutions. It comes as no surprise, then, that citizens and consumers all over the world tend to be skeptical about recombinant DNA technology and refuse to remain complacent and unthinking on the issue. They are, to put it bluntly, unwilling to be force-fed the products of this technology.

While consumers are concerned about all GMOs due to the environmental risks they entail, the most pressing concerns revolve around GM foods because of potential

[1] According to the conclusions of a 1996 survey by the *Agriculture Council of America* on emotional attachments to food.

[2] The term "biotechnology" covers a wide range of scientific tools and techniques, including genetic modification or genetic engineering.

unforeseen health impacts. Yet these foods have already entered the food chain and are regularly ingested by consumers, who can do little to avoid them. Whether the risk is potential, actual, or merely perceived, it is our view that citizens and consumers have the right to know and express opinions about the way their government handles these foods, especially given the freedom of choice that nominally characterizes our market economy.

Further to the recommendations of the Royal Society of Canada in 2001, the Canadian Biotechnology Advisory Committee (CBAC) in 2002, and Quebec's Commission de l'Éthique de la Science et de la Technologie in 2003, Option consommateurs published a research report in 2004 which, we hope, will help our governments muster the will to preserve and enhance transparency and public participation in GM food and crop regulation.

Food safety regulation is largely a scientific enterprise, no doubt, but it must also involve the many concerned stakeholders, including public authorities, scientists, industry, consumers, and their representatives, and must integrate their enlightened views into the process. This, of course, implies that these groups be equipped with the necessary knowledge and understanding.

In this report, we will focus on the two parts of the regulatory process in which public information and participation are most important: the GMO approval process and GM food labeling. We begin with an examination of the current Canadian regulatory model, analyzing it to determine its fit with the expectations of Canadian consumers. We then go on to explore the US, European, Australian, and New Zealand models to identify aspects that may prove useful in improving the Canadian system.

I. GMO REGULATION, TRANSPARENCY, AND PUBLIC CONSULTATION: THE CANADIAN MODEL

In 1993, the federal government adopted a regulatory framework for products of biotechnology in Canada. One principle of the framework is that these products are regulated under the existing legislation by existing agencies, instead of creating new legislation and agencies. New regulations and administrative procedures have been added, though, to address the special issues of these products as compared with those obtained from conventional processes.

Regulated products of biotechnology include field crops (soy, corn, cotton, etc.), our principal concern in this report, as well as biological and gene products (vaccines, therapies, etc.), therapeutic products (drugs) and pest control products.

1. REGULATION OF GM FOODS AND CROPS

The web of agencies responsible for regulation of GMOs are complex, as are the regulations themselves. Two key entities are involved: the Canadian Food Inspection Agency (CFIA) and Health Canada. CFIA is responsible for regulating the following products under the federal statutes indicated:

- plants with novel traits (PNT); field and horticultural crops: *Plant Protection Act* and *Seeds Act;*
- veterinary biologics: *Health of Animals Act* (permits are mandatory);
- biofertilizers (*Rhizobium* inoculants and other types of nitrogen-fixing bacteria, and certain fungi): *Fertilizers Act*;
- novel feeds (including microbial products, PNTs, and products of fermentation)**:** *Feeds Act*.

The main products of interest to us are PNTs and novel feeds. Two directives are relevant: Regulatory Directive 95–03 concerns the assessment of PNTs used as livestock feed, while Regulatory Directive 94–08 concerns assessment criteria for determining the environmental risk of PNTs.

Health Canada is, under the *Food and Drugs Act*, the primary body responsible for human health aspects. Health Canada sets standards guaranteeing the safety of the food supply, including biotechnology-derived or "novel" foods. Its *Guidelines for the Safety Assessment of Novel Foods* state the criteria used in assessing the human health risks of microorganisms and GM plants.

Pest control products are regulated under the *Pest Control Products Act* by Health Canada's Pest Management Regulatory Agency.

Environment Canada helps the federal regulatory agencies develop environmental assessment standards to ensure that all regulations dealing with environmental assessment are rigorous and complete. Since agricultural products derived from biotechnology are regulated under agricultural laws that provide for environmental safety assessment, it is not mandatory to conduct additional testing under the *Canadian Environmental Protection Act*, which is administered by Environment Canada.

As regards food, biotechnology-derived foods fall under the category of "novel foods" and are regulated under Title 28 of the *Food and Drug Act and Regulation* (*Novel Foods Regulation*). The definition of a novel food for the purposes of the regulation is:[3]

> (a) a substance, including a microorganism, that does not have a history of safe use as a food;
>
> (b) a food that has been manufactured, prepared, preserved or packaged by a process that
>
> - has not been previously applied to that food, and
>
> - causes the food to undergo a major change; and
>
> (c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that

- the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,

- the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or

- one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.[4]

The two key structures, then, are the Canadian Food Inspection Agency (CFIA) and Health Canada. We will concern ourselves with the organization of these two agencies and the processes they follow in approving GMOs.

2. ORGANIZATION: STRUCTURE AND ROLES OF THE REGULATORY BODIES

2.1 MANDATE OF THE CANADIAN FOOD INSPECTION AGENCY

CFIA is responsible for conducting environmental risk assessment of PNTs and novel feeds, fertilizers, and veterinary biologics, including those derived from biotechnology. For GM crop plants, CFIA assesses the potential risk of adverse environmental impacts, authorizes and oversees import permits, confined trials, unconfined release, and variety registration.

CFIA is responsible for regulating both the performance (or efficacy) and environmental safety of the product in question. Regulations passed in 1996 clearly describe how the CFIA will conduct environmental assessments of agricultural products of biotechnology. CFIA is also responsible for inspection and monitoring so that registered products continue to meet quality and safety standards after their approval.

[3] *Food and Drug Regulations,* [Amendment (Schedule no. 948), published in *Canada Gazette Part II,* 27 October 1999].

[4] See online at http://www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/e_division28.html.

This inspection and monitoring includes imported products that are products of biotechnology.[5]

2.2 HEALTH CANADA'S MANDATE

Health Canada is responsible for carrying out food safety assessments for new foods, including those developed using biotechnology. Health Canada is responsible, under the *Food and Drugs Act* and its Regulations, for provisions related to public health, food safety and nutrition. Through science-based regulation, guidelines and public health policy, as well as health risk assessments concerning chemical, physical and microbiological contaminants, toxicants and allergens in the food supply, Health Canada works to protect the health and safety of Canadians. Health Canada also conducts pre-market evaluations to assess the safety and nutritional adequacy of novel foods proposed for sale in Canada, including foods derived from biotechnology.[6]

3. GMO APPROVAL PROCESS, PUBLIC INFORMATION AND PARTICIPATION

The procedures have existed since 1993. In 1998, the requirements of CFIA, Health Canada, and the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) were harmonized.

3.1. CURRENT PROCESS

Our study will focus on the approval process for GM plants (PNTs in CFIA's terminology) used in livestock feed or otherwise, as well as novel foods (Health Canada's terminology).

[5] See online at http://www.inspection.gc.ca/english/sci/biotech/reg/bioage.shtml.

[6] See online at http://www.hc-sc.gc.ca/english/protection/biotech/regulation.htm.

Any GM plant marketed in Canada must be approved for use in both food and feed. Therefore, it must pass both the CFIA and the Health Canada approval processes. Health Canada remains the primary entity responsible for orchestrating GMO approvals.

3.1.1 CFIA Process

At CFIA, the Feeds Section is responsible for approving PNTs intended for use in feed. The information required under Directive 95–03 consists of a description of the novel traits, nutritional data, and toxicity data. Trials are performed on lab animals or livestock.

The Plant Biosafety Office is responsible for environmental safety assessment of PNTs. An important part of this regulatory system is the confined field trial, which is intended to give developers of plants with novel traits the opportunity to evaluate these plants under highly controlled conditions. Field trials are designed to limit the impact of plants on the environment and to prevent their introduction into the food and feed systems until they are fully assessed.

When a developer wishes to market a plant, it must provide the Plant Biosafety Office with all of the information required to carry out an environmental safety assessment. The applicant must provide detailed information about the novel trait, the method used to introduce the novel trait into the plant, and the effects and impacts resulting from the release of the plant.

Scientists assess all the information provided to them by the applicant and, if necessary, may ask the applicant to supply them with more or different information from that which was originally provided.

When the scientists have made their decision about the environmental safety of the plant in question, they inform the applicant. A summary of the assessment, called a "decision document," is made publicly available.[7]

[7] The decision documents may be viewed at http://www.inspection.gc.ca/english/plaveg/bio/pbobbve.shtml.

For a PNT to be granted release, scientists must consider the potential of the plant to become a weed of agriculture or to be invasive of natural habitats, the potential for gene-flow to wild relatives, the potential for the plant to become a plant pest, the potential impact of the plant or its gene products on non-target species (including humans), and the potential impact on biodiversity.[8]

3.1.2 Health Canada Process

Manufacturers and importers who wish to sell or advertise a GM food in Canada, must submit data to Health Canada for a pre-market safety assessment, as required in the Novel Foods Regulation. This safety assessment provides assurance that the food is safe when prepared or consumed according to its intended use.

The eight steps in the regulatory process are as follows:

1. Pre-submission consultation

Health Canada encourages industry to consult with the Novel Foods Section in advance of submitting a GM food to Health Canada for safety assessment. This clarifies the regulatory process for industry and identifies any specific safety issues that the GM food being submitted may present.

2. Pre-market notification

When an industry proponent believes it has sufficient information about the safety of a GM food to address Health Canada's criteria, a submission is made to the Novel Foods Section. This office coordinates a full safety assessment of the product, which involves a rigorous scientific evaluation by Health Canada.

3. Scientific evaluation

[8] See online at http://www.inspection.gc.ca/english/sci/biotech/enviro/evale.shtml.

Scientific evaluators, with individual expertise in molecular biology, toxicology, chemistry, nutritional sciences and microbiology, assess the following:

- development of the food crop, including the molecular biological data that characterizes the genetic change;
- composition of and nutritional information about the GM food compared to a non-modified counterpart food;
- the potential for production of new toxins in the food;
- the potential for causing allergic reactions;
- the potential for any unintended or secondary effects;
- key nutrients and toxicants;
- major constituents (e.g., fats, proteins, carbohydrates) and minor constituents (e.g., minerals and vitamins); and,
- microbiological and chemical safety of the food.

4. Requests for additional information

If Health Canada evaluators conclude any of the information provided about a GM food is insufficient, further information or data is requested from the manufacturer. Health Canada does not give any further consideration of the GM food until all requested data is provided.

5. Summary report of findings

Once evaluators have completed their assessments, they summarize their findings and recommendations in a report.

6. Preparation of food rulings proposal

If the results of the evaluation conclude there are no health risks associated with consumption of the GM food product in question, a Health Canada Food Rulings Proposal is prepared. This proposal is reviewed by senior staff in the Food Directorate of Health Canada and a decision is made whether or not to approve the product.

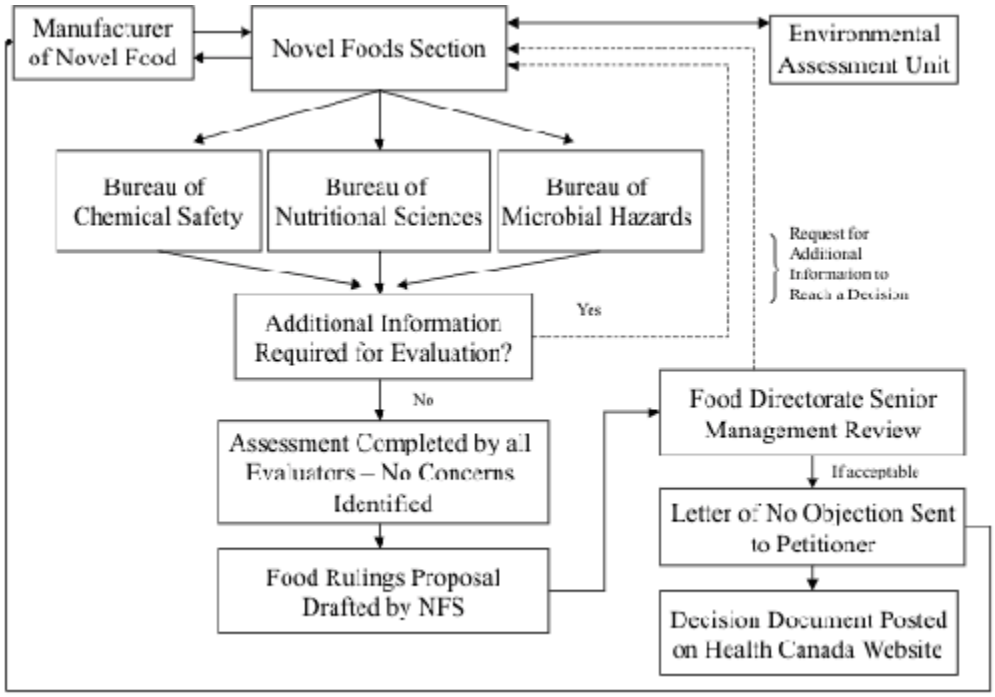
7. Letter of No Objection

If a product is approved, and the other regulatory approvals such as environmental and feed safety are in place, a "Letter of No Objection" is sent to the proponent. This letter indicates that the product can be sold in Canada for the intended uses, as listed in the submission. It also outlines any restrictions or requirements relevant to the Health Canada decision.

8. Decision Document on Health Canada Website

A decision document, describing the novel food and summarizing the safety information used to determine its safety as a food, is posted on the *Novel Foods and Ingredients* page of Health Canada's website.[9]

The novel food approval process and the interactions between the responsible bodies are summarized in the diagram below:[10]



[9] See online at http://www.hc-sc.gc.ca/english/protection/biotech/regulation.htm.

It is clear, then, that there is no public consultation mechanism in the process at this time, yet an actual decision is being made to approve a GMO. The regulatory bodies have shouldered the entire responsibility for deciding and announcing that an approved GM food is safe.

Apart from the question of public participation, the ethical and social issues raised by products of biotechnology are not taken into account in this process. The evaluation offices are composed of scientists with backgrounds in the pure sciences only (10–12 for Health Canada and 7–8 for CFIA).

Public information and participation in the CFIA/Health Canada approval process itself are limited to an opportunity to read the decision documents, which describe the evaluation and its outcome. In parallel with this process, the regulatory bodies have produced publications aimed at the general public. The Office of Biotechnology, in particular, has produced communication materials for an event booth. The components of the booth are a poster describing the key phases in the regulation of agricultural biotechnology over the last 15 years, a brochure dealing with biotechnology regulation by CFIA, and an information package containing fact sheets on the following subjects:

- the regulatory approval process for products of biotechnology;
- the safety of biotechnology-derived crops;
- frequently asked questions about biotechnology-derived foods;
- labeling of biotechnology-derived foods in Canada;
- a list of information sources.

In addition, consultations were held in July 2003 in connection with the review of Health Canada's *Revised Guidelines for the Safety Assessment of Novel Foods* as well as

[10] This diagram is taken from the Health Canada website at http://www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/e_novel_notification.html.

the revised draft Regulatory Directives 95–03 (PNT for feed) and 94–08 (environmental risks of PNT). These consultations give the public a chance to participate in defining the regulatory approaches to be adopted.

One part of the Health Canada consultation dealt with transparency and public participation. Specifically, the consultation document presented its plan of action further to the recommendations of the reports of the Royal Society of Canada (2001) and the Canadian Biotechnology Advisory Committee (CBAC; 2002). Three pilot projects were launched with the goal of making improvements in this area.

3.2 HEALTH CANADA PROCESS

Since January 2002, five half-yearly Health Canada progress reports have been published further to the action plan.

In addition to transparency-related activities such as the publication of communication aids and an improved website design, three pilot projects were planned to begin as of December 2002. The first calls for the participation of external experts on the committee. The second is inspired by the Food Standards Australia and New Zealand (FSANZ)[11] procedures which provide for public participation at two levels. Health Canada seeks to implement an identical procedure under the auspices of its pilot project. The third pilot project, complementary to the second, is designed to make submissions for approval public.

To date, much work has been done by the federal government, particularly Health Canada and CFIA. As well, the Environment Canada site has been redesigned and now contains more information. Approved GMOs are posted quite rapidly on the Health Canada site.

[11] Food Standards Australia and New Zealand is the body responsible for regulating GM foods in Australia and New Zealand.

The information is also clearer and access to it has been expedited, as witness the following information appearing at the end of the evaluation of a GMO developed by Dow AgroSciences Canada as part of the CropLife pilot project:[12]

> For more information on this product, please contact:
>
> Dow AgroSciences Canada Inc.
> 201, 1144 29 Ave., N.E.
> Calgary (Alberta)
> T2E 7P1
>
> For more information on the regulatory system, please contact:
>
> Feed Section
> Animal Products Directorate
> Canadian Food Inspection Agency
> 59 Camelot Drive
> Nepean, Ontario
> K1A 0Y9
> (613) 225-2342
>
> Novel Foods Section
> Food Directorate
> Health Products and Food Branch
> Health Canada
> Tunney's Pasture
> Ottawa, Ontario
> K1A 0L2
> (613) 954-8921
>
> Plant Biosafety Office
> Plant Products Directorate
> Canadian Food Inspection Agency
> 59 Camelot Drive
> Nepean, Ontario
> K1A 0Y9
> (613) 225-2342

It is also possible, on the CFIA website, to subscribe to a mailing list that includes mailings of new submissions for approval.[13]

Fact sheets on the regulatory process for biotechnology-derived products have been produced and are available in the Biotechnology section of the CFIA website under the "Fact Sheets" and "Questions and Answers" links.

The segment of the pilot project calling for the participation of external experts on the decision-making committee is underway and no data has yet been made public. The regulatory bodies are still reviewing the procedures for selection, inclusion, and monitoring of an external expert. The progress report for this pilot project and the

[12] Online at http://www.inspection.gc.ca/english/plaveg/bio/subs/2003/2003001e.shtml. CropLife is an association of biotechnology companies.

[13] "If you would like to receive e-mail notification of new submissions when they are posted, please join the notification subscription service using the form available at:http://www.inspection.gc.ca/english/tools/listserv/listsube.shtml?biosub_biodem"; online at http://www.inspection.gc.ca/english/plaveg/bio/subs/subliste.shtml.

regulators' response to the August 2002 CBAC report on GM food regulation are to be published this summer.

The pilot projects on posting of submissions for approval and allowance for public comment have now been merged through the CropLife initiative. The first notice was posted on 1 December 2003. Comments were to be mailed or e-mailed to CFIA or Health Canada within 60 days of posting. The posted information included a description of the host plant, a description of the modification, the heredity and stability of the introduced trait, a description of the novel traits, the toxicity of the new gene products, a nutritional assessment of the PNT, allergenicity, and environmental impact assessment of the PNT.

CropLife initiated the process. The key feature of this pilot project — a call for comments upon receipt of the submission — is not fixed and may change over time. But the incorporation of such a procedure into the approval process is encountering a major hurdle: that of the exceptions defined under the *Access to Information Act*, especially for confidential third-party information. These exceptions constitute a major impediment to greater transparency. Under the Act developers may refuse to disclose confined field trial data and the exact location of trials. A commitment to transparency certainly dictates disclosure of this information, but failing voluntary compliance on the developers' part, mandatory disclosure provisions could be included as part of Health Canada's ongoing legislative renewal, whose aim is to revise a set of existing statutes including the *Food and Drugs Act*. Legislative amendments could require disclosure of more detailed information about novel foods submitted and evaluated by the regulators. This option is currently under discussion. However, the legislative renewal is a long process that is not expected to conclude until 2008–2010.

Transparency and public participation procedures could be provided by law, as is done in the European Union (Directive 2001/18)[14] or set down in policy statements. The absence of legal constraints could render this approach less systematic. Furthermore, no recourse would be available in cases where the procedures are not observed. Once again, the decision to include transparency and public participation procedures would not be

specific to novel foods but would apply to all products covered by the legislative renewal, including natural health products.

