



Canadian Perceptions of the Role of Government in the Regulation of Biotechnology Products

Fisheries and Oceans Canada and Agriculture and
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Table of Contents

Introduction.....	1
Executive Summary	4
Résumé	8
Key Findings	13
Overall Findings – Attitudes Toward Biotechnology	13
Prevailing Attitudes About Regulatory Governance	15
Aquatic Biotechnology	18
Plant Molecular Farming.....	28

Appendix

Moderator's Guide (English and French)

Introduction

Decima Research is pleased to present the following report to Fisheries and Oceans Canada and Agriculture and Agri-Food Canada, summarizing the results of the recently completed qualitative research about key issues associated with the regulation of biotechnology in two areas: Aquatic Biotechnology and Plant Molecular Farming (PMF).

Fisheries and Oceans Canada (DFO) is involved in conducting research and policy analysis related to the regulation of novel aquatic organisms. DFO undertook this study of *Canadian's Perceptions of the Role of Government in the Regulation of Biotechnology Products* to inform program and policy development, including the potential development of new regulations for aquatic biotechnology.

Agriculture and Agri-Food Canada (AAFC) was interested in conducting POR on the issue of plant molecular farming, and contributed an additional module to this initiative. DFO increased efficiencies by adding AAFC modules to the POR and developed synergies through collaborating with AAFC on this initiative.

The key objectives of the discussions were:

- To gain a more in-depth understanding of Canadians' attitudes, perceptions and beliefs regarding:
 - The consideration of socioeconomics and ethics in regulatory design and regulatory decision-making
 - Views on product labelling
 - Views on public involvement in decision-making
 - Views on what the Government of Canada could do to ensure it is representing the interests of the Canadian Public
 - Expectations regarding timeframes for regulatory decisions and action
- To explore Canadian attitudes towards plant molecular farming through AAFC's module on that topic; and
- To identify trusted sources of information on these topics used by the Canadian Public.

To meet the objectives of this research, Decima conducted a series of qualitative focus groups. Two focus groups were conducted in each of the following six geographic locations for a total of twelve focus groups:

- Toronto – March 13, 2007 (English);
- Edmonton – March 14, 2007 (English);
- Quebec City – March 19, 2007 (French);
- Charlottetown – March 20, 2007 (English);
- St. John's – March 21, 2007 (English); and
- Vancouver – March 27, 2007 (English).

The focus groups were standard groups, two hours in length, with ten participants invited for each session. Most sessions were conducted with our proprietary *Involved Canadians* segment. When conducting public opinion research it is important to understand the difficulty in effectively communicating with a public that is largely disinterested, preoccupied with other issues, or flooded with information. One of the reasons interest groups have reached such prominence and influence is because the public at large often delegates, by default, to these groups. In order to deal with these kinds of issues, Decima has developed a very useful segmentation of opinion, one we call *Involved Canadians*. This group represents roughly 30% of Canadians and our research has shown conclusively that this group is heavily involved in setting and altering the media and issue agendas of the country, using a variety of means to participate in debates about contemporary issues.

Involved Canadians are selected based on how they answer a series of nine proprietary questions. Based on their responses, we then determine if participants are considered to be an *Involved Canadian*, or if they are considered "general public".

In essence, the arguments for focusing on this target audience are:

- *Involved Canadians* are the front lines of information dissemination – they help shape the debate and lead public opinion, either positively or negatively; and

- *Involved Canadians* are far more likely to consume the messages government is communicating and should probably form a key target group for follow-on communications efforts.

Our research shows that *Involved Canadians* are responsible for a remarkable amount of the public affairs activity that takes place in Canada (including signing petitions, joining organizations, writing letters, giving speeches, etc.). Looking at this group provides useful insight into how government communications are consumed and often contributes to the effective design of public communications and consultative processes.

Executive Summary

The results of this research are based on twelve focus groups conducted over six evenings in the following cities: Toronto, Quebec City, Charlottetown, St. John's (NL), Edmonton, and Vancouver.

This research program was designed to complete research on two different applications of biotechnology for two different clients. Groups were conducted on either Aquatic Biotechnology or Plant Molecular Farming (PMF). There is some cross-over in terms of themes presented and areas explored (e.g. overall awareness and familiarity with biotechnology), but there are also application-specific findings. Unless otherwise noted, findings presented are based on both areas of exploration.

Outlined below are the key findings from the research:

1. **Biotechnology is not a top-of-mind new technology.** Electronics and computers are most often mentioned in relation to new technologies. Only upon prompting were health-related applications and Genetically Modified (GM) foods named as biotechnology applications.

Awareness and familiarity with Aquatic Biotechnology and Plant Molecular Farming (PMF) is relatively low and this is largely consistent with other research we have conducted on this subject matter.

2. **Long-term risks continue to be the key barrier to acceptance of these technologies.** For most, without fully understanding potential long-term effects of these products, there is resistance to their acceptance. Having said that, they will evaluate these products based on the potential benefit to society at large. Therefore, participants are more accepting of applications that are health related than others.
3. **Participants are not confident that current regulatory frameworks match the advances in the products being regulated.** For most, the prevailing view is that federal regulatory bodies (and their staff) are well intentioned, but overworked, do not have enough resources to address the issues adequately (or "keep up"), and are under significant pressure to "approve" products that they may or may not feel are truly safe.

4. Participants seek strong regulations that encompass a variety of areas.

Indeed, they want the federal government to develop and continuously monitor the science. They are seeking regulations that are strongly based on science and are rigorously enforced.

Moreover, regulations must convey a sense of independence from industry stakeholders and must include a peer review component. Specifically, participants want to be reassured that regulations are created on the basis of science and not in response to industry pressures and preferences. For them, this goes to the core credibility of the regulatory framework. In essence, regulations established by government are considered more credible than those with strong input from industry. While they recognize that industry should be consulted in terms of practicality, this is viewed as one small component.

5. Socio-economic considerations. On the question of socio-economic considerations, there was a near consensus across all groups in all regions of the country that socio-economic considerations ***should not*** be included as factors within the regulatory approval system for products of Aquatic Biotechnology or PMF products. There was a consistent view that the science on risk should be the only factor that should govern regulatory decisions.

6. The preferred approach of the majority was to make a much more significant commitment to transparency, but not necessarily direct public involvement in regulatory decision-making. There were a small number who felt that there should be a "seat" at the decision-making table for ordinary citizens. While most want to be made aware of research, applications and the commercial developments being undertaken, they don't necessarily feel the need to be involved in the regulatory decision-making process. The main reason was that they do not feel they are qualified to assess the science that informs regulatory decisions.

Aquatic Biotechnology Specific Views

7. **Ethical considerations.** On the question of incorporating ethical considerations into the regulatory approval process, there was a broad, if not unanimous point of view across the groups that it should not be included as a factor within the case-by-case regulatory approval system for products of Aquatic Biotechnology.

Aquatic Biotechnology is not presently an area that raises significant ethical concerns. However, there remains a strong expectation that a broad spectrum or overarching ethical governance framework be in place within the regulatory system – such as in the banning of human cloning.

A large number of participants were concerned about what they observe as a gap in the ethical governance of privately funded research. There is a sense that something should be done to appropriately address ethical considerations in private research, although for most, the regulatory system is not the right vehicle to do that.

Plant Molecular Farming (PMF) Specific Findings

8. **The main area of concern regards the potential for cross-pollination and contamination of food crops, when PMF crops are grown outdoors.** This tended to be the most dominant issue that was raised. People were extremely concerned that contamination of food crops could occur following the acceptance of PMF applications in fields.
9. **There is no awareness of the current Canadian Food Inspection Agency (CFIA) regulations in place for PMF.** When prompted, no one thought there were regulations in place for these products, and were pleasantly surprised to find that a set regulations did exist, and that they had been in place since 1994.

The regulations conveyed a sense that CFIA was taking the right issues into account, and that they were taking appropriate care to keep a close watch on what was happening in the field. The elements which had the strongest positive reaction were: restrictions on use of land following PMF use; controlled use of harvested material; requirement for inspectors to witness

disposal; on site surprise inspections; and the removal of the reproductive organs from the plants.

- 10. Participants in the sessions were cautious to the point of being resistant to the expansion of the regulations.** There was broad acceptance that in order to make PMF products commercially viable, they would need to be grown in larger plot areas. There was also acknowledgement that since PMF had been researched in test plots for 13 years, which should provide a level of knowledge as to what works and what doesn't. However, most participants wanted to know more about the rationale for changes under a new regulatory approach, and more about studies done on the test plots. Lacking this, their impressions were that there was an insufficient science/research basis behind a new regulatory approach.