4. GM FOOD AND CROP LABELING POLICY

Responsibility for the important issue of labeling is shared. CFIA is responsible for labelling aspects unrelated to product safety, i.e., optional labelling and consumer fraud cases, while Health Canada is responsible for mandatory product safety and health-related labelling, including allergenicity, changes in nutritional composition, and so on. Health Canada sets mandatory food health and safety labelling requirements, and CFIA applies them.

Current legislation in Canada requires that all novel foods, including those derived through biotechnology, be labelled if there are any changes in composition, nutrition, or end-use. Since approved GMOs do not fall into these categories, they are unlabelled. The Canadian standard offers food manufacturers the choice to indicate "product of biotechnology" or "not a product of biotechnology" provided that this information is truthful, not misleading, and in compliance with other regulatory requirements.

In 1995, the Canadian Council of Grocery Distributors (CCGD), along with the Canadian General Standards Board (CGSB), began the process of developing a standard for the voluntary labelling of biotechnology-derived foods. The committee tasked with developing the standard consists of approximately 60 voting members and 60 non-voting members and includes a balance of stakeholder representation (from consumer groups; producers' associations; government bodies, including the CFIA; universities; environmental groups; and general interest groups, and industry representatives).[15]

[14] See section 2.1 of this report.

[15] See online at http://www.inspection.gc.ca/english/sci/biotech/2001-02ar/biotech-003e.shtml.

Consensus was reached under the rules defined by the CGSB in 2004 and the standard was adopted 15 April 2004 by the Standards Council of Canada (SCC) and Ottawa.[16]

Bill C–287 to amend the *Food and Drugs Act* by making labelling of biotechnology-derived foods mandatory was defeated on 17 October 2001 after its second reading in the House of Commons.

Internationally, Canada chairs the Codex Alimentarius Committee on Food Labelling. Canada seems to be making common cause there with the United States, Mexico, Argentina and Australia in discouraging other countries' mandatory GM food labelling initiatives.

5. NUMBER OF GMOS APPROVED

Canada's biotechnology sector is highly active. From 1988 to 1997, some 3,000 trials took place, including 812 in 1997. The country accounts for 6.5% of the world's total area planted to these crops, with 3.4 million hectares.

As of December 2003, 63 novel foods, including 60 GM foods derived from various species, had been approved for sale in Canada. Not one submission had been rejected.

6. CONCLUSION

The demand for authorization to market transgenic plants has not given rise to the development of new structures; authorization remains grounded in the existing Canadian regulatory framework. Approval power is vested in CFIA, Health Canada, and Environment Canada, which marshal a team of scientific evaluators in this effort.

[16] For further information, see the website of the Canada General Standards Bureau online at http://www.pwgsc.gc.ca/cgsb/home/index-e.html.

Labelling is only required where there is a health risk (presence of allergens or significant changes in nutritional composition). Voluntary labelling is now possible under the new standard.

The fact that approved foods and crops are considered *a priori* no riskier than conventional ones constitutes a fundamental principle of the Canadian biotechnology regulatory model. Post-market and long-term surveillance of public health impacts have therefore not been regarded as a priority. As a result, there is no system for segregating GM from non-GM foods, nor any comprehensive labeling system.

In fact, no country has implemented a human health impact surveillance program. In Canada as elsewhere, post-market surveillance of GMOs is the responsibility of the developer, which is expected to control present and future product-related risks and notify the regulatory authorities if new information becomes available.

Some work has been done on transparency and public participation. The consultation process for the review of Health Canada's *Revised Guidelines for the Safety Assessment of Novel Foods* is an example that amounts to a quasi-systematic consultation process carried out by Health Canada and CFIA during policy development. This process, though laudable, is insufficient; it must be complemented by mandatory legal provisions for public information and participation during the approval process as such, i.e., during the evaluation of each proposed GMO.

Where a few years ago there was essentially a void, the approval process today comprises some procedures that have already proven their value (improved website, publication of decisions) or have yielded encouraging results during the testing phase (pilot projects). Several aspects are still outstanding. In the CropLife pilot project, for example, the submission for approval describes the material provided to the regulatory authorities (the developer's studies) but does not mention the conclusions derived from it. For example, did the nutritional assessment show that the nutritional value is the same or different? Did the toxicity studies indicate an absence of toxicity, minimal toxicity, or heightened toxicity in certain species?

Moreover, the provisions to improve public information and participation during the GMO approval process are not included in the existing act. The absence of such provisions means that public information and participation are not mandatory, and it impairs the authorities' powers of oversight where the procedures are not observed.

In the next section, we proceed to compare the structure and operation of this regulatory model with the needs of Canadian consumers.

II. ASSESSMENT OF CANADIAN CONSUMERS' NEEDS

1. METHODOLOGY

This type of research project traditionally requires four 10-member focus groups at two different locations in order to be methodologically valid. We therefore adopted this methodology.

Focus groups are a powerful, open-ended, interactive means of gaining insight into perceptions and concerns that might be encountered if each person were interviewed individually. We commissioned the Environics firm, specializing in this type of survey, to hold four focus groups. The participants were chosen to be representative in terms of their gender, age, origin, and occupational category. The discussion guide is included in Appendix 9 of this report.

We opted to hold the focus groups in Montreal (Quebec) and Toronto (Ontario), cities where intense debate is ongoing around the issues of GM foods and crops and where public awareness is high. The four focus groups were held in December 2003.

We selected consumers who stated that they were very concerned about the impact of GMOs and their regulation by the government. On this point it should be recalled that 87% of Canadians want mandatory GM food labelling.[17]

[17] According to a Léger Marketing survey commissioned by Option consommateurs, Union des consommateurs, and Greenpeace in April 2004.

2. GENERAL PERCEPTION OF GMOS AND PARTICIPANTS' MOTIVATIONS

2.1 GENERAL PERCEPTION OF GMOS

First, the participants were asked to write down the first three words that came to mind when they thought of GMOs. The majority of the participants associated GMOs with the science of genetics and with agriculture, and expressed their concerns about the potential long-term health and environmental impacts of GMOs. Most of the participants regarded GMOs as a concept whose complexities they had not yet fully grasped.

2.2 PARTICIPANTS' MOTIVATIONS

The great majority of the participants expressed concerns about GMOs. These concerns mainly revolved around health and environmental issues. The health concerns had to do with long-term reactions of the human body and possible effects on cell physiology. The environmental concerns had to do with the possible loss of biodiversity and the long-term effects on ecosystems.

Certain participants expressed ethical concerns about GMOs as well as concern about their socioeconomic impacts. The ethical concerns saw the creation of GMOs as running counter to the "natural order of things" or as "scientists trying to play God." The socioeconomic concerns regarded GMOs as a means of increasing corporate profits to the detriment of public safety. GMOs were not seen as indispensable since they are not necessarily beneficial to the average Canadian.

Finally, several participants in Toronto, and a few less emphatically in Montreal, claimed that GMOs were not a major concern for them. One participant found them to be interesting from a scientific point of view and believed that they might make it possible to feed more people if higher yields can be obtained.

3. CONSUMER KNOWLEDGE OF GMO REGULATION IN CANADA

3.1 AWARENESS OF GMO REGULATIONS IN CANADA

Consumers opinions were divided on whether GMOs are specifically regulated in Canada. Most participants did not believe that there are any regulations, that manufacturers are free to sell GM products as they see fit. Others thought that there may be some form of oversight but that they ultimately had no knowledge of the existence of specific regulations. No one, in fact, knew the details of the assessment process for novel foods. Numerous participants in both cities associated GMO regulation with the European Union, where GMOs are a more controversial issue, or with the United States Food and Drug Administration (FDA). Very few spontaneously mentioned CFIA or Health Canada in this connection.

3.2 AWARENESS OF NOVEL FOODS AND GMO ASSESSMENT PROCESS

Nearly all participants in both cities expressed a lack of knowledge about novel foods and the government's GMO assessment process. Some Montreal participants presumed that Agriculture and Agri-Food Canada (AAFC) has laboratories where tests are performed or that biotechnology groups work together to assess GMOs. The term "novel foods" was unknown to the participants.

When asked whether they wondered or were concerned about the manner in which the government regulates the creation of new GMOs, the majority of the participants said that due to a lack of information, they had not really wondered or been concerned about this issue. Among the participants who expressed concerns or questions, these related to the whole assessment process, the influence of the biotechnology industry on the regulators, or the government's ability to take a long-term view of the matter.

3.3 KNOWLEDGE OF THE REGULATORY AUTHORITIES

In both cities, the participants expressed a considerable lack of knowledge about the regulatory authorities and their roles in the GMO assessment process. In Toronto, only two participants were able to name CFIA. The Montreal participants were more knowledgeable. While some rightly named Health Canada as an important player, they also supposed that AAFC plays a role in the process and that the two bodies conduct testing in conjunction with the biotechnology industry.

There was a clear sentiment among all the participants that the public must be kept informed and up-to-date and that the government is keeping them in the dark on the subject of GMO assessment. This impression of secrecy even nurtures the opinion that perhaps nothing is being done, that the field of GMOs is wide open and unregulated, or that the government might be taking advantage of the situation.

3.4 KNOWLEDGE OF NOVEL FOOD ASSESSMENT

After the concept of novel foods was explained to the participants, they were asked whether they knew how many novel foods have been assessed in Canada. The majority of participants had no idea; guesses ranged from several hundred to more than a thousand. A few participants were closer to the real figure, estimating 50–100. This exaggerated perception may be due to a confusion between the number of foods available that may contain GMOs and the number of approved GM crops.

When the participants learned that 63 novel foods had been assessed since 1994, that 60 of them were GMOs, and that all had been approved, they became more suspicious of the process. They wondered whether the assessment process was simply a rubber stamp for any proposed GMO. They would have liked to see at least one GMO assessed and then rejected for some reason.

4. RELEVANCE OF CURRENT REGULATORY SYSTEM AND CONSUMERS' SUGGESTIONS FOR IMPROVEMENT

Once the current GMO regulatory process was explained, almost all the participants agreed that the system, in its current form, is inadequate to approve a new GMO. The sentiment among the participants was that the existing regulations are too broad and too general. Some added that the tests were inadequate since they are not specifically designed for GM organisms and therefore create a system insufficiently rigorous to address the specific challenges of GMOs. Their view was that it is totally inappropriate to approve a GMO simply because it is substantially equivalent to a non-GMO counterpart. One might, they contended, derive the impression that the assessment process begs the question by declining to address the severest criticisms of GMOs. In considering the weaknesses of the current system, the participants were unanimous on the lack of long-term testing necessary to reveal human health effects. Some participants also mentioned the same weakness in regard to long-term environmental impacts.

4.1 GMO ASSESSMENT ASPECTS TO CONSIDER

The participants were asked about aspects that should be considered when a decision is made to approve or reject a GMO. In both cities, the long-term health effects of any new GMO were frequently mentioned. Participants referred to the possible impacts on human physiology, and particularly the possibility that gene transfer from one species to another could cause allergic reactions. Many participants also mentioned the need for long-term analysis from an ethical perspective, what with humanity going so far in its experimentation with nature. Finally, environmental concerns were seen as relevant in view of the possible impact of GMOs on ecosystems. This was amplified by the perception that a new GMO could affect other crops with which it comes in contact.

4.2 ETHICAL ASPECTS

Although some participants spontaneously brought up ethical concerns, most were more concerned about practical matters such as health, environmental, and

socioeconomic impacts. Still, the majority, when questioned more specifically on ethical issues, agreed that these must be taken into consideration. The participants were unanimous on the need for wider-ranging and more inclusive discussions on GMOs.

5. A CLEARLY EXPRESSED NEED FOR INFORMATION

5.1 WHO ARE THE DECISION-MAKERS?

The participants agreed that it would be relevant for the public to know who is involved in the GMO approval process. The general feeling was that things cannot be done in secret and that the public must be made more aware of these issues. They feared that the process as it stands could be indicative of an intention to keep the public ignorant, such that once GMOs are approved and abundantly present in the food chain, it would be too late to do anything about it.

5.2 INFORMATION ON DECISIONS ABOUT NOVEL FOODS

The participants were unanimous in wanting to obtain more information about the approval or rejection of each novel food, the genetic modification techniques used, and the results of tests, among other things. They wanted this information before the product goes to market. One group of participants mentioned the need to have information as quickly as possible on the outcome of decisions. Another group expressed an interest in knowing where and how to obtain this information.

All participants agreed that it is absolutely necessary for the public to know which GMOs have been approved and rejected as well as the reasons for these decisions. The principle of transparency was invoked by the participants, who added that revealing the results to the public would provide assurance that the process is impartial and free of corruption or conflicts of interest.

The participants emphasized the importance of obtaining information before decisions are made so that independent persons and organizations can be given an opportunity to comment. This information should be presented in clear and simple language. Overly

technical and scientific language would considerably diminish the potential for public involvement and education.

5.3 DISSEMINATION OF INFORMATION ON NOVEL FOODS

When they were shown pages from the Health Canada website summarizing the GMOs approved in recent years, the participants made some suggestions as to how these pages can be made more informative. Besides the need for simpler explanations and more easily comprehensible terms, the participants wanted to know how the GMO would be used, how and for what purpose it was developed, what are its advantages and risks, in what products it will appear, what tests and criteria were used in evaluating it, how long the evaluation period lasted, and what are the possible harmful effects of the GMO.

In addition to this information, the participants wanted to receive information on the company that developed the GMO and the other products it manufactures. They were pleased to discover that a considerable amount of information is available on the Health Canada website but would like the site's existence to be better publicized.

5.4 PUBLIC INFORMATION: THE BEST METHODS

In addition to traditional media (television, newspapers, ad campaigns) and more modern media (websites), several groups were open to the idea of the governments holding public meetings or consultations. They explained that placing announcements in newspapers as is done, say, for zoning changes would be an excellent way of raising public awareness and eliciting public involvement.

The Montreal groups put forward the idea of pamphlets being made available in grocery stores and supermarkets. This approach would have the advantage of reaching the consumer directly.

While Internet was seen as an ideal vector of detailed information to interested persons, consumers must be informed of the types of data available on the Web and given the links and addresses where specific information on GMOs can be obtained.

6. PUBLIC CONFIDENCE IN THE APPROVAL PROCESS

6.1 CONFIDENCE IN GOVERNMENT'S METHODS AND PROCEDURES

The participants in all four groups expressed their lack of confidence in the government's capacity to make decisions on GMOs. They mentioned the paucity of information disclosed by the government, its failure to investigate long-term impacts, and the small size of the decision-making committee (a dozen members). Finally, they expressed their deep concern about the undue influence of the biotechnology industry in shaping GMO regulations. They pointed to the fact that all 60 GMO applications to date had been speedily approved.

Deep suspicions were expressed as to the government's integrity in view of the indirect financial support it receives from the industry as well as other pressures to approve the products. Reference was made to the government employees who were shouted down after expressing their disagreement with the government's modus operandi. These factors were seen as possibly outweighing public health and safety concerns. But if the government can show that it is in control of GMOs in the short and long term, then encouraging steps will have been taken toward increasing public trust.

6.2 THE PRECAUTIONARY PRINCIPLE VERSUS SUBSTANTIAL EQUIVALENCE

The participants unanimously preferred the precautionary principle to the substantial equivalence approach, invoking long-term health and environmental impacts among other concerns. The precautionary principle errs sensibly on the side of caution, they said, while substantial equivalence seems to err radically on the side of permissiveness.

Substantial equivalence was seen as too broad and general, too open to interpretation, and likely to exclude examination of important aspects of GMOs. The participants felt that GM foods are simply not equivalent to non-GM counterparts and that they should not be approved on this basis alone.

7. DESIRED LEVEL OF PUBLIC INVOLVEMENT

7.1 PUBLIC PARTICIPATION IN THE APPROVAL PROCESS

The majority of the participants in both cities stated that it is important for the public to participate in the debate on GMOs, since it can make a necessary contribution in regard to ethical, environmental, and political aspects. Up to now, the debate has been essentially scientific in nature, as they see it. However, some participants felt that, given the complexity of the GMO issue, it would be difficult for the public to make a meaningful contribution.

The participants suggested the holding of public forums and consultations through the medium of television and public announcements in the newspapers. Some evoked the possibility of citizens' movements like those formed in Europe around the GMO debate.

7.2 PUBLIC REPRESENTATION

The participants hoped that individuals representing academia, farmers, environmentalists, and consumers' associations such as Option consommateurs will participate directly in the assessment process. They also stressed the importance of external experts and independent scientists being given input so as to counterbalance that of the Health Canada scientists.

As to the composition of the decision-making committee, they wanted to see several representatives of the public on the committee; in fact some participants felt it should be composed of scientists and public representatives in equal numbers. Others suggested the formation of a parallel committee composed solely of external experts and consumer representatives. This committee could produce its own report, which would be given due consideration alongside the report of the scientific experts.

8. NEED FOR INFORMATION AND ACCESS TO INFORMATION

The participants stated that they do not know as much as they would like to. Particularly in Montreal, consumers' associations such as Option consommateurs and environmental groups such as Greenpeace were viewed as ideal candidates to assist with public education efforts. In Toronto, the participants were less vocal in advocating this idea. All groups, however, felt that Health Canada and the government have a mandate to educate the public on GMOs.

For access to information, the media mentioned were government websites, traditional media (including magazines), ad campaigns, and pamphlets displayed in supermarkets. Several participants also liked the idea of independent consumers' organizations issuing press releases.

9. CONCLUSION

Canadian consumers are relatively well versed in the issues surrounding GMOs. In terms of regulations, consumers are aware or are satisfied to learn of the efforts made, but they still consider the level of transparency insufficient. The primary need expressed is that of being reassured. Real doubts and suspicions persist as to the government's integrity, impartiality, and conscientiousness, in particular where the long-term effects are concerned. Our focus group participants want enhanced access to more thorough, popularized, and publicized information about the decision-makers (who are they? what do they do?), the regulations themselves, the nature of the testing, the decisions made, and the reasoning behind these decisions. The term "novel food" was unknown to all participants and ought to be either publicized or abandoned.

Beyond the need for reassurance, Canadian consumers have additional demands. They want ethical and socioeconomic considerations to be a part of the approval process. They also call for a new balance to be struck between the narrowly scientific vision of the government and the biotechnology companies, on the one hand, and broader public interest concerns, on the other. This entails that they be allowed to participate directly or

indirectly in the approval process. Judging by our sample, Canadian consumers prefer the indirect route, with the participation of consumer representatives such as Option consommateurs, environmental groups such as Greenpeace, and the formation of an ethics committee.

Finally, in terms of public information and participation in the GMO regulatory process, consumers believe that the precautionary principle is superior to the prevailing substantial equivalence approach. Furthermore, and very important, public information fundamentally depends on mandatory labeling of genetically modified ingredients in food.

III. GMO REGULATIONS, TRANSPARENCY, AND PUBLIC PARTICIPATION: INTERNATIONAL MODELS

In this section we examine international GMO regulatory models to derive interesting approaches from them as regards transparency and public participation. We focus on three essential areas: the GMO regulatory framework; the assessment process per se, with emphasis on transparency and consumer participation mechanisms; and GMO food labeling policy.

1. REGULATION, TRANSPARENCY, AND PUBLIC PARTICIPATION IN THE UNITED STATES

The United States was one of the first countries to adopt a biotechnology regulatory framework. The first environmental release of a GMO took place in 1983 following the approval of the National Institutes of Health (NIH).

1.1 GMO ASSESSMENT PROCESS: REGULATION AND ORGANIZATION

The regulation of products of biotechnology is a federal responsibility.

1.1.1 Regulatory Framework

The federal government decided in 1986 that the Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) would regulate GM crops under existing laws. It is the responsibility of these agencies to ensure that GM crops are safe for humans, animals, and the environment.