Résumé

Les résultats de la recherche proviennent de douze groupes de discussion qui se sont déroulés en six soirées dans les villes suivantes : Toronto, Québec, Charlottetown, St. John's (Terre-Neuve), Edmonton et Vancouver.

Le programme de cette recherche a été conçu pour étudier deux applications différentes de la biotechnologie pour deux clients différents. Les groupes portaient soit sur la biotechnologie aquatique, soit sur la moléculature végétale (MV). Les thèmes présentés et les domaines explorés se recoupent parfois (p. ex., la connaissance globale de la biotechnologie), mais il y a aussi des résultats propres à chacune des applications. Sauf lorsqu'indiqué, les résultats concernent les deux applications sous étude.

Les principaux résultats qui ressortent de la recherche sont les suivants :

1. **La biotechnologie ne fait pas partie des nouvelles technologies que les participants nomment spontanément.** Les appareils électroniques et les ordinateurs sont les nouvelles technologies qu'ils mentionnent le plus souvent. Ils nomment uniquement les applications dans le domaine de la santé et les aliments génétiquement modifiés (GM) lorsqu'on leur demande de nommer des applications dans le domaine de la biotechnologie.

La connaissance de la biotechnologie aquatique et de la moléculature végétale (MV) est relativement faible, ce qui vient grandement corroborer d'autres recherches que nous avons faites sur le sujet.

2. **Les risques à long terme demeurent le principal obstacle à l'acceptation de ces technologies.** La plupart des participants sont réticents à accepter les produits lorsqu'ils ne comprennent pas tout à fait leurs effets potentiels à long terme. Cela dit, ils évaluent les produits selon les bienfaits possibles pour l'ensemble de la société. Les participants acceptent donc davantage les applications dans le domaine de la santé que les autres.
3. **Les participants ne croient pas que les cadres réglementaires actuels suivent les avancées des produits réglementés.** La plupart d'entre eux pensent que les organismes de réglementation fédéraux (et leurs employés)

ont de bonnes intentions, mais qu'ils sont surchargés, qu'ils n'ont pas suffisamment de ressources pour s'attaquer à ces enjeux de façon adéquate (ou pour « se tenir au courant ») et qu'une forte pression est exercée sur eux pour qu'ils « approuvent » des produits qu'ils ne trouvent peut-être pas tout à fait sécuritaires.

4. **Les participants veulent des règlements stricts qui englobent divers domaines.** En effet, ils veulent que le gouvernement fédéral développe et surveille la science de façon continue. Ils demandent à ce que les règlements s'appuient solidement sur des données scientifiques et soient appliqués avec rigueur.

En outre, les règlements doivent témoigner d'une certaine indépendance à l'égard des intervenants de l'industrie et faire l'objet d'un contrôle par les pairs. Précisément, les participants veulent avoir l'assurance que les règlements sont créés en fonction de la science et non en réponse aux pressions et aux préférences de l'industrie. Pour eux, cette préoccupation est au cœur de la crédibilité du cadre réglementaire. Essentiellement, les règlements établis par le gouvernement sont jugés plus crédibles que ceux qui ont fait l'objet d'une vaste consultation de l'industrie. Bien qu'ils reconnaissent que l'industrie doit être consultée pour les aspects pratiques, il s'agit pour eux d'un élément mineur.

5. **Considérations socioéconomiques.** Dans l'ensemble des régions du pays, les participants de tous les groupes sont quasi unanimes pour dire que les considérations socioéconomiques **ne devraient pas** faire partie des facteurs pris en compte dans le système d'approbation réglementaire pour les produits issus de la biotechnologie aquatique ou de la MV. Une majorité de participants pensent que la science du risque devrait être le seul facteur à régir les décisions en matière de réglementation.
6. **L'approche que préfèrent la majorité des participants est de prendre un engagement beaucoup plus fort envers la transparence, mais de ne pas nécessairement impliquer directement la population dans la prise de décisions en matière de réglementation.** Un petit nombre de participants croient que les citoyens ordinaires devraient avoir un « siège » à la table des décisions. Tandis que la plupart des participants veulent être tenus au

courant de la recherche, des applications et des développements commerciaux en cours, ils ne ressentent pas nécessairement le besoin d'être impliqués dans le processus décisionnel en matière de réglementation. La principale raison invoquée est qu'ils n'ont pas l'impression d'avoir les compétences nécessaires pour évaluer la science sur laquelle s'appuient les décisions en matière de réglementation.

Biotechnologie aquatique – Résultats

- 7. Considérations éthiques.** Les participants devaient donner leur avis sur l'intégration des considérations éthiques au processus d'approbation réglementaire. La plupart d'entre eux, si ce n'est la totalité, pensent que pour les produits issus de la biotechnologie aquatique, ces considérations ne devraient pas faire partie des facteurs à prendre en compte dans le système d'approbation réglementaire au cas par cas.

À l'heure actuelle, la biotechnologie aquatique ne soulève pas d'importantes inquiétudes au point de vue de l'éthique. Il y a toutefois de fortes attentes quant à la mise en place d'un cadre de gouvernance éthique obligatoire ou de portée très large au sein du système de réglementation, comme pour l'interdiction du clonage humain.

Un grand nombre de participants sont inquiets des lacunes qu'ils remarquent dans la gouvernance éthique de la recherche privée. Ils croient qu'il faut agir pour aborder de façon adéquate les questions éthiques dans la recherche privée, quoique la plupart d'entre eux pensent que le système de réglementation n'est pas le véhicule approprié pour le faire.

Moléculature végétale (MV) – Résultats

- 8. La pollinisation croisée et la contamination des cultures alimentaires sont la principale inquiétude des participants lorsque la MV se fait à l'extérieur.** Il s'agit généralement de la plus importante inquiétude soulevée. Les gens sont extrêmement inquiets à l'idée que les cultures alimentaires puissent être contaminées après l'autorisation des applications de la MV dans les champs.

- 9. Les participants ne connaissent pas les règlements de l'Agence canadienne d'inspection des aliments (ACIA) actuellement en vigueur concernant la MV.** Lorsqu'on le leur demande, aucun participant ne croit qu'il existe des règlements en vigueur pour ce genre de produits et ils sont agréablement surpris d'apprendre qu'il en existe bel et bien depuis 1994.

Les règlements transmettent l'idée que l'ACIA tient compte des bons enjeux et qu'elle s'assure de bien surveiller ce qui se passe dans le domaine. Les éléments qui ont suscité les réactions positives les plus vives sont les restrictions qui encadrent l'utilisation des champs qui ont servi à la MV, le fait que l'utilisation des récoltes est contrôlée, l'obligation que des inspecteurs soient témoins de l'élimination, les inspections-surprises sur place et le fait que les organes reproducteurs des plantes doivent être coupés.

- 10. Les participants aux groupes sont prudents au point d'être réfractaires à l'accroissement de la réglementation.** La plupart des participants reconnaissent que les produits issus de la MV ne peuvent être viables commercialement que s'ils sont cultivés dans des lots de plus grande superficie. Les participants reconnaissent également que comme des recherches sur la MV sont effectuées depuis 13 dans des lots d'essai, le niveau de connaissance acquis devrait permettre de savoir ce qui fonctionne et ce qui ne fonctionne pas. Cependant, la plupart des participants voulaient en apprendre davantage sur les raisons qui motivent les changements dans la nouvelle approche en matière de réglementation et sur les études effectuées dans les lots d'essai. En l'absence de ces renseignements, ils croient que la nouvelle approche en matière de réglementation manque de fondement scientifique et ne s'appuie pas suffisamment sur la recherche.

Key Findings

This report presents the findings from six evenings of focus groups in Toronto, Edmonton, Quebec City, Charlottetown, St. John's (NL), and Vancouver among Canadians about Aquatic Biotechnology and Plant Molecular Farming (PMF).

This research program has been informed by previous research conducted by Decima on public attitudes toward biotechnology. Some of Decima's most recent research has explored broad level attitudes regarding GM fish and GM crops, specifically those that would be utilized for molecular farming.

The orientation of this project was informed in part by that previous work. The main focus here is specifically geared toward exploring key questions related to Aquatic Biotechnology and PMF, addressing regulatory issues and governance of these emerging areas of biotechnology on behalf of Fisheries and Oceans Canada and Agriculture and Agri-Food Canada respectively. It is in those areas that this report places its overall focus.