The USDA administers the following provisions:

- Part 7, chapter 340 of the *Code of Federal Regulations* (7 CFR 340), *Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests*, effective 16 June 1987;
- *Genetically Engineered Organisms and Products, Notification Procedures for the Introduction of Certain Regulated Articles, and Petition for Nonregulated Status*, effective 31 March 1993;
- *Simplification of Requirements and Procedures for Genetically Engineered Organisms and Products*, effective 2 May 1997.

The *Federal Food, Drug and Cosmetic Act* empowers the FDA to regulate food and feed, including products containing biotechnology-derived plants. The FDA is an agency of the Department of Health.

The *National Environmental Policy Act* (NEPA) is one of the legal foundations of the programs administered by the EPA, which is an agency of the White House.

1.1.2 Organization: Roles and Responsibilities of the Authorities

Although a rigorous assessment is conducted as a coordinated effort of the USDA, the EPA, and the FDA, the market in the United States is essentially self-regulated by the industry. The federal agencies have shared responsibility for control and surveillance of transgenic plants.

a) The USDA

The USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for ensuring that GM crops are not harmful to agriculture and the environment. APHIS oversees interstate trade, imports, and transgenic field trials to guarantee their environmental safety. It also inspects products derived from transgenic plants, which

must not differ from conventional products. This indicates that the regulators place the focus on the product to the exclusion of the production process. For APHIS, eight years of experiments with and use of GM seeds are a sufficient guarantee of the validity of the applicable laws.

b) The FDA

The FDA is responsible for the food safety aspects of GMOs. Since it considers them equivalent to conventional products rather than tantamount to food additives, it opposes the identification of transgenic plants. The FDA has therefore ruled out GM food labeling, although its position could change if allergenic properties were discovered. Its view is that GM product safety research is currently unnecessary.

The FDA is responsible for ensuring that all foods marketed in the United States are safe. However, the FDA has no legal authority to approve GM crops before they are brought to market. The FDA regulates GM foods and crops through a voluntary rather than mandatory declaration process. In this process, the GM crop developer submits a summary of the data showing that the GM crop is substantially equivalent to its conventional counterpart. The FDA reviews the data submitted and notifies the developer if it has any concerns about the latter's assessment.

c) The EPA

The EPA is responsible for the safety of pesticides, including plants such as Bt corn and Bt cotton which have been modified to produce a pesticide. As such it intervenes in the assessment of transgenic plants resistant to pests and diseases, which are tested in the same way as pesticides.

Where a crop is genetically modified to produce its own pesticide (e.g., Bt corn), the EPA reviews and approves the safety of this crop before it is marketed. In its mandatory process, the EPA assesses the environmental risks and any potential advantages. It establishes the conditions necessary to minimize or eliminate potential harm to the environment. The EPA approval process also assesses food and feed safety if the

chemical compound is to be ingested. A tolerance limit is established under which the pesticide is considered to be safe.

For all other GM crops, the USDA is responsible for ensuring that they will not have harmful effects on agriculture and the environment. The USDA has established an application and permitting process for field trials with which developers must comply before growing any GM plant in the field. The USDA also has a process whereby developers can apply to "deregulate" a GM plant, meaning it can be grown commercially without regulatory obligations or restrictions. To date, more than 9000 field trials have passed through the USDA regulatory process and more than 75 crops have been deregulated.

Unlike the FDA, the USDA and the EPA conduct a mandatory approval process for the marketing of the GMOs under their jurisdiction. Developers may not market a new product until it is formally authorized.

The FDA, in fact, does not formally approve any GM crop as being safe for consumption. While it has the authority to approve new additives, for example, the FDA considers new GM plants not to fall under its authority. Instead, it has created a voluntary review process for developers' data to ensure compliance with the existing laws. This process is not, as the agency itself acknowledges,[18] a complete scientific review of the data. The reverse is true for plants synthesizing a pesticide and transgenic animals, which require pre-market FDA approval.

1.2 PUBLIC INFORMATION AND PARTICIPATION PROVISIONS

1.2.1 Existing Provisions

The USDA and the EPA call for public comment during the review process, respond to these comments in the formal decision documents, and provide details of the final decision in a publicly available document.

a) USDA Provisions

Developers can apply to APHIS for deregulation of a new product, a status granting the product exemption from legal oversight. This procedure only concerns marketing and does not apply to field trials. Upon receipt of an application, APHIS publishes an announcement in the *Federal Register*[19] and creates a public record. General information on the application is then posted on the Internet, including the general characteristics of the GM plant and the role of the other regulatory agencies (EPA and FDA). The posting explains the procedure to follow to submit comments (within a 50-day period), obtain further information, or obtain a copy of the application (minus any confidential data).

Following the review of the application, APHIS publishes a second announcement in the *Federal Register* stating the final decision. A decision document informs the public of the reasons for the decision and summarizes the written comments received.[20]

b) EPA Provisions

Similar to the USDA, the EPA uses the *Federal Register* and the Internet to inform the public and allows 30 days for comment. After completing its review, the EPA announces its decision in the *Federal Register* and a new comment period begins, during which written objections and requests for a formal hearing may be submitted. As for pesticide registration applications, the EPA produces public documents explaining the scientific foundations of the decision.

All field trials are must meet standards designed to maintain a degree of confinement and minimize accidental releases. EPA does not conduct public consultations on the risks of environmental contamination unless the crop has a distinctly novel characteristic. However, it does publish periodic announcements in the *Federal Register* indicating

[18] Gregory Jaffe, *A Consumer Perspective on Regulating Agricultural Biotechnology*, CSPI, March 2002.

[19] The *Federal Register* is an official government publication that is updated daily. It is the official US journal reporting on decisions of the government.

[20] Publications of APHIS final decisions in the *Federal Register* are viewable online at http://www.aphis.usda.gov/ppd/rad/webrepor/brs.html.

where the list of ongoing field trials may be obtained. EPA does not place any limits on the area of experimental fields.

For field trials larger than 10 acres of transgenic plants synthesizing pesticides, the developer must obtain an Experimental Use Permit (EUP) from the EPA, first contacting the agency to ascertain the data necessary to obtain the permit. In the EUP evaluation process, the public is notified and invited to comment through an announcement in the *Federal Register*.

The EPA is evidently the most transparent of the three agencies, as the following discussion of the FDA indicates.

c) FDA Provisions

Developers who have gathered data they consider to be sufficient to guarantee the safety of their product and meet the requirements of the regulation may submit a summary of the nutritional and safety assessment to the FDA. This typically includes:

- the purpose of the genetic modification and a description of the applications or uses of the GM food, including its use as feed;
- a molecular characterization including identity, origin and function of the introduced genetic material;
- information on the protein expressed by the introduced genes;
- information on the known or suspected toxicity or allergenicity of products expressed in the plant;
- information on the composition and nutritional characteristics of the food, including anti-nutrients;
- for allergenic foods, information specifying whether the allergens were eliminated by the genetic modification;
- in certain cases, results of comparative studies between a diet containing the genetically modified food and a diet containing the equivalent conventional food.

Due to the voluntary nature of the process, there is no obligation to inform the public via the *Federal Register* nor to call for public participation. The FDA does not publish a product approval as such but informs the developer by mail that it has no additional questions about the information presented and reminds the developer of its legal responsibilities. The FDA does publish a list of completed assessments, stating the developer's name, the introduced characteristic, and the identity of the introduced genes as well as the year during which the assessment took place.

1.2.2 Proposals for Improved Transparency

In May 2000, the US government announced new initiatives to enhance the system's transparency by putting an emphasis on information provided to consumers and farmers. The following three points are noteworthy:

- a review of environmental regulations by the Council on Environmental Quality;
- steps by the FDA to establish a system requiring mandatory approval at least 120 days before the introduction of a new crop or product into the food chain, as well as a proposal to make public the information submitted and the agency's conclusions;
- guidelines developed by the FDA toward voluntary labelling of food products, indicating reliably and formally that they contain or do not contain GMOs.

In January 2001 under the Clinton administration, the FDA published a concrete proposal for mandatory prior application to market GMOs. This new rule confirmed that the FDA would require a data submission 120 days prior to marketing, whether the GMO is intended for food or feed. The change did not take place.

In May 2003 under the Bush administration, the FDA again announced that its system would undergo improvement in order to enhance public confidence, but once again the change did not take place.

If the plan were to undergo consultation today and required developers to file a mandatory submission for approval of their GM products, it would still have major weaknesses. The proposal would improve the current process in requiring a systematic review by the agency and enhancing transparency, but this would not change the agency's scientific review, nor would it give rise to an official determination of safety. After the mandatory submission for approval, the FDA would still be unable to state that the food is safe for consumption. Moreover, if a developer markets a GM food without notifying the FDA, the onus would still be on the agency to prove the food unsafe before it could be ordered withdrawn from the market.

In short, the proposal would not create an ideal system for consumers since it would fall far short of a fair, transparent, mandatory pre-market approval or certification system with opportunities for public participation. At any rate, this proposal appears to be low on the agency's list of priorities, and transparency advocates are left with uncertainty as to the resolution of this issue.

The FDA, then, is less open than the other two agencies (whose processes are less than ideal) to incorporating public information and participation into its process. Under the prevailing system, industry claims are not subject to independent verification and nothing requires the FDA to share the responsibility for the final safety decision.

The US regulatory system remains incomplete, since some GM foods cannot be released without prior approval while others can. If the developers' claims that they are already conducting sufficient testing to guarantee food product safety are truthful, then a bona fide regulatory system would probably not place a significantly heavier burden on industry. Such a system would more closely resemble the European and Canadian systems, in which GM foods and crops are not released into the environment or onto the market until a governmental authority declares them fit for consumption.

John Turner of APHIS specifies that while public comments were rare in the early 1990s, they often number in the hundreds today. Consumers' associations are the most vocal.

Gregory Jaffe, Director, Project on Biotechnology, Center for Science in the Public Interest (CSPI), explains that one positive outcome of public participation has been to specify the conditions necessary for public acceptance of an approval. This, for example, led to a stepped-up research and control program on Bt resistance.

There is currently no legal provision for judicial review.

1.3 NUMBER OF GMOS APPROVED

In the period 1987–1997, the regulatory system allowed some 3332 field trials on 48 species and cultivation of 30 transgenic plant varieties; it authorized more than 20 species for consumption. About 60 GMOs have been approved in the United States to date.[21] GM crops cover 32.5 million hectares in the country, accounting for 63% of the world total.[22]

1.4 GM FOOD AND CROP LABELLING POLICY

The FDA has had to take a position on the status of genetically modified ingredients. In its 1992 policy, it stated that there is no justification for concluding that GM foods differ significantly or uniformly from other foods. It stated that they do not, as a food group, pose different or greater hazards than conventional foods, and so labeling regulations are unnecessary. Consequently, GM foods are not labeled as such. They are covered by the same labeling laws as conventional foods, which require labelling only where there is a health risk (modified nutritional properties, presence of an allergen).

As one might expect, this refusal to label GMOs in foods in both Canada and the United States has stoked consumers' suspicions as to the potential risks. Consumers reason that if the governments are keeping something from us, then it may be because they have something to hide.

[21] See online at http://www.essentialbiosafety.info.

[22] *Bio-bulle*, no. 47, April 2004, and Appendix 8 of this report.

1.5 CONCLUSION

US biotechnology regulatory policy since 1992 has been based on the principle that the techniques of genetic engineering do not represent a particular hazard. More specifically:

- the existing laws are, for the most part, adequate to regulate biotechnology;
- the products, not the process, are regulated;
- GMOs are not fundamentally different from other organisms;
- regulatory authority should only be exercised where the risk of introduction is proved to be unreasonable.

Today, the FDA does not require a notice from the biotechnology industry stating its intention to bring a GMO to market where the company concludes that its product is "generally recognized as safe" (GRAS). However, the FDA determined that the introduction of a new gene into a conventional food falls under the food additive provisions of the *Food, Drug and Cosmetic Act* of 1958, except where the resulting food is "substantially equivalent" to a GRAS conventional counterpart. But when the FDA approves an application for a new additive, it publishes a regulatory notice declaring that the additive is safe, indicating the data in support of that decision, and establishing provisions for the use and labeling of the additive. Moreover, the changes under consideration by the agency will not always require the FDA to approve GM products before they are marketed.

On another note, the USDA recently came in for criticism by the National Research Council (NRC) for its inability to involve the public in policymaking and decision-making on biotechnology issues in agriculture. The NRC recommended that the USDA call for public comment on its product-related decisions (NRC, 2002).

GM food and crop regulations in the United States and Canada are similar in several respects. Both countries have adopted a coordinated approach in which regulatory

responsibility is shared among several agencies and risk assessment is supported by solid scientific evidence. Both systems give central importance to the novel nature of the product. This product-oriented approach differs from the process-oriented approach developed by other countries such as the European Union, Australia, and New Zealand, and found in the Cartagena Protocol on Biosafety.

2. REGULATION, TRANSPARENCY, AND PUBLIC PARTICIPATION IN THE EUROPEAN UNION[23]

European and North American legislation differs on how GMOs are regulated. Whereas the United States and Canada consider the risks of biotechnology-derived and conventional products to be *a priori* identical, the European Union holds that transgenic plants are not ordinary plants. In the spirit of precaution, any possible impact of genetic manipulation must be assessed by a committee of experts.

In this section we analyze the European provisions. It should be noted that our analysis predates the entry of the ten new countries into the EU on 1 May 2004.

2.1 THE REGULATORY FRAMEWORK: DIRECTIVES 90/220 AND 2001/18

In the European Union, GMOs may not be deliberately released into the environment without prior authorization, whether for purposes of experimentation or commercialization. The GMO regulatory framework has been in force since the early 1990s and has been amended and refined throughout the decade. Europe has adopted specific provisions to protect its citizens' health and the environment while creating a unified biotechnology market. Three types of procedures exist, according to the nature of the application.

[23] Adapted from *Report of European Workshop*: *Public Information and Public Participation in the Context of EU Directives 90/220 and 2001/18,* Schenkelaars Biotechnology Consultancy, Leiden, 2002.

Directive 90/220/EEC was the main instrument whereby experimental releases and marketing of GMOs were authorized until 17 October 2002. This directive was then repealed by a new, updated directive (2001/18/EC) on deliberate release of GMOs. Part B of both directives deals with authorization for releases as part of research and development activities, while part C deals with marketing authorization.

Directive 2001/18, like its predecessor, sets up a step-by-step authorization procedure based on a case-by-case assessment of human health and environmental risks prior to any environmental release or marketing of GMOs or products containing them, such as corn, tomatoes, or microorganisms.

GM products are covered by different laws. Products such as concentrate or ketchup made from GM tomatoes fall outside the scope of this horizontal directive, coming under vertical sectoral legislation, particularly regulation 258/97 of 27 January 1997 concerning novel foods and food ingredients, which mainly concerns labeling rules.

Finally, directive 90/219/EEC, as amended by directive 98/81/EC, governs the confined (greenhouse or lab) use of GM microorganisms in research and industry.

As is logical given our purpose here, we will focus on directives 90/220 and 2001/18 and their application.

2.1.1 Assessment of GMO Submissions

At the inception of the regulatory system, around 1990–91, there was a clear awareness of the importance of appropriate regulations to develop a climate of public trust in biotechnology regulation. In this context, it was acknowledged that public information and participation in decision-making processes around experimental and marketing applications could be crucial in creating such a climate. Thus Article 19 of Directive 90/220 provides for access to information. This article also details which information must be made public, including a description of the GMO, the name and address of the notifier, and the outcome of the risk assessment. Where a notifier wishes its data to be given confidential treatment, it must provide valid justification.

On the issue of public participation, Article 7 of the Directive leaves the responsibility for deciding whether or not to consult the public in the hands of the competent authorities of each member state.

Some 12 years later, in February 2002, Directive 90/220 came up for review. This led to the passage of Directive 2001/18, which includes legal provisions on public information and participation in GMO approval decisions.

2.1.2 Foundations of the System in the Member Countries: Policies under Directive 90/220

Directive 90/220 has now been replaced by Directive 2001/18, which took effect on 17 October 2002. However, with the new directive still recent and its ratification in process, many states still operate on the foundation of the system they implemented and used from 1990 to 2002 on the basis of Directive 90/220. Furthermore, some states already had in place highly evolved public information and consultation policies that met the requirements of the new directive.

With reference to Directive 90/220, the member countries developed their own public information and consultation policies. It is interesting to study these policies since they demonstrate the will of certain countries to inform and consult the public despite the initial absence of any obligation to do so. Furthermore, since the new directive is undergoing a gradual process of implementation, many of these country-level policies are still valid.

2.2 PUBLIC INFORMATION

Even before the advent of the new European directive, four situations prevailed regarding domestic public information provisions:

- Public information on proposed new GMOs was provided for in legislation specific to GMOs in Belgium, France, Germany, and Ireland.

- Public information was provided for in general administrative legislation in Denmark, Finland, the Netherlands, Slovenia, Sweden, and the United Kingdom.
- Public information was provided for by a combination of legislation specific to GMOs and general administrative legislation in Austria, Estonia, and Poland.
- There were no legal provisions for public information in Italy, Portugal, or Spain.

The competent authorities[24] of Italy, Portugal, Spain, and Finland (despite the law) do not inform the public of applications for GMO approvals. In other countries, the competent authority informs the public by placing a notice in:

- Austria: government gazette and two local newspapers
- Belgium: website
- Denmark: website
- Estonia: government gazette and website
- France: city hall of the municipality closest to the site of the trial, website
- Germany: government gazette, local and regional newspapers, website
- Ireland: local and regional newspapers
- The Netherlands: government gazette, national, regional, and local newspapers, website
- Poland: city hall, website
- Slovenia: national newspapers, city hall of the municipality closest to the sites of trials, website
- Sweden: distribution of application to interested parties
- United Kingdom: local newspapers.

[24] The competent authority designates the national organization with authority in the country.

Where an organization or citizen believes that a request for information was wrongly denied or inadequately responded to, they have access to a judicial review procedure in Austria, Estonia, France, Germany, Ireland, the Netherlands, Poland, Slovenia, Spain, Sweden and the United Kingdom.

2.3 PUBLIC PARTICIPATION

Likewise, four situations prevail regarding domestic public participation since 1990:

- There are no legal provisions for public participation in decision-making on new GMOs in Belgium, Finland, France, Portugal, Spain and Sweden.
- Public participation is provided for in legislation specific to GMOs in Austria and Estonia.
- Public participation in decision-making is provided for by a combination of legislation specific to GMOs and general administrative legislation in Denmark, Germany, Poland and Slovenia.
- Public participation in decision-making is provided for in general administrative legislation in Ireland, Italy and the Netherlands.

In Austria, Denmark, Estonia, Germany, Ireland, the Netherlands, Poland, Slovenia, Portugal and Belgium (despite the absence of applicable legal provisions in the last two countries), the public is authorized to submit comments during a certain period.

The competent authorities of Finland, France, Portugal and Austria do not inform the public of decisions on applications. In the other countries, the competent authority informs the public of the decision by placing a notice in:

- Belgium: website
- Denmark: Parliament website

- Estonia: government gazette and website
- Germany: website and, optionally, government gazette, national, regional and local newspapers
- Ireland: national, regional and local newspapers
- Italy: website
- Netherlands: government gazette, national, regional and local newspapers, website
- Poland: website
- Slovenia: website
- Spain: website
- Sweden: website
- United Kingdom: website

Where an organization or citizen believes that the competent authority did not follow the public participation procedure in making a decision, they have access to a judicial review procedure in France, Ireland, Italy, the Netherlands, Poland, Slovenia, Sweden and the United Kingdom. In Austria, access to such remedies is provided by the communes and provinces involved, while in Germany, access is provided for persons who claim that their personal rights were violated.

2.4 PUBLIC RECORDS

The competent authorities of the following countries maintain publicly available records as indicated below:

- Austria: government library, website
- Belgium: website
- Denmark: Parliament website

- France: government library, website
- Germany: website
- Ireland: access on request
- Italy: government library
- The Netherlands: government library, website
- Poland: website
- Spain: website
- Sweden: website
- United Kingdom: website

In Austria, Denmark, Finland, France, Germany, Ireland, the Netherlands, Slovenia and the United Kingdom, organizations and/or citizens have used the legal provisions on public information and participation in the decision-making process.

According to a study[25] commissioned by the European Commission in May 2002:

- the competent authorities of Austria, Denmark, Finland, France, Germany, Ireland, Slovenia and the United Kingdom indicate that the results of public consultations were taken into account in the decision-making process;
- the competent authority of the Netherlands goes further, indicating that this resulted in:

  1) further specification of legal obligations;

  2) greater clarification of decision-making criteria;

  3) amendments to permitting provisions

[25] Schenkelaars Biotechnology Consultancy, *Public Information and Public Participation.*

4) in-depth policy debates on specific topics such as the use of herbicide-resistant plants, organic agriculture, and insurance and liability concepts.

- None of the competent authorities indicated that the issues raised by the public consultation led to new topics of scientific research.

The following table indicates the kinds of information made publicly available in each country:

	Risk assessment	Decisions of competent authority	Field trial sites	Advisory committee comments	Limits or conditions placed on permits	Outcome of approval process	New information with significant consequences	Resources and contacts for more information
Austria								yes
Belgium	yes	yes	yes	yes	yes		yes	yes
Denmark	yes	yes	yes	yes	yes			
France			yes					
Germany		yes	yes		yes			
Ireland	yes	yes	yes	yes	yes	yes	yes	yes
Italy	yes	yes	yes	yes	yes	yes	yes	yes
Netherlands	yes	yes	yes	yes	yes	yes	yes	yes
Poland	yes	yes	yes	yes	yes	yes	yes	yes
Spain		yes		yes	yes	yes	yes	yes
Sweden	yes	yes	yes	yes	yes	yes	yes	yes
UK	yes	yes	yes	yes	yes	yes	yes	yes

We proceed, in the next section, to further explore the public information and consultation procedures operating in a few sample countries under Directive 90/220 (the previous directive).

2.5 SYSTEMS OF DENMARK, UNITED KINGDOM AND SLOVENIA: A DETAILED ANALYSIS

We will pay special attention to the procedures developed in Denmark, since the procedures of the United Kingdom and Slovenia are similar.

2.5.1 Regulatory Framework

There are no legal provisions on public information, but this is an implicit part of the mandatory public consultation procedure.

The competent authority is the Department of the Environment but, in practice, the Forests and Nature Agency prepares decisions in the form of a notice to the Department. In preparing this decision, the agency consults experts from:

- the National Institute for Environmental Research (on nature and environmental issues)
- the Danish Council of Plants (on agricultural issues)
- the Food Security and Toxicology Institute (on health issues)

The notices to the Department of the Environment are posted on the website of the Danish parliament and available to the public. In addition, under Denmark's access to information regime, the competent authority must provide information other than confidential information upon request by any citizen, free of charge.

2.5.2 Public Information and Participation

The obligation for the competent authority to inform and involve the public in decision-making on GMO releases is fulfilled by distributing a portion of the application to 50 stakeholders, including the main environmental and consumer groups. On request, the remainder of the application (except confidential information) may be obtained from the Forest and Nature Agency. The comment period is approximately 30 days (48 for the United Kingdom). Comments are incorporated into the notice to the Department of the Environment, which makes the final decision.

New GMO applications are also posted on the authority's website. The information includes a general description of the GMO, the applicant's name and address, the purpose of the application, the site or sites where the GM plant will be cultivated, the intended use

of the GMO, a description of the potential environmental and human health effects, a description of measures taken to limit harmful effects, a description of the plan to control the effects, a description of measures to handle GM crop residues, and a description of the emergency plan of action. The United Kingdom adds the permit limits and conditions, any new information that comes to light, and instructions for obtaining additional information.

In addition, for applications to market GMOs as products or product constituents, an opinion is required from the Special Committee on Environmental Issues, on which other departments and agencies are represented.

Approvals may not be appealed administratively (although this is possible in Slovenia and the United Kingdom), since the committee in question does not have the power to review decisions of the Department of the Environment. Approvals may be appealed before the courts, but for the same reasons, the courts are only competent to review errors of fact or form in decisions, not the reasoning itself.

Organizations have made use of the public participation provisions on several occasions. The governments continue to explore other legal mechanisms for involving the public in the decision-making process.

With the passage of Directive 2001/18, the existing procedures will be converted into legal provisions.

2.6 SYSTEMS OF AUSTRIA, GERMANY, AND THE NETHERLANDS: A DETAILED ANALYSIS

We will pay special attention to the procedures developed in Austria, since the procedures of Germany and the Netherlands are similar.

2.6.1 Regulatory Framework

The legal provisions on public information are contained in a regulation specific to GMOs and in general administrative legislation. When it receives an application, the competent authority provides information on the public authority responsible for the decision, the relevant procedures, the opportunities for public participation, the public authority with which the information was filed for public examination, the authority to which comments and questions may be submitted, and details on the available information concerning environmental impact.

The competent authority for an application from governmental scientific institutions or universities is the federal Department of Education, Science and Culture, while for an application from a private source, the competent authority is the federal Department of Security and Social Affairs. The Federal Environmental Agency, a body of the Department of Agriculture, Forests, Environment, and Water, receives a copy of the application for comment. The Scientific Subcommittee on Deliberate Releases and the marketing unit of the Austrian Genetic Engineering Advisory Committee issue a scientific/technical opinion. No ethics bodies are consulted.

2.6.2 Public Information

The competent authority informs the public of an application by placing an announcement in the official government gazette, two local newspapers, and on the official website. It informs the region and commune where the release will take place as well as the neighbouring communes, by sending a copy of the application to the relevant officials.

Publicly available information includes a general description of the GMO, the applicant's name and address, the purpose of the application, the site or sites where the GM plant will be grown, the intended use of the GMO, a description of the potential environmental and human health effects, a description of measures taken to limit harmful effects, a description of the plan to control the effects, a description of measures to handle

GM crop residues, a description of the emergency plan of action, the main reports and advice issued by the advisory committee, and a non-technical summary.

There may be a fee to obtain excerpts or copies, depending on the number of copies requested. In some circumstances, the fees may be reduced or waived.

Where a public interest organization or individual citizen believes that a request for information was wrongly denied or inadequately responded to, they have access to a judicial review procedure.

2.6.3 Public Participation

The legal provisions on public participation are contained in a regulation specific to GMOs. The public participation procedure allows the public to submit comments during a 3-week period (4 weeks in the Netherlands). Following this, a public hearing must take place within a period ranging from 8 to 21 days if comments have been submitted. Each intervenor is allotted a maximum of 15 minutes. The hearing protocol must be sent to the applicant, the advisory committee members, and the Department of the Environment. The text of the final decision indicates the extent to which the points raised by the public were taken into account. In the Netherlands, the decision may be appealed within the six weeks following its announcement.

It is planned to inform the public of the competent authority's decision by posting it on the official website, where the text will also be available.

If the localities or provinces concerned are dissatisfied with the attention paid to the comments as part of the public consultation procedure, they have access to a judicial review procedure.

Records are kept by the competent authority. They are publicly available in government libraries and on the government's official website. The records contain information on the places where additional information may be obtained.

Organizations and individual citizens have used the public information and participation provisions on several occasions. In 1996, two public hearings were held. Of a total of five applications submitted, four were withdrawn by the applicants. The fifth was rejected by the competent authority. It should be noted that in the wake of a popular initiative of 1997 seeking to outlaw GM trials and crops, public opposition to experimental and commercial GMO releases is overwhelming.

The passage of Directive 2001/18 does not fundamentally change the procedures used in these three countries since 1990.

2.7 OTHER COUNTRIES

Other countries have adopted some particularly interesting practices. We will focus on three such practices, each current in one or more countries.

2.7.1 Public Information in Belgium: Consumer-Oriented Provisions

In Belgium, the law provides that every application for experimental or commercial release of GMOs must contain a public information dossier. This dossier has an educational function in that it is designed to give citizens the means to gather knowledge, measure the advantages and risks, form their own opinion, and so on. The applicant is asked to use clear and simple language, to explain scientific concepts and terms, and to avoid scientifically unfounded assertions, since these are perceived by the public with suspicion and skepticism. In addition, the public dossier must contain information on the socioeconomic aspects of the application. The secretariat of the Council on Biosafety has drafted guidelines on the production of these dossiers. The public dossiers are posted on the government's official website along with the notices of the Council on Biosafety, the authorization of the competent department, and the GMO cultivation protocols.

In Belgium, the issuance of Directive 2001/18 is accompanied by an increasing emphasis on socioeconomic impacts and sustainable development issues.

2.7.2 Public Participation in France and Ireland: A Consumer Representative Advises the Competent Authority

In France, the competent authority for GMO assessment is the Department of Agriculture and Fisheries, which also consults the Department of Land Use Planning and Environment. An opinion is solicited from the Committee on Biomolecular Engineering, which is composed of biomolecular engineering experts plus six other members, including one consumer representative.

In Ireland, the competent authority is the Environmental Protection Agency, which consults other government departments and bodies. An opinion is requested from a 15-member advisory committee whose members include the Department of Health and Children, the Health and Safety Authority, the Director of Consumer Affairs, and a representative of consumer associations.

The Irish competent authority is exploring other mechanisms for involving the public apart from those required by law. It is developing a consultation document on GMO releases and organizing a national consultation as well as several seminars.

2.7.3 Sweden: Ethical Aspects Considered

In Sweden, the Advisory Committee on Gene Technology has the special mandate to control the development of biotechnology nationally and internationally, to provide advice on ethical issues, to promote the safe use of gene technology, and to inform the public of advances in this technology. The members of this committee are appointed by the government. They include the chair (a lawyer), the vice-chair, seven members of Parliament, an ethics expert, an animal protection expert, an ecology expert, and four genetic engineering experts.

Where legal provisions as described in this chapter exist, they may offer the possibility for organizations to appeal decisions. Since the early 1990s, various organizations have brought legal actions where the information on an approved GMO was not publicly

available. Greenpeace in the Netherlands has intervened on environmental protection issues. In the fall of 2000, the organization appealed six approvals of permits issued by the Department of the Environment, calling for their immediate suspension. One year later, the court ruled that the Department should have requested a detailed description of the sites under consideration by the applicant, Advanta. The Department had to revoke the permits and is now requesting a detailed description of the sites.

Despite the opportunities offered to organizations and citizens with a view to improving the GMO assessment process, its transparency, and the level of consultation, there remains no possibility of citizen challenges around underlying issues such as the insufficiency of scientific evidence on safety, gene transfer into non-transgenic and organic crops and wild plants, potential harm to biodiversity, liability issues, etc. Judicial reviews are limited to procedural issues. Therefore, scientific and technical controversies are essentially excluded from the public consultation process.

2.8. LEGISLATIVE DEVELOPMENTS FURTHER TO DIRECTIVE 2001/18

Directive 2001/18 of 12 March 2001 repealed Directive 90/220 of 17 October 2002, but its implementation has been a very gradual process. As of December 2003, numerous states had not yet enshrined the new directive in their domestic law.[26] However, the situation has begun to change rapidly in the first half of 2004.

The main purpose of Directive 2001/18 is to make the GMO deliberate release and marketing authorization procedure more efficient and transparent, to limit authorization to a renewable 10-year period, and to introduce mandatory control, labeling, and traceability at all stages of GMO marketing.

[26] These members include Belgium, Germany, Greece, France, Spain, Luxembourg, the Netherlands, and Finland.

It also provides for a common method for assessment of risks associated with GMO releases[27] and a mechanism for amending, suspending, or halting GMO releases where new information is obtained on the associated risks.

Public information and participation provisions have been enhanced in the new directive, and indeed, these are now legal obligations. The relevant provisions are dispersed throughout the text, and are discussed below.

- **Preamble**

Clause 10 of the preamble provides: "For a comprehensive and transparent legislative framework, it is necessary to ensure that the public is consulted by either the Commission or the Member States during the preparation of measures and that they are informed of the measures taken during the implementation of this Directive."

Clause 46 reads: "Comments by the public should be taken into consideration in the drafts of measures submitted to the Regulatory Committee."

Following Part A, "General Provisions," is Part B, "Deliberate Release of GMOs for Any Other Purpose than for Placing on the Market."

- **Part B, Article 9: Consultation of and Information to the Public**

Article 9 provides as follows:

> 1. Member States shall… [with exceptions] consult the public and, where appropriate, groups on the proposed deliberate release. In doing so, Member States shall lay down arrangements for this consultation, including a reasonable time-period, in order to give the public or groups the opportunity to express an opinion.
>
> 2. … Member States shall [with exceptions] make available to the public information on all part B releases of GMOs in their territory;

[27] The principles applicable to environmental risk assessment are given in Appendix II of the directive.

The Commission shall make available to the public the information contained in the system of exchange of information pursuant to Article 11. [Article 11 defines the mechanisms for exchange of information among the competent authorities and the Commission].

- **Part B, Article 7: Differentiated Procedures**

If sufficient experience has been obtained of releases of certain GMOs in certain ecosystems… a competent authority may submit to the Commission a reasoned proposal for the application of differentiated procedures to such types of GMOs.

…

2(b). The Commission shall make available the proposal to the public which may, within 60 days, make comments; and

…

- **Part B, Article 8: Handling of Modifications and New Information**

2. If information becomes available to the competent authority… which could have significant consequences with regard to risks for human health and the environment…, the competent authority shall evaluate such information and make it available to the public. It may require the notifier to modify the conditions of, suspend or terminate the deliberate release and shall inform the public thereof.

Part C concerns the marketing of GMOs as products or product constituents. The public information and participation provisions are as follows:

- **Part C, Article 16: Criteria and Information for Specified GMOs**

3. Before the procedure laid down in Article 30(2) for a decision on criteria and information requirements referred to in paragraph 1 is initiated, the Commission shall make the proposal available to the public. The public may make comments to the Commission within 60 days. The Commission shall forward any such comments, together with an analysis, to the Committee set up pursuant to Article 30.

- **Part C, Article 24: Information to the Public**

1. Without prejudice to Article 25, upon receipt of a notification in accordance with Article 13(1), the Commission shall immediately make available to the public the summary referred to in Article 13(2)(h). The Commission shall also make available to the public assessment reports in the case referred to in Article 14(3)(a). The public may make comments to the Commission within 30 days. The Commission shall immediately forward the comments to the competent authorities.

2. Without prejudice to Article 25, for all GMOs which have received written consent for placing on the market or whose placing on the market was rejected as or in products under this Directive, the assessment reports carried out for these GMOs and the opinion(s) of the Scientific Committees consulted shall be made available to the public. For each product, the GMO or GMOs contained therein and the use or uses shall be clearly specified.

Part D contains the final provisions.

- **Part D, Article 25: Confidentiality**

4. In no case may the following information when submitted according to Articles 6, 7, 8, 13, 17, 20 or 23 be kept confidential:

– general description of the GMO or GMOs, name and address of the notifier, purpose of the release, location of release and intended uses;

– methods and plans for monitoring of the GMO or GMOs and for emergency response;

– environmental risk assessment.

- **Part D, Article 29: Consultation of Committee(s) on Ethics**

1. Without prejudice to the competence of Member States as regards ethical issues, the Commission shall, on its own initiative or at the request of the European Parliament or the Council, consult any committee it has created with a view to obtaining its advice on the ethical implications of biotechnology, such as the European Group on Ethics in Science and New Technologies, on ethical issues of a general nature.

This consultation may also take place at the request of a member state.

2. This consultation is conducted under clear rules of openness, transparency and public accessibility. Its outcome shall be accessible to the public.

- **Article 31: Exchange of Information and Reporting**

…

2. The Commission shall establish one or several register(s) for the purpose of recording the information on genetic modifications in GMOs mentioned in point A No 7 of Annex IV. Without prejudice to Article 25, the register(s) shall include a part which is accessible to the public…

3. Without prejudice to paragraph 2 and point A No 7 of Annex IV,

(a) Member States shall establish public registers in which the location of the release of the GMOs under part B is recorded.

b) Member States shall also establish registers for recording the location of GMOs grown under part C, inter alia so that the possible effects of such GMOs on the environment may be monitored in accordance with the provisions of Articles 19(3)(f) and 20(1). Without prejudice to such provisions in Articles 19 and 20, the said locations shall:

– be notified to the competent authorities, and

– be made known to the public in the manner deemed appropriate by the competent authorities and in accordance with national provisions.

These provisions give legal, mandatory status to the procedures related to public information and participation. They also specify the minimum information that must be made public. During the notification process, consumers have access to public data on the Internet (http://gmoinfo.jrc.it)[28] including a summary of the notification, the assessment reports of the competent authorities, and the opinion of scientific committees.

Finally, Article 33 establishes a policy for applying penalties in the event of non-compliance with the legal provisions of this directive. It stipulates that "Member States shall determine the penalties applicable to breaches of the national provisions adopted pursuant to this Directive. Those penalties shall be effective, proportionate and dissuasive."

[28] See home page in appendices.

In summary, the new directive makes public consultation and GMO labeling mandatory. The notification information exchange system established by Directive 90/220/EEC is maintained. The Commission is now required to consult the competent scientific committees on any issue likely to have human health and/or environmental impacts. It may also consult ethics committees. Also mandatory is the establishment of several registers concerning information on GMOs and the location of GMO trials.

To ensure the system's effectiveness, the Commission must publish a triennial summary of measures taken by member states to implement this directive. In 2003, the Commission published its triennial report of experiences with GMO marketing. A report on ethical issues is to be published annually.

2.9 IMPLEMENTATION OF THE EUROPEAN FOOD SAFETY AUTHORITY (EFSA)

The implementation, on 28 January 2002, of the European Food Safety Authority (EFSA) is a step forward for transparency. This authority's essential mission is to assist and provide independent scientific advice and to create a network for close cooperation among counterpart bodies in member states. It assesses risks related to the food chain and informs the general public thereof. EFSA has been entrusted with six main responsibilities:

(1) at the request of the Commission, the European Parliament, and the member states, to provide independent scientific advice on food safety issues and related matters, such as animal health and well-being, plant protection, GMOs, and nutrition, which advice serves as the basis for risk management decision-making;

(2) to issue opinions on technical food issues as guidance for policies and legislation related to the food chain;

(3) to collect and analyze data on foodborne exposure, as well as other information concerning any potential risk, that is necessary to control safety throughout the food chain in the European Union;

(4) to identify and give early notice of emerging risks;

(5) to assist the Commission in the event of a crisis;

(6) to oversee communication with the general public on all issues arising from its mandate.

For reasons of scientific consistency, EFSA also provides scientific advice on all GMO-related issues. When a GMO application is filed with a state, the latter issues a preliminary opinion. The Commission in Brussels then distributes it to the member countries for comments. EFSA considers the resulting comments and renders the final decision.

EFSA is composed of four bodies: The Management Board, the Executive Director's office, the Advisory Forum, and the Scientific Committee and Panels.

The composition and selection procedure for EFSA's 15-member Management Board are such as to guarantee its independence. The selection criteria are designed to select highly competent members with diversified experience in food safety. One member of the Board is a European Commission representative[29] while five members represent consumers. The Commission's representative is Robert Coleman, Director General of Health and Consumer Protection. Members are appointed for a 4–6 year period.

The Authority actively informs the public of its activities and their results. The information is objective, reliable, and comprehensible to the general public.

[29] See composition of Board of Directors in Appendix 4.

2.10 NUMBER OF GMOS APPROVED

Since Directive 90/220 took effect in October 1991, commercial distribution of 18 GMOs has been authorized in the European Union, while some have also been authorized as crops.

One application for approval received an unfavourable opinion due to an insufficient risk assessment in terms of the presence of one or more uncharacterized genes in the GM plant variety, in particular, the gene coding for resistance to amikacin, an important medical antibiotic. This application was withdrawn.