However, in order to get to those questions in the discussions, participants were first invited to provide initial impressions of these respective areas of technology, and overall perceptions involving regulatory governance.

This research program was designed to complete research on two different applications of biotechnology for two different clients. Groups were conducted either on Aquatic Biotechnology or Plant Molecular Farming (PMF). There is some cross-over in terms of themes presented and areas explored (e.g. overall awareness and familiarity with biotechnology), but there are also application-specific findings. Unless otherwise noted, findings presented are based on both areas of exploration.

Overall Findings – Attitudes Toward Biotechnology

Canadians see their lives becoming increasingly influenced by new emerging technologies in a wide range of fields. Most Canadians believe emerging technologies such as new communications technologies, the internet, and areas like stem cell research provide many benefits to them, and to society as a whole. At the same time, it is also clear that some of these emerging technologies pose

significant risks, and some raise ethical concerns. On balance, most accept and embrace new technologies, although there are clear concerns that not enough attention is being placed on issues such as risk and ethical concern in the “race” to adopt new technologies.

In this research, consistent with what we have found over the past couple of years, biotechnology was not often immediately cited as one of the new “revolutionary” technologies affecting society. Where 5 years ago biotechnology and GM products tended to be raised as top-of-mind examples of revolutionary technologies, this is less the case today. However, once prompted, these areas of inquiry are viewed as being extremely important and influential areas, notwithstanding that they seem to have become less newsworthy in recent times.

Awareness of the two major areas of biotechnology being explored in these focus groups, Aquatic Biotechnology and Plant Molecular Farming (PMF) was very low. None of the participants in these groups had heard of either of these fields of inquiry, although few expressed surprise that they were occurring.

There was a notable tendency against endorsing broadly, in principle, the exploration of applications of Aquatic Biotechnology and PMF. Instead participants tended to support certain applications more than others, tending to evaluate the acceptability of applications on a case-by-case basis. As with other research we have done in this area, participants essentially conduct a risk-benefit analysis of the applications, and if the benefit is seen as substantially beneficial to society or them personally, it tends to be found acceptable.

The core of concern about biotechnology applications that Canadians in all of these groups expressed centres on risks of the products/processes, specifically long-term risks. Because the applications which were being discussed are very new to participants, their immediate default is to say the ideas sound appealing, but they question the potential long-term effects.

“I think it is good. It will move us forward. We are making a mess. We need biotech to correct our mistakes.”

Prevailing Attitudes about Regulatory Governance

This research has reinforced a clear sense that one of the key drivers of support or opposition to advancing in areas of technology like biotechnology has to do with perceptions of regulatory and ethical governance. In other words, comfort about the extent to which risks and ethical considerations are being appropriately managed is very closely tied to perceptions of these systems of governance in Canada. Overall, and in the specific cases of Aquatic Biotechnology and PMF, the results suggest there are prevailing concerns about the efficacy of Canada's regulatory systems, which act as an inhibitor to acceptability. In short, public confidence in Canada's regulatory systems governing these technologies is not all that high, and it tends to be weakening or remaining the same over time, rather than improving.

For most, the prevailing view is that federal regulatory bodies (and their staff) are well intentioned, but overworked, do not have enough resources to address the issues adequately (or "keep up"), and are under significant pressure to "approve" products that they may or may not feel are truly safe. The reality is that Canadians draw examples from what they know about other regulatory issues or events, and relate those to the regulatory system for biotechnology products. There are myriad examples that people raise in groups across the country that reinforce negative attitudes about regulatory governance. In recent years, there have been a number of examples that people reference as examples.

In the safety/risk regulatory sphere, the prime overall concerns are:

- Concerns about a lack of knowledge about regulatory systems, and in the absence of knowledge, there is a tendency to default to a sense that systems are probably not working very well;
- Concerns that people who work in regulatory systems are not able to "keep up" with new technologies, or that there are not enough staff/scientists to appropriately play the role that needs to be played;
- Concerns that corporate influence or political influence can have undue influence on decisions made by regulatory bodies, both the decisions

"How can the public be involved when they don't know about it."

themselves as well as the timeframes within which decisions will be made. People cite examples of scientists that have been pushed aside or fired when their decisions have been set aside in order to allow certain products to develop;

- Cases like the recall of Vioxx and Celebrex, as well as other cases like the Schmeiser case¹, or the Olivieri case², suggest that government and regulatory agencies are under pressure from political or corporate influence to take measures (or to not take measures which should be taken); and
- The lack of labels on GM products. In many groups, participants raise questions about the efficacy of the regulatory system when the products are not labelled. There is a concern that authorities are “hiding” something when they do not require that producers label GM products.