The committee has published three favourable opinions on novel foods of plant origin (tomato and corn) and four on products of microbial origin.

Several member states have invoked Article 16 (known as the "safeguard clause") of Directive 90/220 to temporarily prohibit the entry of GM corn and oilseed products into their markets. Nine safeguard cases were filed under Article 16, involving Austria, Luxembourg, France, Greece, Germany and the United Kingdom. These cases were reviewed by the scientific committee on plants which, in all cases, found that the information submitted by the member states did not justify their bans.

The Commission has now received 22 opinions under the new Directive 2001/18, including 11 limited to importation and processing, the rest relating to cultivation. Seven of these latter concern products that were pending under Directive 90/220 at the time of its repeal. Appendix 3 summarizes the situation as of 24 December 2003.

The cultivated area under GM crops in Europe is very small, as the figures in Appendix 8 suggest.

2.11 GM FOOD AND CROP LABELING POLICY

The European Union states that it recognizes consumers' right to information and labeling as tools for making enlightened choices.

Labeling of these products is governed by regulation 258/97 on novel foods, pursuant to which the presence of GMOs must be indicated where the GMO derivatives are not equivalent to the comparable existing products. A subsequent instrument, regulation 1139/98, details the concept of equivalence and specifies the information that must appear on the label. Although they refer to products derived from Bt-176 corn and Monsanto soy, their provisions are transposable to all products authorized under regulation 258/97.

Since 17 October 2002, Directive 2001/18 provides that member states must take all measures necessary to guarantee labeling of GMOs for products at all stages of marketing. Products not equivalent to their counterparts, thus subject to the labeling obligation, are those containing DNA or proteins linked to genetic modification. Labels must bear the notice, "produced from genetically modified soy/maize" or "genetically modified," either right after the name of the ingredient or in an asterisked note following the list of ingredients. The same information must appear on labels of products for which there is no ingredient list or where one of the ingredients is itself composed of GMO ingredients. These obligations do not apply to ingredients composed of less than 1% GM ingredients or to "adventitious contamination."[30] Operators must be in a position to demonstrate that they used appropriate measures to prevent such contamination. Claims that a product is GMO-free are prohibited if unproven.

Finally, the regulation prescribes the drafting, after obtaining the opinion of scientific committees, of a list of products considered equivalent and therefore dispensed from labeling requirements.

Meanwhile, in January 2000, the Commission adopted Regulation 50/2000 to ensure that additives and seasonings are also labeled if GM-derived DNA or protein is present in the final product. Under Directive 98/95, GM seed varieties must also be clearly labeled.

[30] Pursuant to Regulation 49/2000 concerning the problem of the adventitious presence of GM material in conventional food.

The tolerance limit was decreased from 1% to 0.9% on 28 November 2002. Following this, on 22 July 2003, the European ministers of agriculture adopted two Commission proposals on GMOs to establish a labeling and traceability system and to regulate the marketing of GM-derived feed. This decision paved the way for the GMO moratorium in force since 1999 to be lifted. The EU regulations strengthening the labeling obligations for GM-based or -derived products for food or feed took effect on 18 April 2004. Animal products (milk, meat, eggs) are excluded. The text covers highly refined genetically engineered products (e.g., soya lecithin) in which there is no longer any trace of recombinant DNA. This text, which reinforces the previous regulations enacted in 1997 and 1998, requires a field-to-table traceability chain for GM-derived raw materials in addition to the usual testing.

Restaurant and snack bar menus as well as fast food restaurant signs are covered by this mandatory labeling requirement, even if the ingredient in question is a minor one.

Currently, in Europe, the issue of labeling arises only for GM-derived products that may be used today as ingredients in food. For the time being, there are no GMOs as such (e.g., transgenic tomatoes) on the European market. Surveys continue to show that European consumers are highly suspicious of GMOs; the Eurobarometer for 6 December 2001found that 70.9% do not want to eat them.

2.12 CONCLUSION

The major strength of the European system is its entrenchment in the law of the right to public information and participation. Such provisions apply differently in the 15 countries depending on what had already been implemented in the 1990s prior to the enactment of Directive 2001/18, which made these procedures mandatory. This directive guarantees a minimum of transparency and consultation in all EU countries.

The official Internet sites are heavily used. These differ from their Canadian and US counterparts in that the sites of field trials are disclosed, the information on GMOs is more complete, and a non-scientific summary is sometimes provided. Non-disclosure of information on the grounds that it is confidential appears difficult to justify in such a

context. The consultation periods are of the same duration as in Canada and the United States.

A major difference between the European and North American systems is the presence of advisory committees revolving around the competent authority. This allows for the consideration of the ethical dimension in GMO assessment, particularly in Sweden, which does so systematically. France and Ireland are notable in allowing consumer representatives to sit on these committees. In Denmark, the United Kingdom, and Slovenia, a portion of the application is sent to an organization representing consumers; it includes a plan to control any harmful effects and an emergency action plan, as well as the addition of any new information that may arise. Belgium is exemplary in making a comprehensive, clearly-worded summary, including socioeconomic aspects, available to the public. Public hearings are held in Austria, Germany and the Netherlands. Finally, consumers and their representatives have access to judicial review if they believe that the procedures used were contrary to law.

Besides the legally binding nature of its provisions and the comprehensive labeling and traceability system it sets up, Directive 2001/18 limits the term of approvals to 10 years (renewable).

In parallel with public involvement in the approval process, European countries have held public consultations. It should be said that the public has never been democratically consulted on the advisability of GMO introduction, except in Switzerland, where this issue was the subject of a referendum in 1998. Nevertheless, several EU governments have held consensus meetings with small groups of citizens on the subject — in the Netherlands in 1993, Norway in 1996, France in 1998 and Denmark in 1999. Follow-up to the recommendations of the citizens' conference held in France in June 1998 appears to be scant, however.

In 2003, in preparing its decision to authorize new transgenic crop trials, the French Department of Agriculture stated that it did not want to rely solely on the opinion of the Biomolecular Engineering Commission but also wanted to consult public opinion via its website. This consultation took place rather discreetly, according to consumers'

associations. The results of this consultation are now available on the Department's website. Of 565 e-mails received, 96.5% of them opposed the trials; only 20 e-mails were favourable. Yet the Department authorized new trials in 2003.

The European Union has stated that it will hear consumers' concerns in meetings with citizens. The French Economic and Social Council held a public debate on GMOs and field trials in February 2002. On 6 March 2002, the "four sages" appointed by the French government published a report on the outcome of this debate.[31]

Moreover, the European Commission has created a website devoted to biotechnology on which the public is invited to comment on the new strategy that is set to make the European Union one of the world leaders in this field. The text discusses important points such as GMOs, cloning, and so on. "We want to hear those whose business it is to make the final decision: citizens, consumers, and patients," stated EC President Romano Prodi at the launching of the site. The home page is illustrated in Appendix 5 of this report.[32]

In France, a public consultation took place 10–24 May 2004. The ministers responsible for agriculture, research, and the environment set up an online public information and consultation procedure (http://www.ogm.gouv.fr) on new GMO research programs for 2004. Citizens can e-mail their comments on the 8 new research programs filed this year to brab.sdrrcc.dgal@agriculture.gouv.fr during the consultation period.

At the conclusion of this consultation, Hervé Gaymard, Minister of Agriculture, Food, Fisheries, and Rural Affairs, in conjunction with Serge Lepeltier, Minister of the Environment and Sustainable Development, will announce decisions on the new research programs. These will appear on the interdepartmental website at http://www.ogm.gouv.fr.

An interesting parallel initiative and an important contribution to the public debate on GMOs was the GM Jury Project held in the United Kingdom in the summer of 2003. It was organized by the DIY Citizens Jury Project, which is based at the University of

[31] See report in the public reports library online at http://www.ladocumentationfrancaise.fr/brp/notices/024000118.shtml.

[32] Online at http://europa.eu.int/comm/biotechnology.

Newcastle and funded by the Joseph Rowntree Charitable Trust.[33] The Consumers' Association, Greenpeace, the Co-op, and Unilever funded two 8-week juries in an effort to help the government make decisions on the authorization of GM crops in the United Kingdom.

The juries were composed of 30 members from a variety of backgrounds. Sessions were held twice a week for eight weeks, with independent witnesses testifying on the issues surrounding GMOs. The jurors were supervised by a team from the Policy, Ethics and Life Sciences Research Institute at the University of Newcastle.

The list of witnesses heard was approved by an oversight panel to guarantee that a complete range of perspectives on GMO issues would be heard. The panel was composed of experts on citizen participation initiatives on the one hand and GMO issues on the other.

Summaries of the testimony and videos were made public. The hearings themselves were public as well.

This work served to identify three major shared interests among the stakeholders: in the spirit of the precautionary principle, a halt to the sale of GM foods and to the proposed commercial growing of GM crops due to an absence of clear benefits; the need to conduct long-term research on the environmental and health risks; and an end to blanket assertions that GM crops are necessary to feed the starving in the Third World, given the complex social and economic factors that lie behind hunger.

3. REGULATION, TRANSPARENCY, AND PUBLIC PARTICIPATION IN AUSTRALIA AND NEW ZEALAND

We will focus on Australia, which has signed a treaty with New Zealand to harmonize some aspects of their regulatory systems.

[33] Online at http://www.gmjury.org/.

A consensus conference on biotechnology in March 1999 gave 14 citizens an opportunity to question various stakeholders (scientists, academics, etc.).

The 12 main recommendations of the Australian citizens' panel were as follows:

1. An independent authority made up of all parties should govern genetic engineering, with the power to sanction violators. The debates should be public.
2. Responsibility for regulation of genetic engineering should rest with the Department of Health, not the Department of Agriculture.
3. All transgenic products must be labeled. We reject the use of the term "substantial equivalence" because of its narrow scientific application.
4. They should be no new authorization to market or grow GMOs as long as regulations have not been adopted, Australia's position on the Biosafety Protocol is not clarified, and the labeling system is not in place.
5. Current regulation is too narrow in its focus on science. The overriding principle when drafting legislation should be the environment and the physical, mental and social health of individuals.
6. Australia should support the inclusion of the precautionary principle in the Biosafety Protocol, a specific liability regime, and segregation and labelling of all products.
7. The departments concerned should develop strategies to prevent any possible negative effects of GMOs on health and the environment.
8. Independent assessment of the impacts of choosing non-GMO options should be carried out and the results disclosed to the public.
9. An ethicist should be involved in the formulation of major decisions regarding GMO policies.
10. Multinational monopolies in the food industry should be investigated and prevented.

11. Public education on GMOs should include varying perspectives, as in the case of the consensus conference itself.
12. The government should commit to finding beneficial solutions for all stakeholders rather than giving in to any particular lobby.

Four or five years later, what is the status of the Australian regulations?

3.1 GMO ASSESSMENT PROCESS: REGULATION AND ORGANIZATION

3.1.1 The New National Regulatory Régime and the OGTR

The *Gene Technology Act of 2000* (GTA) came into force on 21 June 2001. It was developed in consultation with all Australian jurisdictions with a view to achieving a consistent national regulatory system for genetic engineering. The Act is supported by a set of laws and regulations ensuing from an intergovernmental agreement, which are currently applied in all the states and territories.[34]

The objective of the Act is to "protect the health and safety of Australians and the Australian environment by identifying risks posed by or as a result of gene technology, and to manage those risks by regulating certain dealings with genetically modified organisms." It provides for the creation of the Office of the Gene Technology Regulator (OGTR), an independent body headed by the Gene Technology Regulator. The OGTR has a staff of 50 scientific, legal, policy, professional, and administrative employees.

The Act also establishes the obligation of transparent and responsible enforcement, and creates a Ministerial Council to guide this process. The Act puts the emphasis on living, viable GMOs but also grants the power to regulate certain GM products (e.g., fodder) as necessary. Genetic manipulation of humans is exempted.

[34] Australia is a federation of states and territories and a member state of the Commonwealth.

While most GM products are regulated by agencies such as Food Standards Australia New Zealand (FSANZ), for food and beverages, the Therapeutic Goods Administration (TGA), for medical and pharmaceutical products, and the National Registration Authority for Agricultural and Veterinary Chemicals (NRA), for pesticides, herbicides and veterinary products, all GM products not covered by existing national regulations are now regulated by the OGTR.

The act prohibits all activities with GMOs except where these are:

- authorized in a permit issued by the OGTR;
- notified as being low risk;
- exempt from the authorization requirement, or
- included in the GMO Register.

The GMO Register also defines the activities for which a permit is not necessary.

The law introduces a permitting system for all GMO environmental releases and requires the OGTR to conduct an in-depth environmental and health risk assessment of such projects. Public hearings are mandatory wherever such releases could entail significant environmental or public health risks. The law confers extensive enforcement powers and imposes heavy penalties for violators. Persons who release GMOs without authorization are liable to prison sentences and fines ranging from AUD $55 000 to $1.1 million.[35] Penalties and compensation are also prescribed under the consumer protection provisions of the Trade Practices Act 1974, administered by the Australian Competition and Consumer Commission, which places a priority on observance of GM food labeling and advertising standards.

The Act empowers the OGTR to assess proposed activities with GMOs from confined work in certified laboratories to unconfined environmental release, and to inspect and monitor authorization conditions.

Finally, it establishes three committees to advise the OGTR and the Ministerial Council: the Gene Technology Technical Advisory Committee (GTTAC), for scientific and technical advice, the Gene Technology Ethics Committee (GTEC), for ethical issues, and the Gene Technology Community Consultative Committee (GTCCC), for general public interest issues.

The GTTAC advises the OGTR and the Ministerial Council on the conduct of the risk assessment and risk management plan. As provided by the Act, the GTTAC includes a member of the GTEC and the GTCCC.

The role of the GTEC is to provide advice on ethics to the Ministerial Council and the OGTR. As provided by the Act, the GTEC includes a member of the GTTAC and the Australian Health Ethics Committee.

Finally, at the request of the Ministerial Council or the OGTR, the GTCCC provides advice on matters of general interest. As provided by the Act, the GTCCC includes a member of the GTEC and the GTTAC.

The OGTR, with satellite bodies including FSANZ, TGA, and NRA, coordinates approvals for the use and marketing of GM products.

3.1.2 Satellite Bodies

In Australia and New Zealand, GMOs and GM products are controlled by five other major regulatory systems. Chief among these is FSANZ. Its analysis is of interest here since it regulates GM foods and crops.

1. Food Standards Australia and New-Zealand (FSANZ)

a) Regulation of GM Foods and Crops

[35] The Australian dollar is valued at close to par with the Canadian dollar.

In July 1996, a treaty took effect between Australia and New Zealand to establish a common system of food standards.

In August 1999, the Australia New Zealand Food Standards Council (ANZFSC) sought to adopt mandatory labeling of GM foods through an amendment to Australian standard A18, *Food Produced Using Gene Technology* (now section 1.5.2 of the *Australia New Zealand Food Standards Code*). An interministerial working group was tasked with drafting the amendment. In July 2000, ANZFSC adopted the amendment as proposed.

A18/1.5.2 is now a mandatory standard divided into two parts. Division 1 concerns product safety and prohibits the sale of GMOs without prior approval. Division 2 concerns labeling and prescribes comprehensive labeling of GM foods and ingredients.

In November 2000, ANZFSC formally adopted A18/1.5.2, incorporating it into the Food Standards Code. Division 2 entered into force on 7 December 2001.

To guarantee enforcement of the standard, the *Food Acts of the Australian States and Territories* and the *Imported Food Control Act 1992* (of the Commonwealth) require all foods sold or imported in Australia to comply with the requirements of standard A18/1.5.2.

b) Structure and Role of FSANZ

FSANZ plays a role in standard setting for food that is sold, prepared for sale, or imported into Australia and New Zealand. FSANZ's remit extends to approval of GM foods for marketing and use as well as food labeling.

The mission of FSANZ, in decreasing order of priority, is to:

i) protect public health;

ii) provide adequate information on food to allow consumers to make informed choices;

iii) prevent deceitful or misleading conduct.

c) FSANZ Approval Process

FSANZ sees to the protection of public health in Australia and New Zealand by making sure that GM foods are fit for consumption. FSANZ holds the view that the level of safety associated with GM foods is at least as high as that of conventional foods since the approval process for GM foods is much stricter. Every GM product must go through the FSANZ approval process, be declared safe, and be approved by ANZFSC before it can legally be sold in the two countries.

Under the new standard, GM product manufacturers must apply to FSANZ for approval to introduce the product into the food chain. This mandatory submission applies to the product at the component or ingredient stage. As long as it is not approved, it is illegal to sell foods containing it or its derivatives.

FSANZ requires extensive scientific information in order to conduct a comprehensive safety assessment. All scientific data must be produced according to international standards of good laboratory practice in labs audited by an independent body.

ANZFA complements this data with information from a variety of sources: the scientific literature, general technical information, independent scientists, other standards bodies, international organizations, and the community-at-large. More detailed information on the scientific data used by FSANZ in assessing the GM food safety may be found in section 6.5 of the standard.

In general, a GM food is recognized as safe for human consumption if FSANZ is satisfied that:

- All new genetic material has been examined in detail.
- The novel genetic material remains the same and is transmitted predictably from generation to generation.
- The novel proteins have been examined in detail (location, size, structure, expected and actual biological activity).

- The novel proteins are very probably non-toxic and non-allergenic.
- The novel proteins do not engender any detectable toxicity in animal studies.
- The potential transfer of novel genetic material to cells in the human digestive tract will not have a significant impact on human health.
- The levels of toxins, allergens, and anti-nutrients intrinsically present in the GM product are not significantly higher than those found in the equivalent non-GM product.
- The composition of the product is not significantly changed compared with the equivalent non-GM product.

At any time, FSANZ may request additional information from the applicant. This may occur if the information submitted by the applicant is insufficient or if new information emerges and requires further consideration.

2. Therapeutics Goods Administration (TGA)

The TGA regulates GMOs related to prescription medicines and complementary medicines (also known as “traditional” or “alternative” medicines).

a) Legislation

The *Therapeutic Goods Act 1989*, in force as of 15 February 1991, creates a national regulatory framework for therapeutic products in Australia that is designed to guarantee their quality, safety, and efficacy.

b) Structure and role of the TGA

The TGA is an agency of the federal Department of Health and Aging and is responsible for the enforcement of the Act; that is, for performing the evaluations and inspections necessary to guarantee that therapeutic products in Australia are up to standard.

3. National Registration Authority for Agricultural and Veterinary Chemicals (NRA)

a) Legislation

Agricultural and veterinary chemicals ("agvet"), including genetically modified ones, are regulated under a national plan administered by the NRA. The regulations centre around the *Agvet Code,* enacted under the *Agricultural and Veterinary Chemicals Act 1994* (of the Commonwealth).

b) Structure and Role

The agricultural authorities of the states and territories retain responsibility for regulatory activities such as permitting of pest control companies and aerial spraying.

In conclusion, the OGTR and FSANZ are two key structures in the GMO regulatory framework of Australia and New Zealand that are of particular interest to consumers and their representatives. FSANZ regulates GMOs used in food. The OGTR enforces the *Gene Technology Act 2000* and regulates all practices (crops, trials, etc.) using GMOs. The OGTR, for example, regulates GM seeds and their cultivation by assessing their human health and environmental impacts, while FSANZ regulates the use of these crops in food products as well as labeling requirements. We will therefore limit our discussion of public information and participation provisions to these two organizations.

3.2 PUBLIC INFORMATION AND PARTICIPATION

3.2.1 Transparency and Public Participation in FSANZ

GM foods may be marketed after being assessed, found safe, and approved.

Before approving any GM food, FSANZ must prepare a detailed safety assessment report, have it reviewed by a group of independent external experts, and produce a final report for public comment. Consultation is part of the approval process, and legitimate questions raised by members of the public must be addressed before a final decision is made. Two consultation periods are required, between steps 3 and 4 and between steps 4 and 5 of the decision-making process, as shown in the following sequence:[36]

1. Submission by applicant/identification of issue
2. Drafting of work plan
3. Initial assessment by FSANZ (rejection or approval)
4. Draft assessment (rejection or approval)
5. Final assessment (rejection or approval)
6. Review by the ministerial council
7. Amendment in the gazette

The FSANZ procedures are open to the public, and all submissions or applications received are systematically placed in the FSANZ public registry and available for consultation. FSANZ requires applicants to specify the information they would like to keep confidential and provide justification for such action.

3.3 TRANSPARENCY AND PUBLIC CONSULTATION BY THE OGTR

The new system itself underwent a wide-ranging consultation process. Emerging from this, the *Gene Technology Act 2000* and the OGTR regulate all activities or dealings involving GMOs that are not already controlled by another of the regulatory satellites

[36] See diagram in Appendix 6.

described above. Legal provisions for transparency and public participation were incorporated into the Act.

3.3.1 Provisions of the Act

The provisions on public participation and, in large part, public information were defined with reference to the role of the OGTR. According to the Act, in view of the importance of making information available to the community and to non-governmental stakeholders, one of the OGTR's functions is to provide GMO regulatory information to the public.

During the public consultations, the manner in which the OGTR proposed to inform the public and consider its comments on GMO releases aroused great interest. The proposed act provided for a system in which the OGTR would:

- call for public comment on the possible risks and risk management measures;
- publish an announcement in the Gazette, post a notice on the OGTR website, and respond by e-mail to persons who express an interest in receiving information on applications for environmental release;
- consult the GTTAC, the states and territories, the appropriate Commonwealth agencies (including Environment Australia) and any appropriate local council.

The bill provided that the OGTR would have to prepare a complete risk assessment by consulting other agencies such as the GTTAC, including local and regional structures and members of the public, and incorporating any relevant independent research. It was also stated that the OGTR would hold a second round of public consultation on the draft assessment and risk management plan. Again, the text provided that planned public consultations would be announced over the Web, in the Gazette, and in various media, that the final decision would be made public, and that annual reports would be published.

Finally, during the consultations on the new regulatory system, the weaknesses of the OGTR's site were pointed out, including poor navigability, complicated URL, and frequently outdated information. Today, the site is highly user-friendly, its address has

been simplified, and it contains links to other health-related departments and government sites. The content is regularly updated, with Public Information Sheets posted rapidly after they are produced.

Apart from the efforts to improve the website, the bill legally established the provisions to be made for an adequate level of transparency and public consultation.

3.3.2 Current Procedures

The OGTR is evidently quite serious about inviting and encouraging the public and community organizations to take part in the assessment process for environmental releases of GMOs.

The creation of the GTCCC serves as a means of soliciting comments from a group representing the interests of the community.

The new law, as we have seen, creates three advisory committees to the OGTR and the Ministerial Council (the GTTAC, the GTEC, and the GTCCC for advice on scientific/technical, ethical, and general public interest issues, respectively). The GTCCC issues its recommendations after consultation on the OGTR's assessment procedures. The GTCCC is composed of 12 members with expertise in environmental issues, consumer protection, and the impacts of genetic engineering on society. Elaine Attwood, Consumer Affairs Advisor, National Council of Women of Australia, currently sits on the committee.

The tools used for more direct public consultation are:

i) Notices

When the OGTR receives a GMO environmental release application, a public notice thereof is posted on the OGTR website as well as mailed or e-mailed to persons registered with the OGTR.

Once the draft risk assessment and risk management plan is prepared, a notice is placed in the following media to invite the Australian community to comment:

- the *Commonwealth Government Notices Gazette*;
- *The Australian* newspaper;
- any relevant regional media;
- the OGTR website at www.ogtr.gov.au.

ii) Public Comment Period of 30 Days

A risk assessment and risk management plan is prepared for each submission on environmental release of GMOs. Members of the public can comment on these documents during a period of at least 30 days.

The submissions, the risk assessment and management plan, and a summary prepared by the OGTR are publicly available:

- on the OGTR website;

- by calling the OGTR's toll-free number;

- at the OGTR library (complete submission).

iii) OGTR Mailing List

Anyone may subscribe to the OGTR mailing list by clicking a link on the website or by requesting a subscription by regular mail.

iv) Public Record

The regulation creates a public record of GMO-related activities and products approved in Australia.

This exhaustive record describes all activities affecting OGTR-approved living or viable GMOs as well as all GM products approved in other jurisdictions. This record is available on the OGTR website at www.ogtr.gov.au. It provides the Australian public with access to information on GMOs and GM products regulated in Australia.

The contents of the record include the submission, the permit conditions, and the sites of GMO releases. The OGTR keeps this information up-to-date.

Summarizing, opportunities for public involvement are situated between steps 1 and 2 and between steps 2 and 3 in the following list:

1) Receipt of a submission and preliminary assessment;

2) Risk assessment and risk management plan;

3) Decision to grant or deny permit and conditions thereof;

4) Inspection, audit, and compliance reports, sanctions.

The extent of the first consultation depends on the preliminary assessment of the submission. If the risk is considerable, there is a public consultation. If not, there is merely a public notice of submission. In all cases, the summary of the submission is posted on the website and external experts are consulted for advice.

The second opportunity for public involvement is a public consultation on the draft risk assessment and risk management plan announced in the Gazette, the newspapers, and by mail.

At step 3, the public is notified of the final decision.

3.4 NUMBER OF GMOS APPROVED

GMO field trials concern plants such as potato, lupine, cotton, clover, canola, sugarcane, Indian mustard, pineapple, grape, pea, barley, papaya, lettuce, poppy, and

wheat, as well as microorganisms such as *Pseudomonas*. In 2001, some 100 notifications led to trials in this country.

Canadian and US firms grow GM canola in Australia, half of which is exported. Two GMOs have been authorized in Australia for commercial use: cotton and carnations.[37]

Australia is the world's sixth-largest GMO producer, with 100,000 hectares in 1999. Tasmania, it should be noted, is demanding the right to be a GMO-free zone.

Appendix 7 shows that as of April 2003, 12 GMOs had been jointly approved by Australia and New Zealand.

3.5. GM FOOD AND CROP LABELING POLICY

Under standard 1.5.2, Australia and New Zealand jointly adopted one of the world's strictest labeling policies.

Since 2002, both countries have required foods and ingredients to be labeled where the DNA and/or the recombinant protein is present in the final food or where the characteristics of the food have changed. Foods prepared at time of sale, e.g., in restaurants, are exempt from labeling requirements. Likewise, highly refined foods such as oils and sugars produced from GM crops are not subject to labeling if they contain no DNA or recombinant protein because these have been eliminated in the manufacturing process.

Australia and New Zealand set the tolerance level for accidental or involuntary contamination at 1%. The inspection process consists of physical inspections and paper audits. The system is supported by the large majority of the states and territories as well as by the Australian and New Zealand governments, and took effect on 7 December 2001.

[37] *Agra Europe*, 21 April 2000.

Standard A18/1.5.2 places the onus on agri-food stakeholders including manufacturers, importers and retailers, as applicable, to ensure that the GM foods or ingredients (including additives and processing aids) they use are approved and to comply with the corresponding labeling requirements.

3.6 CONCLUSION

Australia is today in a paradoxical situation, with some 100,000 hectares of transgenic crops, an increasingly worried populace, and strict legislation that renders labeling mandatory. The Australian government is apparently seeking to promote the development of the biotechnology industry. To this end, it offers the public detailed explanations of the regulatory system, semi-scientific arguments on the advantages of the ongoing trials, and FAQ-type information capsules (see ANZFA website at http://www.anzfa.gov.au). At the same time, it is trying to respect the demands of a population that is deeply concerned about GMOs.

FSANZ contends that all foods have benefits and risks, the former coming in the form of nutrients and the latter in the form of toxins or allergens. Therefore, no food can be guaranteed to be absolutely safe for everyone. This is equally true for GM foods, despite the additional testing they undergo. Nevertheless, FSANZ maintains that the level of safety associated with GM foods is at least as high as that of any other product due to the much stricter assessment process. This process, unlike that of the US FDA, for example, is designed to guarantee that approved GM foods offer all the advantages of their conventional counterparts without any additional risks.

In Australia and New Zealand, as in Europe, labeling is inseparable from regulation. This approach differs from those of Canada and the United States, which provide for assessment only, not mandatory labeling. Yet labeling is, for Option consommateurs, a fundamental element of any government’s attempt at transparency.

In addition, the Australian system, like the European and Canadian systems, involves a mandatory application procedure. The national authority takes responsibility for

guaranteeing that GM foods placed on the market are safe. The US system is off the mark on this point.

Another strong point of the Australian transparency and public participation policy is that the concepts of ethics and public interest are incorporated into the approval process in the form of advisory committees dedicated to these issues. A further feature of interest is the dual opportunity for comment, especially since the first opportunity takes place upstream in the process while the FSANZ assessment is still in draft form.

Generally speaking, the implementation of this regulatory system represents a strong commitment on the government's part to succeed in informing and involving the public. The user-friendliness of the websites illustrates this commitment, facilitating users' understanding of the complex issues associated with GMO regulation.

IV. SUMMARY AND CONCLUSIONS: RECOMMENDED IMPROVEMENTS

1. SUMMARY AND CONCLUSIONS

The countries we have focused on in this report have opted to regulate agricultural biotechnology either under existing laws or with the passage of new ones. The United States and Canada are examples of the former situation. The advantages of this approach are that the standards can be enforced more quickly and that the agencies and procedures are already in place.

However, existing laws have the disadvantage that they are not usually specific to biotechnology and may require complex legal finagling in order to be made applicable to its products. The attempt to adapt the existing law to the demands of biotechnology may entail a set of new laws and agencies, resulting in a complex, confusing process. This is the prevailing situation in the United States and Canada.

When a country uses existing laws, certain products maybe over- or under-regulated (with respect to their relative risk) while others may fall through the cracks in the system, remaining essentially unregulated. In the United States, the use of existing laws has led to a complex patchwork of laws and agencies regulating biotechnology products under different standards and procedures. This regulatory system is far from ideal because it is relatively opaque, lacks the power to stop potentially hazardous products from entering the food chain, and does not treat all products fairly and equitably. Other countries, such as Australia, New Zealand, and the European Union and its member countries have passed new laws and/or regulations specifically governing the products of agricultural biotechnology.

In terms of disadvantages, the time necessary to draft a new law may require the use of decrees and moratoriums until such time as the law has been passed and its regulations taken effect. This was what happened in Europe. But the advantage of these new laws is

that they are specifically designed to regulate this technology and offer a level of transparency equal to the public's concerns.

Currently, Canadian consumers and their representatives have to deal with a complex system in which several agencies interact as harmoniously as they can. This makes their task of communicating with the public especially difficult, yet communication is indispensable if there is any hope of conveying the workings of this system to the public. Moreover, communication is exactly what consumers want, for in the current situation they are unknowingly buying the products of biotechnology without being given any opportunity to dissent. Finally, communication is the first step toward creating consumer confidence in the regulatory system and the products it approves. Our recommendations aim to amend the existing laws and structures with the provisions and procedures necessary for genuine dialogue between the authorities and the public to take place. We view these recommendations as being realistic and readily applicable.

2. RECOMMENDATIONS

If Canadians are to choose their foods based on their fundamental values and interests, the authorities must pursue their efforts to promote reflection, participation, and informed decision-making. Therefore, on the strength of our focus group results and our analysis of the regulatory systems of Canada and other countries, Option consommateurs hereby puts forward the following 21 recommendations, all of equal importance:

TRANSPARENCY AND PUBLIC INFORMATION

Recommendation 1

GM food-related issues are complex and often discussed in technical language. Efforts have been made to facilitate the public's comprehension of these concepts, which affect them directly.

Option consommateurs recommends that Health Canada, CFIA, and Environment Canada pursue efforts on their respective websites to clarify the information on the organization and roles of the GMO regulatory authorities.

Recommendation 2

Option consommateurs recommends that the regulatory authorities publish all results of studies of GMO impacts on health and the environment in the government's possession.

Recommendation 3

Option consommateurs recommends that publications distributed by the regulatory authorities relate to regional, national, and international affairs.

Recommendation 4

As is done in most countries of the European Union, in Australia and New Zealand, and by the EPA and APHIS in the United States, factual and accurate product information must be distributed before a product is approved. Systematic pre-approval distribution of information will promote dialogue and public comment and allow sufficient time for independent assessment as necessary.

Option consommateurs recommends that GMO submissions for approval be systematically published on receipt. Publication should take the same form as in the CropLife pilot project, i.e., posting of a notice on the CFIA website, but should also include publication in at least one large-circulation newspaper. The website should be updated whenever new relevant information is obtained.

Recommendation 5

Option consommateurs recommends that concerned stakeholders such as consumer associations and the main environmental groups be systematically informed of the filing of submissions and the corresponding decisions.

Recommendation 6

Information essential to consumers, such as the results of product safety studies and the sites of GMO field trials, should never be kept confidential. Applicants' requests to

keep additional information confidential should never take precedence over the need for transparency and external oversight in the approval process.

Option consommateurs recommends, pursuant to the *Access to Information Act* and as part of Health Canada's ongoing legislative renewal, that the regulatory framework clearly specify a limited number of types of information that may be kept confidential and that it require proper justification for confidentiality requests.

Recommendation 7

CFIA representatives have explained in the media[38] that the sites of field trials must be kept secret to prevent them from being destroyed. This argument simply does not trump the need to inform neighbours and local farmers of the existence of such trials.

Option consommateurs recommends that, in the context of submissions for approval to conduct field trials, the site(s) where GM plants are to be grown be disclosed.

Option consommateurs recommends that the competent authority inform the municipality where the release will take place, as well as the neighbouring municipalities, by sending them a copy of the submission.

Recommendation 8

Our review of public information procedures in connection with decision documents in the European Union, and specifically in Denmark, the United Kingdom, Slovenia, Austria, Germany and the Netherlands, shows that there is no difficulty in supplying the public with any additional information it may require.

Option consommateurs recommends that decision documents contain the following items: a description of the potential environmental and human health effects, a description of measures taken to limit harmful effects, a description of the plan to control the effects, a description of measures to handle GM crop residues, and a description of the emergency plan of action. Where field trials are concerned, the decision document should also include the sites where GM plants will be grown.

PUBLIC COMPREHENSION OF AND TRUST IN THE REGULATORY PROCESS

[38] *Journal de Montréal,* 30 January 2004, p. 4.

Recommendation 9

In the interests of transparency and improved public comprehension of governmental information on Canadian GMO regulations,

Option consommateurs recommends that the regulations distinguish between novel foods and GMOs so that the latter can be subjected to special assessment and treatment, acknowledging that they have special characteristics and often raise issues not raised by other novel foods.

Recommendation 10

In order to win the confidence of Canadians, Canada's regulatory system does well to reject the option of deregulation, an undesirable feature of the US regulations. This approach should be maintained. It is true that the EPA conducts post-approval monitoring of PNTs that produce pesticides. As for the USDA, however, when a GM food or crop goes to market, its developer can apply for it to be deregulated, or exempted from further scrutiny by the USDA. Deregulation means that the USDA no longer has any legal authority over the crop, and no environmental oversight can be exercised.[39]

In order to give consumers confidence in the GM food and crop regulatory process, Option consommateurs recommends that deregulation of approved products be rejected as a regulatory approach.

Recommendation 11

Post-approval surveillance is essential to consumer confidence. The regulatory agencies must have the authority and resources necessary to do follow-up, take product samples, order unsafe products recalled, and circumscribe incipient environmental problems, as well as to bring legal actions.

In Canada, this oversight on the part of the regulatory agencies is nonexistent or nearly so. The Center for Science in the Public Interest provides a US example illustrative of the consequences of this weakness, also evident in the US system. Further

[39] NRC report, 2002.

to an assessment of a Bt corn variety, the EPA required farmers to cultivate non-Bt corn "refuge zones" so as to avert the development of insect resistance. In the following years, it was estimated that 20–30% of Bt corn producers had failed to comply with this requirement yet had not been disciplined in any way.

The public cannot have full confidence in a regulatory system that approves products with certain restrictions and then fails to enforce them. Enforcement is important for guaranteeing health and biosafety but also for enhancing public confidence that the government is fulfilling its regulatory role. Government must have independent oversight over health and safety issues and must not depend solely on scientific research produced by the industry or the universities.

Option consommateurs recommends that stricter, more comprehensive post-approval surveillance be exercised so as to discern the long-term health and environmental impacts of trials and crops.

PUBLIC PARTICIPATION

Public participation in the regulatory process is essential.

Recommendation 12

Option consommateurs recommends that more numerous opportunities be offered to debate the issues surrounding GM foods so that Canadian consumers and their representatives can be better informed, hence better able to make informed food choices and provide judicious advice to the government.

In order for consumers and their representatives to act accordingly, it will be necessary to devote resources exclusively to the provision of information.

The CBAC is a good model for facilitating public debate on GM foods, since its mission is to inform the largest possible number of people and it is composed of a multidisciplinary group of specialists. However, its influence is limited.

The media remain the primary source of consumer information, but this is insufficient.

It is important to incorporate the ethical issues of biotechnology into school science curricula.

Recommendation 13

Option consommateurs recommends that two opportunities for public involvement be added to the approval process. The first should take place upon receipt of a submission for approval and publication thereof, as in the current Health Canada/CFIA/CropLife pilot project. The second should take place between the committee's publication of the evaluation results and the final decision.

Thus, the two opportunities for public involvement would take place between steps 2 and 3 and between steps 6 and 7 in the following sequence, which represents the current Canadian approval process:

1. Pre-submission consultation

2. Pre-market notification

3. Scientific evaluation

4. Requests for additional information

5. Summary report of findings

6. Preparation of food rulings proposal

7. Letter of no objection

8. Decision document on Health Canada website

Recommendation 14

Option consommateurs recommends that the 60-day length of the first comment period be maintained as proposed in the CropLife pilot project. The length of the second comment period should also be 60 days. Public participation should also include the holding of public hearings.

In order for citizens/consumers to make useful contributions, the public consultation system should be based on a process of popular education and awareness-raising. Comments of all types should be taken into consideration and referred to the appropriate committees (scientific, ethical issues, or socioeconomic issues; see Recommendation 17).

Recommendation 15

Option consommateurs recommends, in the context of Health Canada's proposed pilot project, that independent external experts be appointed to participate in the scientific approval process.

Option consommateurs recommends that these scientists be free of financial and other conflicts of interest with the novel foods or PNTs assessed.

Recommendation 16

Option consommateurs recommends that public information and public participation be specifically provided for in amendments to existing laws in the context of Health Canada's ongoing legislative renewal.

CONSIDERATION OF SOCIOECONOMIC AND ETHICAL ISSUES

Recommendation 17

The decision-making committee must take into consideration the socioeconomic issues associated with a GM product. These include impacts on consumers' and animals' quality of life, integrity and knowledge of the food source, impacts on farming, environmental impacts, consumers' freedom of choice, farmers' freedom of choice, impacts on agro-industry, consequences of the patentability of life (intellectual property rights over seed), impacts on employment, sustainability of communities, impacts on the trade practices of other countries, promotion of or impediment to sustainable development.

Likewise, the decision-making committee must acquire the intellectual, philosophical, and emotional capacities necessary to take account of the ethical issues surrounding GM products, in view of the diversity of cultures and diets among Canadians. Relevant issues

include culinary values and objectives; value, role, and benefits of agriculture in our society; diversity and independence of farmers.

Option consommateurs recommends that two advisory committees be created, one on ethical issues and the other on socioeconomic and general public interest issues.

These two committees, whose role is to provide advice to the decision-making committee on each assessment, should comprise 5–10 members and include consumer representatives.

In this way, the information made public could include information on the social, ethical, and economic — not merely the scientific — consequences of the product.

Recommendation 18

The two advisory committees should also include scientists.

In order to guarantee that decisions are made in an unbiased manner, the scientists sitting on the advisory committees or the decision-making committee must not be former or current employees of biotechnology companies or members of industry organizations, nor should they be in any other potential conflict-of-interest situation.

Option consommateurs recommends that scientists who sit on the advisory committees be free of financial and other conflicts of interest with the novel foods or PNTs assessed.

Recommendation 19

Option consommateurs recommends that all the committees (the existing scientific committee backed by the advisory committee on ethical issues and the advisory committee on socioeconomic and general public interest issues) define a liability regime applicable in the event of genetic pollution or health harm.

FOOD LABELLING

Recommendation 20

Option consommateurs recommends that Canada urgently adopt regulations for mandatory labeling of GMOs in food as well as an adequate traceability system.

Recommendation 21

Option consommateurs recommends that labeling indicate not only the presence or absence of detectable GMOs in a product (product approach) but also the manufacturing process for the food product (process approach).

This approach is more transparent since it enables consumers to choose foods based on ethical considerations related to GM food manufacturing processes.[40]

Our recommendations as to the model that would best meet Canada's public information and participation needs are summarized in Appendix 1.

[40] According to the report of the Halifax workshop, if consumers had to bear additional costs, "a study done in Australia and cited in B.C. has shown that the increase to consumers may be around 0.1%, which was considered an acceptable trade-off for labelling."

CONCLUSION

The GM food and crop regulation process in Canada may be thought of as a hybrid of the US process with those of the European Union, Australia, and New Zealand. Canada shares with the United States a product-based approach governed by existing laws. It shares with the European Union, Australia and New Zealand a system in which the authorities retain genuine power to approve environmental releases and marketing of GM products as well as a stated commitment to transparency, public information and public participation. Canada's voluntary labeling approach occupies a middle ground between the US and EU approaches (no labeling and mandatory labeling, respectively).

In no country, be it said, is the regulatory process ideal, but each possesses interesting features from which Canada can draw, adapting them to its own system. Our comparative analysis points to a number of these possibilities. Beyond comparisons, however, Canada has developed a unique model that deserves to be further refined, rendering it more effective and appropriate. We laud the efforts already undertaken by the government, through the pilot projects in particular, to enhance public information and participation. But information and participation possibilities will remain limited unless they become legally prescribed requirements, and unless new structures and provisions are inserted into the current procedures. This is possible and consistent with the stated intentions of Health Canada, CFIA, and Environment Canada. The current context seems favourable. Health Canada's ongoing legislative renewal is an opportunity to make amendments to strengthen the existing criteria defining authorized exceptions under the *Access to Information Act.* Public information must be the default option while confidential information must be limited to the strict minimum. Furthermore, information must be expanded to meet the needs of consumers and their representatives and to answer questions of "who," "what," "how," and "where" at all times. Public participation should be a multi-step process involving two comment periods and two independent assessment periods.

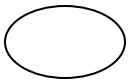
Generally speaking, public information and participation procedures should adopt a popular education and awareness-raising focus so as to improve interaction between the authorities and the public, including external experts, consumer advocacy organizations, and environmental associations.

Comprehensive labeling and a clear liability régime are additional features that are indispensable to transparency and an effective right to information.

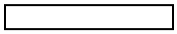
Finally, although the more pragmatic issues related to the health and environmental impacts are a priority for consumers, it is also necessary to incorporate consideration of the ethical and socioeconomic impacts into the regulatory process. By creating advisory committees devoted to these issues, the government will be privy to important advice on the assessment of novel foods from these perspectives, which are currently excluded from the strictly science-based process. Only by integrating these three dimensions, all of them inseparable from the issues surrounding GMO regulation, can Canada apply transparent, participatory policies respectful of its citizens and consumers.

APPENDICES

APPENDIX 1- MODEL OF THE REGULATORY PROCESS



: existing structure/provision



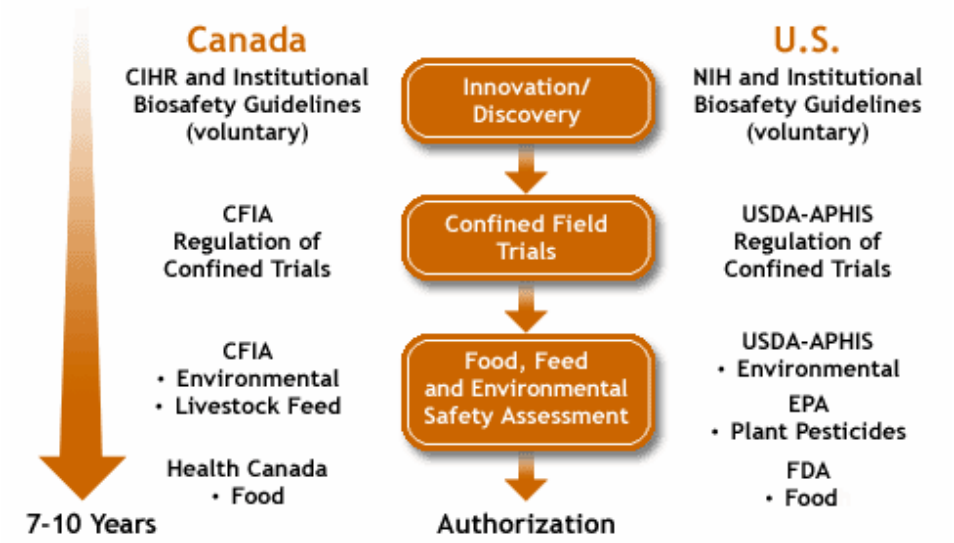
: recommended complementary structure/provision

APPENDIX 2 - DISTRIBUTION OF ROLES BETWEEN HEALTH CANADA AND CFIA

Fig. 2: Deliniation of regulatory responsibilities within the Canadian regulatory framework for biotechnology.

Category	CFIA	Health Canada
Human health & food safety		
•Approval of novel foods		★
•Allergens		★
•Nutritional content		★
•Potential presence of toxins		★
Food labelling policies		
•Nutritional content		★
•Allergens		★
•Special dietary needs		★
•Fraud and consumer protection	★	
Safety assessments		
•Fertilizers	★	
•Seeds	★	
•Plants	★	
•Animals	★	
•Animal vaccines and biologics	★	
•Livestock feeds	★	

APPENDIX 3 – COMPARISON OF CANADIAN AND US ASSESSMENT SYSTEMS



APPENDIX 4 – SUBMISSIONS FOR APPROVAL

Application List

Wednesday, 24 December 2003

List of all applications for the approval of novel (inc GM) foods and novel process

Application under 258/97

	Applicant	Description of Food or Ingredient	Application Date and Member State	Summary of ACNFP Comments	Current Status *
1.	Katholieke Universiteit Leuven Laboratory of Plant Physiology B - 3001 Heverlee	*Stevia rebaudiana* - plant and dried leaves	07 November 1997 Belgium	ACNFP are of the view that product should not be approved as the applicant failed to provide adequate information on the product's safety.	Unfavourable opinion from SCF on 17 June 1999. Decision taken at StCF to reject application on 21 October 1999.
2.	Belovo scrl Zone industrielle, 1 B - 6600 Bastogne	Phospholipids from egg yolk	09 February 1998 Belgium	ACNFP are content for limited approval provided product is labelled correctly.	Favourable opinion from SCF on 17 June 1999. Decision taken at StCF to accept application on 21 October 1999. Authorised for the EU market.
3.	ZENECA Jealott's Hill Research Station Jealott's Hill Bracknell UK - Berkshire RG42 6ET	Genetically Modified Processed Tomatoes	03 March 1998 UK	ACNFP concluded that processed products from these tomatoes are as safe as from non-GM varieties.	Application withdrawn 24 September 2001.
4.	Bejo-Zaden PO Box 50 NL-1749 Warmenhuizen	Genetically modified *Radicchio rosso* with male sterility	08 April 1998 The Netherlands	ACNFP consider that insufficient information on composition of product was contained in the	Application suspended at company's request.

				application.	
5.	Bejo-Zaden PO Box 50 NL-1749 Warmenhuizen	Genetically modified Green hearted Chicory with male sterility	08 April 1998 The Netherlands	ACNFP consider that insufficient information on composition of product was contained in the application.	Application suspended at company's request.
6.	Unilever Research & Engineering Division Unilever UK Central Resources Ltd Unilever House, Blackfriars London EC4P 4BQ	Yellow fat spreads with added phytosterol esters	28 May 1998 The Netherlands	ACNFP approval subject to a maximum incorporation level of 8% for phytosterol ester component.	Favourable opinion by StCF Application accepted 26 June 2000. Authorised for the EU market.
7.	E.I. DuPont Nemours & Co Agricultural Enterprise Optimum Quality Grains L.L.C. Registration and Regulatory Affairs Europe Ebertstr.4 D - 07743 Jena	Genetically modified High Oleic Soybean Sublines derived from transformation event 260-05	25 July 1998 The Netherlands	Not considered by ACNFP.	Application withdrawn 12th December 2002
8.	Biomin Pharma GmbH Provinostr. 15 D - 86153 Augsburg	Vit-Enzym	23 June 1998 Germany	Not considered by ACNFP.	Application withdrawn 6 March 2000.
9.	Monsanto Services International S.A. Ave. de Tervuren 270 – 272 B - 1150 Bruxelles	Genetically modified Roundup Ready Maize line GA21	24 July 1998 The Netherlands	ACNFP considered that applicant provided insufficient data on allergenicity.	Favourable opinion from SCF on 27 February 2002. Awaiting authorisation by StCF.
10.	Groupe Danone 7, rue de Téhéran F - 75381 Paris CEDEX 08	Use as human food of fruit preparations pasteurised using a high-pressure treatment process	3 December 1998 France	ACNFP were content for clearance to be given for fruits listed with the conditions stated in the dossier.	Favourable decision from StCF dated 7th June 2001. Authorised for the EU market.
11.	Pacific Nuts Ltd. La	Noix de	09	ACNFP objected to	Unfavourable

	Meillade nº65 F-34150 Montpeyroux	nangailles	December 1998 France	marketing due to insufficient information provided.	Commission decision dated 19 December 2000.
12.	Plant Genetic Systems N.V. Josef Plateaustraat 22 B-9000 Gent	Genetically modified Liberty Link Soybean by AgrEvo Directive 90/220/EEC No C/BE/98/01	02 February 1999 Belgium	Not yet considered by ACNFP.	Initial Assessment Report Pending
13.	Novartis Seeds Basel CH – 4002 Basel Switzerland	Genetically Modified insect-protected fresh and processed Bt 11 sweet maize	11 February 1999 The Netherlands	ACNFP raised concerns over the data provided by the applicant and requested clarification.	Favourable SCF opinion issued 17 April 2002. Awaiting authorisation by StCF.
14.	Du Pont (UK) Limited Cereals Innovation Centre Block B, The Mill Site 40 Station Road Cambridge CB1 2UJ	Soluble and Insoluble Fractions of CerealBrans	25 March 1999 UK	ACNFP issued favourable opinion.	Referred to SCF, now EFSA.
15.	Puracor n.v. Industrielaan 25 B - 1072 Groot Bijlaan	Bacterial Dextran	09 April 1999 Belgium	ACNFP agreed with Initial Opinion that product could be marketed.	Positive decision from StCF on 30 January 2001. Authorised for the EU market.
16.	Cultor Food Science Applications Laboratory Units 3 - 4 72 - 86 Garlands Road Redhill Surrey, RH1 6YS	Salatrim	28 June 1999 UK	ACNFP recommended approval for the limited uses detailed in the application.	Favourable opinion from SCF on 13 December 2002. Positive decision from StCF on 18 July 2003. Authorised for the EU market.
17.	Regulatory Affairs for Maize, Monsanto Services, International S.A., Avenue de Tervuren 270-272,	Genetically Modified MaisGard® / Roundup Ready® GA21 X	16 March 2000 The Netherlands	Not yet considered by ACNFP.	Initial assessment report pending.

	B - 1160 Brussels.	MON810			
18.	Regulatory Science Manager, Pioneer Overseas Corp., Avenue Tedesco 7, B - 1160 Brussels	Genetically modified maize hybrid T25 X MON810	28 April 2000 The Netherlands	Not considered by ACNFP.	Application withdrawn 12 December 2002
19.	Baker & Mackenzie, Louizalaan 149, B – 1050 Brussels On behalf of Morinda Inc.	Tahitian Noni Juice	28 April 2000 Belgium	ACNFP considered that there was insufficient data on allergenicity and the products intended market.	Favourable opinion from SCF on 8 April 2003. Positive decision from StCF on 05 June 2003. Authorised for the EU market.
20.	Monsanto Europe S. A. Regulatory Affairs - Europe Africa, 270 - 272 Avenue Tervuren B - 1150 Brussels and; Novartis Seeds AB Box 302 S - 26123 Landskrona	Genetically Modified Roundup Ready® Sugar Beet	16 June 2000 The Netherlands	Not yet considered by ACNFP.	Initial Assessment report pending.
21.	Valio Ltd. R & D P. O. Box 30 FIN - 00039	Plantsterol enriched Frankfurters, sausage & cold cuts	30 March 2000 Finland	ACNFP objected due to concerns with its cumulative effects & its perceived desirability to children.	Favourable SCF opinion of 05 March 2003. Currently under discussion by StCF.
22.	Associate Director Regulatory Affairs 200 Abbot Park Road, Illinois 60064-6188, USA	MCT / Sardine oil structured lipid	16 June 2000 The Netherlands	Not considered by ACNFP.	Application withdrawn on 15 March 2002.
23.	Associate Director Regulatory Affairs Abbot Laboratories 200 Abbot Park Road, Illinois 60064-6188, USA	Fungal oil SUN-TGA40S (manufactureds by Suntory, Tokyo, Japan)	16 June 2000 The Netherland	Not yet considered by ACNFP.	Initial Assessment report pending.
24.	Bioresco Ltd on behalf of: Hayashibara Co Ltd 2 - 3 Shimoishii I-chrome, Okayama 700, Japan	Trehalose	25 May 2000 UK	ACNFP issued a favourable opinion.	Authorised for the EU market on 19 July 2001.

25.	Head of DRA/S&D Novartis Consumer Health Rue De Wandstraat 211 - 213 B - 1020 Brussels Belgium	REDUCOL	07 September 2000 Belgium	ACNFP objections due to concerns with its cumulative effects & its perceived desirability to children	Further clarification requested from applicant. Referred to SCF, now EFSA.
26.	The Director Oy Karl Fazer Fazerintie 6 FIN - 0 01230 VANTAA P.O. Box 4 FIN - 09941 Helsinki	Plant sterol enriched bakery products, grain based snack products and gum arabic pastilles	29 August 2000 Finland	ACNFP objections due to concerns with its cumulative effects & its perceived desirability to children.	Favourable SCF opinion of 05 March 2003. Currently under discussion by StCF.
27.	Oil Sales & Product Development John K Kings & Sons Limited The Silo Skellingthorpe Road Lincoln LN6 0EL, UK	Echium Oil	09 October 2000 UK	ACNFP considered that applicant provided insufficient data on toxicology & human consumption.	Application has been withdrawn.
28.	AVEBE R&D Products AVEBE-weg 1 NL-9607 PT Foxtol	Coagulated potato protein and hydrolysates thereof	03 January 2001 The Netherlands	ACNFP considered the applicant provided insufficient data on allergenicity.	Positive Commission decision dated 15 February 2002. Authorised for the EU market.
29.	Pioneer Overseas Corporation Avenue Tedesco 7 B-1160 Brussels	Genetically Modified B.t CRY1F Maize Line 1507	26 February 2001 The Netherlands	Not yet considered by ACNFP.	Initial Assessment Report Pending.
30.	C/o Wacker Chemie Bioresco Ltd. Bundesstr. 29 CH-4045 Basel	Gamma-Cyclodextrin	10 April 2001 Italy	ACNFP agreed that this product is an additive.	Working Group on Food Additives and StCF agreed that this product is an additive.
31.	Manager Regulatory Affairs Europe 21 Bartons Drive Yately Hampshire GU46 6DW, UK for Omega Tech	DHA-rich oil	14 February 2001 UK	ACNFP requested further data from the applicant, which was provided. Positive Initial opinion forwarded to Commission on 20	Positive decision from StCF dated 05 June 2003. Authorised for the EU market.

	Microforum Ring 2 D-55234 Wendelsheim			June 2002.	
32.	Manager Regulatory Affairs for Maize Monsanto Services International S.A. Ave. de Trevuren 270-272 B-1150 Bruxelles	Genetically Modified Roundup Ready maize line NK 603	June 2001 The Netherlands	ACNFP content for consent to be given.	Referred to EFSA.
33.	The Manager Teriakia Ltd. Iiluodontie 17B 00980 Helsinki Finland	Phytosterol enriched fat ingredient-Diminicol	May 2001 Finland	ACNFP concerns with cumulative effects, and potential market.	Favourable SCF opinion of 05 March 2003. Currently under discussion by StCF.
34.	The Manager MB Multibene Health Oy Ltd. Tykkimaentie 15 FIN-105200 Rajamaki	Multibene	26 Oct 2001 Finland	ACNFP objected to the marketing of this product because of: Allergenic concerns, worries regarding over-consumption. May be perceived as potentially desirable to children	Favourable SCF opinion of 04 April 2003. Currently under discussion by the StCF.
35.	Vice President Regulatory Affairs Archer Daniels Midland Company 1001 N. Brush College Rd. Decatur, IL 62521-1656. USA	Plant Sterols and Sterol Esters	14 Nov 2001 The Netherlands	ACNFP agreed with the Initial Opinion and therefore supports the marketing of the product subject to restrictions on labelling and product range.	Favourable SCF opinion expressed 04 April 2003. Currently under discussion by the StCF.
36.	Laboratoires Pharmascience® / Division Industrie Site industriel 3, rue des Quatre Filles 28230 EPERNON	Rapeseed Oil High In Unsaponifiable Matter	18 Dec 2001 France	ACNFP objected to the marketing of this product until specific concerns with the intake and likely use of this product had been addressed.	ACNFP comments forwarded to Commission on 16 April 2002.
37.	Laboratoires Pharmascience® / Division Industrie Site industriel 3, rue	Maize Germ Oil High In Unsaponifiable Matter	18 Dec 2001 France	ACNFP objected to the marketing of this product until specific concerns with the	ACNFP comments forwarded to Commission on 16 April 2002.

	des Quatre Filles 28230 EPERNON			intake and likely use of this product had been addressed.	
38.	Archer Daniels Midland Company 1001 N, Brush College Rd. Decatur,IL 62521-1656, USA	ENOVA™ oil Diacylglycerol Oil	29 May 2002 The Netherlands	ACNFP broadly agreed with the Positive Initial Opinion. Some clarification was requested on enzyme preparation and protein levels in the product.	Additional data from applicant under consideration by Member States.
39.	Unilever Bestfoods Europe London Road Purfleet Essex RM19 1SD UK	Phytosterol esters for use in 'milk' and 'yogurt' type products	07 August 2002 UK	ACNFP agreed to support the marketing of this product subject to the applicant carrying out post market monitoring and complying with any decisions arising from the SCF report on phytosterols.	Currently under discussion by the StCF.
40.	Belovo SA	Iodine enriched wild-type egg	01 July 2002 Belgium	ACNFP were concerned that consumers could easily exceed the safe upper level for iodine and that consumption would be impossible to control. Unfavourable opinion issued.	No objections to the negative initial opinion. Application rejected.
41	Saxenburgstraat 23 I NL-1054 KN Amsterdam	Euro CMO Cetyl esters of fatty acids isolated/extracted from animals	12 September 2002 The Netherlands	Not considered by ACNFP.	Application withdrawn on 17 January 2003.
42.	Regulatory affairs Manager, Monsanto Services International S.A Avenue de Tervuren 270-272 B-1150 Brussels	Genetically Modified Insect protected maize line MON 863 and maize hybrid MON863 X	28 August 2002 Germany	ACNFP concluded that there was insufficient information on the maize hybrid line MON863 X MON810 for the purposes of a complete safety assessment.	ACNFP comments forwarded to the Commission on 05 August 2003.

	MON810			
43. Regulatory Affairs Manager, Oy Foodfiles Ltd Neulaniementie 2L6 FIN – 10210 KUOPIO	Betaine	10 January 2003 Finland	Not yet considered by ACNFP.	Initial Assessment received.
44. Directeur du Departement Lipochimie Centre de R et D des Laboratoires Expansience Rue des 4 Files F-28231	Palm Oil high in unsaponifiable matter	17 January 2003 France	Not yet considered by ACNFP.	Initial Assessment received.
45. Ms Lyne Fortin Velnor Inc 1401 Chemin du Cap St-Honore-de-Chicoutimi Quebec Canada G0V 1L0	Powdered Velvet Antler from Red Deer, *Cervus elaphus*	22 April 2003 France	Not yet considered by ACNFP.	Initial Assessment received.
46. Mr D. Armstrong 76 Old Portglenone Road Ahogill Co. Antrim Northern Ireland BT42 1LQ United Kingdom	Whole Chia (*Salva hispanica* L.) and ground whole Chia	30 June 2003 UK	ACNFP had concerns with allergenicity data and further information was required on production process and storage.	Summary document distributed to Member States.

* Abbreviations:
SCF = Scientific Committee on Food replaced by EFSA = European Food Safety Authority (Feb 2002)
StCF = Standing Committee on Foodstuffs replaced by Standing Committee on the Food Chain and Animal Health (Feb 2002)

Notifications made under Article 5 of Regulation (EC) 258/97 Article 5 of the Novel Food Regulation (EC) 258/97, allows the company concerned to notify the European Commission of their intention to market a novel food, which is substantially equivalent to an existing food in terms of nutritional value, metabolism, intended use and level of undesirable substances.

APPENDIX 5 - COMPOSITION OF EFSA MANAGEMENT BOARD

The 14 members of the EFSA Management Board are:

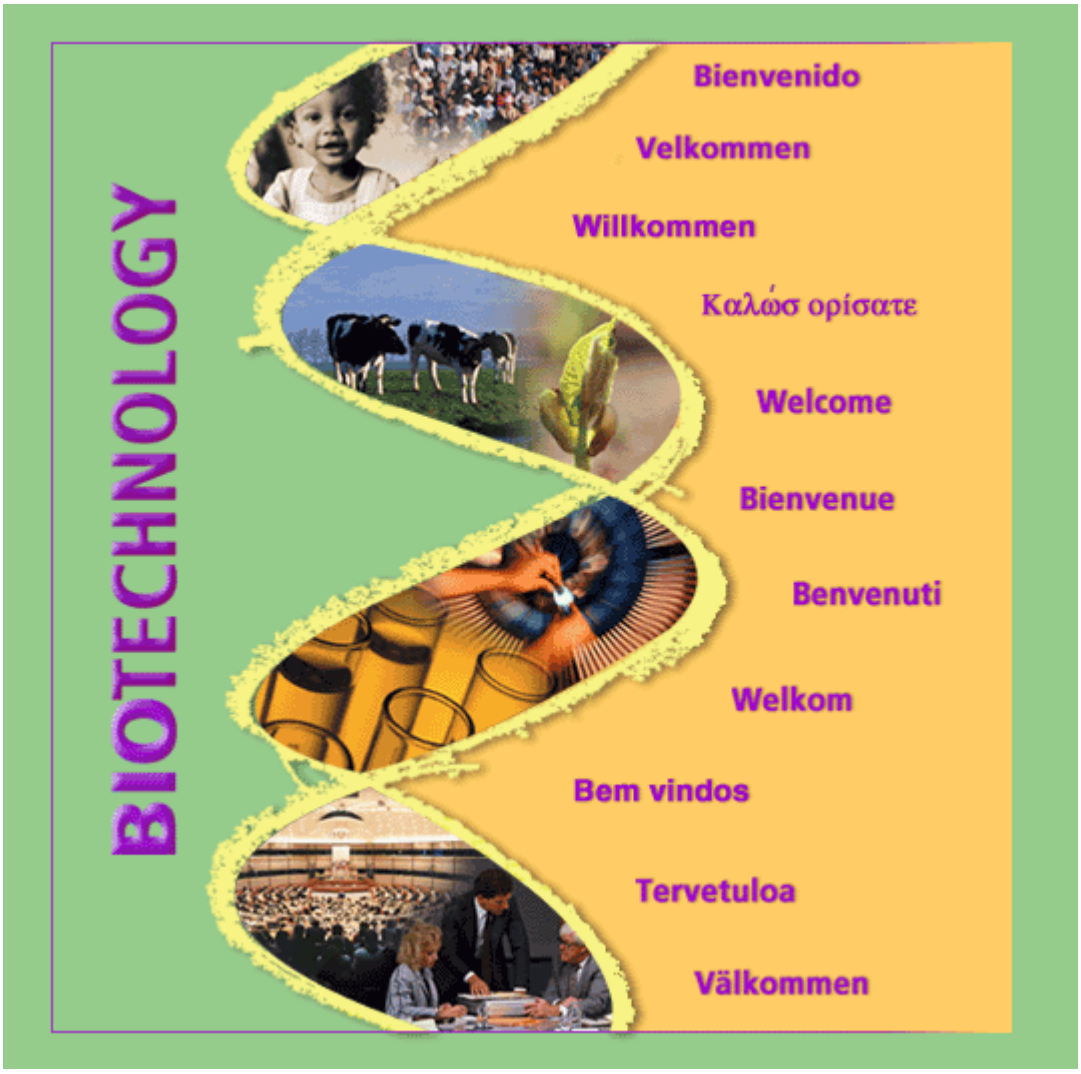
Matthias Horst (DE) - Director-General, Federation of the German Food and Drink Industry
Deirdre Hutton (UK) - President, National Consumer Council, UK
Giorgio Calabrese (IT) – Professor, Università Cattolica del S. Cuore
João Pedro Machado (PT)- Executive Director, Confederaçao dos Agricultores de Portugal
Pirkko Raunemaa (FI) – Director, National Food Agency, Finland
Patrick Wall (IE) - Chief Executive, Food Safety Authority of Ireland
Catherine Geslain-Laneelle (FR) – Director, Food (Ministère de l'Agriculture et de la Pêche)
Peter Gaemelke (DK) – President, Danish Agricultural Council
Angeliki Assimakopoulou (GR) - retired Director-General, General Chemical State Laboratory, Greece
Ernst Bobek (AU) – Director, Sektion in Bundesministerium für soziale Sichereit und Generationen
Roland Vaxelaire (BE) - President and Chief Executive Officer, Carrefour Belgium
Bart Sangster (NL) - Senior Vice-President, Safety and Environmental Assurance, Unilever N.V.
Stuart Slorach (SV) – Deputy Director-General, Swedish National Food Administration
Carlos Escribano Mora (ES) – Director, Livestock, Ministerio de Agricultura, Pesca y Alimentación

The fifteenth member, representing the European Commission, is:

Robert Coleman, Director General of DG Health and Consumer Protection

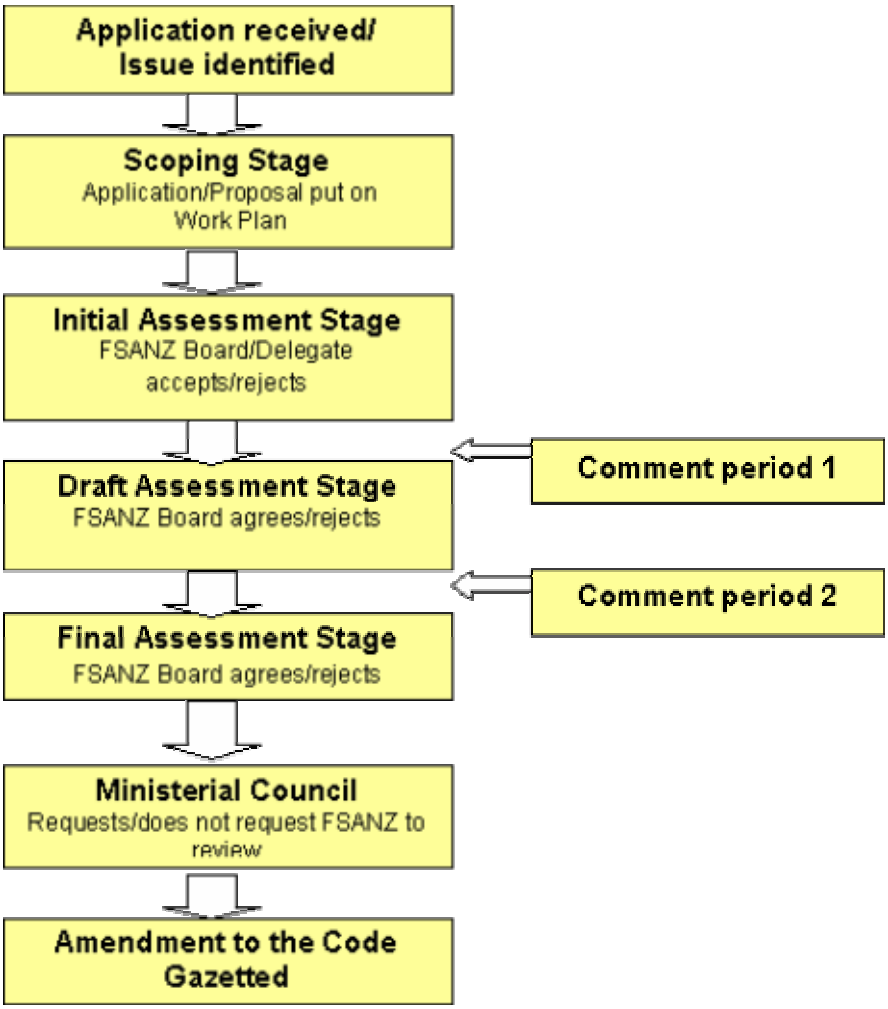
APPENDIX 6 - EUROPEAN UNION SITE

Home page of http://europa.eu.int/comm/biotechnology site



APPENDIX 7 – FSANZ CONSULTATION PROCESS

Insertion of two public comment periods into the FSANZ assessment process:



APPENDIX 8 – SUBMISSIONS AND APPROVALS IN AUSTRALIA/NEW ZEALAND

Genetically modified foods and their approval status (in chronological order):

	Product	Application Number	Proponent	Status
SOYBEAN	Glyphosate tolerant soybean	A338	Monsanto Australia	Approved 2000
	High oleic acid soybeans	A387	Du Pont	Approved 2000
	Glufosinate ammonium tolerant soy	**A481**	Bayer Crop Science	Assessment in progress
CANOLA	Glyphosate tolerant canola GT73	A363	Monsanto Australia	Approved 2000
	Glufosinate ammonium tolerant canola topaz & glufosinate ammonium tolerant canola with fertility traits	A372	Aventis CropScience	Approved 2002
	Canola resistant to bromoxynil	A388	Aventis CropScience	Approved 2002
CORN	Insect-resistant corn Mon 810	A346	Monsanto Australia	Approved 2000
	Glyphosate tolerant corn	A362	Monsanto Australia	Approved 2000
	Insect-resistant corn (Bt-176)	A385	Syngenta Seeds	Approved 2001
	Insect-resistant, glufosinate ammonium tolerant corn line (Bt-11)	A386	Syngenta Seeds	Approved 2001
	Glufosinate ammonium tolerant corn T25	A375	Aventis CropScience	Approved 2002
	Insect-resistant, glufosinate ammonium corn	A380	Monsanto Australia	Approved 2002
	Glufosinate ammonium tolerant DLL25	A381	Monsanto	Withdrawn

	corn		Australia	
	Glyphosate tolerant corn NK603	A416	Monsanto Australia	Approved 2002
	Insect-resistant, glufosinate ammonium corn line 1507	A446	Dow AgroSciences	Assessment in progress
	Insect resistant corn	A484	Monsanto Australia	Assessment in progress
POTATO	Colorado Potato Beetle resistant potato	A382	Monsanto Australia	Approved 2001
	Colorado Potato Beetle resistant potato with resistance to potato leaf roll virus	A383	Monsanto Australia	Approved 2001
	Colorado Potato Beetle resistant potato with resistance to potato virus Y	A384	Monsanto Australia	Approved 2001
SUGARBEET	Glyphosate tolerant sugarbeet GTSB77	A378	Monsanto Australia	Approved 2002
COTTON	Insect resistant cotton	A341	Monsanto Australia	Approved 2000
	Glyphosate tolerant cotton 1445	A355	Monsanto Australia	Approved 2000
	Cotton resistant to bromoxynil	A379	Stoneville Pedigreed Seed Company and Aventis CropScience	Approved 2002
	Insect resistant cotton	A436	Monsanto Australia	Approved 2002

APPENDIX 9 – AREAS UNDER TRANSGENIC CROPS INTERNATIONALLY

[source: http://ogm.agriculture.gouv.fr/savoir_plus/fiches/fiche9.htm]

GM production by country:

Country	1998	2000	2001	2002	2003
North America	**83.8 %**	**73%**	**76 %**	**72 %**	**69.7 %**
United States	73.5 %	66 %	68 %	66 %	63.2 %
Canada	10 %	7 %	6 %	6 %	6.5 %
Argentina	**15.5 %**	**23 %**	**22 %**	**23 %**	**20.5 %**
Australia, France, Mexico, Spain, South Africa, India	1 %	nc	nc	1 %	1.3 %
China			3 %	4 %	4.1 %
Brazil					4.4 %

[Source: ISAAA (International Service for the Acquisition of Agribiotech Applications)]

APPENDIX 10 - DISCUSSION GUIDE

December 16, 2003

Discussion Guide

Environics PN 5428

Regulation of Genetically Modified Foods and Crops

Introduction to Procedures (5 minutes)

Welcome to the group. We want to hear your opinions. Not what you think other people think – but what you think!

Feel free to agree or disagree. Even if you are just one person among ten that takes a certain point of view, you could represent hundreds of thousands of people in the country who feel the same way as you do.

You don't have to direct all your comments to me; you can exchange ideas and arguments with each other too.

You are being taped and observed to help me write my report.

I may take some notes during the group to remind myself of things also.

The hostess will pay you your incentives at the end of the session.

Let's go around the table so that each of you can tell us your name and a little bit about yourself, such as what you do for a living, who lives in your house and what you like to do for fun.

INTRODUCTION OF GMO TOPICS

As you may have guessed from the questions we asked to recruit you, we are going to be discussing some issues relating to the regulation of genetically modified organisms (GMOs) in Canada.

We are going to discuss this subject for Option consommateurs, a consumer association which works to defend the consumers' interests and rights.

Speaking at a larger level, I want you each to write down what three words come to mind when you think of GMOs

DISCUSS WHAT WAS WRITTEN

Are you concerned about them?

What is the nature of your concerns about GMOs? Is it environmental? Health related? Ethical? Socio-economic? Something else?

Regulation of GMOs

As far as you know, are GMOs subject to any specific regulation in Canada?

(Since recently, there has been a special regulation for novel foods. Novel foods include 3 different kinds of foods : GMOs, eating things that people have never eaten before and known food that went through an unknown processing (like irradiation for example))

Do you know by what method or process the government approves GMOs?

Do you ever wonder or worry about how government authorities regulate the creation of new GMOs? The cultivation of GMO crops? The eating of GMOs?

Do you feel that you know « who does what » and « how » in terms of the process of approving GMOs in Canada? Can you guess how it works?

What do you know about the role of Health Canada in this area? What about the CFIA? *[CFIA = Canadian Food Inspection Agency]*

Do you know how many « novel foods » have been evaluated in Canada up to now? Do you know any examples of these?

(40 novel foods have been evaluated by Health Canada and the CFIA since 1994. All GMOs, all approved).

The current GMO Regulation Process ?

Explain the current process (you have the "A" document if you need it) :

An application is made by the corn (for example) GMO manufacturer to Health Canada. An evaluation committee, composed of 10 scientists from Health Canada and the CFIA, evaluate the GMO through known and usually used tests for regular corn (toxicity, nutritional aspects and microbiology). An environmental bureau also analyses the documents given by the manufacturer. If everything is fine, they send an approbation letter to the manufacturer.

Is this system adequat ?

Is anything left out ?

In making a decision on whether or not to approve a new GMO, what aspects should be considered? = What other considerations should be important to the public in studying a new food and deciding whether to approve it or not?

Ethical ? Socio-economical ?

What do you think of the following phrase regarding the societal impact of GMOs ? :

«All human beings live with GMOs and their impact regardless of whether they actually consume them, and that is reason enough to intervene on an ethical level »?

Public Information

Should the public be informed about decisions on whether or not to approve new foods?

Should the public always be told about what GMO has been accepted and what has been refused? What about the reasons given for the final decision?

When governments make these decisions, it comes after they conduct studies and evaluation of the new foods. Should the results of these studies always be made public?

To what extent do you think it would be useful for you to know and be informed about who makes decisions about GMOs and who decides whether a GMO should be authorized or not in Canada? In other words the process.

Should the public be informed before, during or after these decisions are made?

Show document B

And explain : there are links for each new food (left side of the document) :

What do you want to know here ?

What sort of information should the public be getting on these matters?

How would you like to receive this information? What form of communication works best? (i.e.: website postings? Ads in newspapers? Etc…) *(insist)*

Level of public confidence in GMO approval process

How much confidence do you have in the methods and process used by government in making decisions on this subject?

Should we trust the process used by government to evaluate a new GMO? Do you think that the government has enough expertise to do a complete evaluation of a GMO and decide whether to accept it or reject it?

IF NO, why do you feel that way? Is it because government doesn't have the expertise or do you think that GMOs by their very nature cannot be approved because we just don't know enough about them?

Can we trust government to be neutral and unbiased making these decisions?

Are you in favour of « precautionary principle » or « substantial equivalency »?

Explain :

The precautionary principle suggests that we should clearly analyse the benefits and the risks of something before accepting it. This analyse should be made gathering the whole actors, including population, and take into account every aspect of the issue, not only the scientific ones. In paralell, long term tests should be led to try to measure the potential impacts on the environment and on people.

The substantial equivalency states that we consider a GMO crop/food as the equivalent as the regular homologue crop/food. Thus, to evaluate the GMO crop/food, you use the same best scientific analyses you are used to using for the regular homologue crop/food. If tests are OK, then you consider the GMO equivalent to the regular and you accept it.

Level of Public Involvement Wanted

Should the general public be able to participate in the process of deciding whether or not to approve GMOs?

How can this be done? Who should participate? People like yourselves? Representatives of the general public ? (ie : consumers groups)

How could representatives of the general public participate in the approval process of new GMOs? :

How can the public express its views?

What about including experts who are not part of Health Canada or the CFIA in the process ? (= external experts)

Should these external experts represent the public or should they be there in addition to representatives of the general public?

Should the public representatives, whoever they are, be able to express their views on an application for approval of a new product?

Should their input be solicited before or after a decision is rendered by the evaluation committee? If after, how long after?

Or should they belong to the comitee itself for that ?

In that case, does it matter how many representatives of the public are on the evaluation committees? How many public reps should be on a committee of 10? 5 public and 5 government? 2 and 8? 8 and 2?

Need for GMO Information and Access to GMO Information

If you were to participate, directly or indirectly, do you think that you know enough about GMOs and the problems and issues around them in terms of keeping our food supply safe? environmental protection? Social and ethical consequences? Or do you feel you need more information on these topics if you are to play any role in this debate?

What information do you need?

Could one or a several organizations be given a mandate to inform you ?

What sorts of organizations?

What is the best way to get you that information? PROBE

THANK YOU FOR YOUR PARTICIPATION.