In the ethical sphere, there are also concerns, although they tend to owe more to a lack of knowledge/understanding of what is in place, or a perception that there is no governance at all of ethical issues in biotechnology research than a perception that the existing set of practices are not appropriate or effective. Key issues in this sphere:

- A total absence of knowledge about what ethical frameworks are in place to govern the science of these technologies. None of the participants in these groups had heard of the *Human Reproductive Technology Act*, and the ethical guidelines that are enshrined in that *Act*, and only a handful had any knowledge about ethics boards at universities and research institutions. Those few who have had experience with, or know something about the ethical regimes in place through universities or the research community tend not to have significant concerns about ethical issues with regard to biotechnology research. It is those who know nothing about existing frameworks, and who are already predisposed to have concern about these technologies, that express the most concern about the ethical governance regime.

¹ This concerns a court case involving a Saskatchewan farmer growing genetically modified crop using seed derived from a nearby Monsanto crop.

² Toronto hematologist Dr. Nancy Olivieri published on risks of an experimental drug despite public criticism, attempts to discredit her and threats of legal action.

- Concerns that privately funded research takes place largely absent of moral and ethical oversight. If there is one area where many do have concerns, it is that private research and publicly funded research have different regimes of ethical governance. There are concerns about what is happening “behind closed doors” within private companies doing biotechnology research.

Aquatic Biotechnology

Initial Impressions and Attitudes

Decima conducted some preliminary research into public opinion in the field of Aquatic Biotechnology in 2006. This newest round of public opinion research suggests that there have been some subtle changes in terms of core understandings and attitudes on this issue since that time.

Familiarity with this application of biotechnology remains very low, but first impressions of this field tended to be slightly more positive than found in the past – while there was significant trepidation about accidental release of GM fish adversely affecting natural populations, willingness to explore this area tended to be a bit higher than found in the past. The main issues that were raised as concerns were the containment of GM fish and their importation from other countries.

Participants in each session were provided with examples of different applications of Aquatic Biotechnology for discussion purposes. The following examples were presented:

- ***The development of genetically modified fish that can produce human insulin to treat diabetes.*** Conventional injection of insulin by type I diabetics can produce circulatory problems over time. The use of genetically engineered fish cells for transplants could relieve the symptoms of diabetes without the need for insulin injection. These fish would be grown in contained laboratory facilities.
- ***The development of genetically modified algae for the production of pharmaceutical drugs or dietary applications.*** One example of this is GM algae, producing a human protein to protect against infection by a variant of the herpes simplex virus. These algae are grown in contained, land-based manufacturing facilities.
- ***The development of genetically modified tropical fish for use in the aquarium and retail pet industry.*** Zebra fish are genetically modified by adding a fluorescence gene so that the fish absorb light and then re-emit it, creating the perception that they are glowing. These fish are currently developed in other countries and could be imported into Canada.

- ***The development of genetically modified tropical fish for use in medical research, similar to how laboratory mice and rats are used.*** For example, embryonic development can be studied by adding a fluorescence gene to Zebra fish so that their blood vessel development can be continuously observed with a time-lapse camera. This kind of work has many useful applications for medical research. This research is conducted in a contained facility.
- ***The development of genetically modified tropical fish for use in the food industry.***

The discussions of these examples revealed that there is a great deal of scepticism around certain applications of Aquatic Biotechnology. For example, there was some fairly strong resistance to the idea of allowing the genetic modification of tropical fish for the pet industry because this type of application was regarded as “frivolous” and not worth the potential risk that it may present.

It is also clear that production and use of GE fish inside contained facilities with very stringent management procedures is essential to acceptability. Focus groups clearly revealed **no** appetite for exploring applications without contained facilities for production.

The findings from these sessions also indicate that their support for such research is not given writ large but rather acceptance of Aquatic Biotechnology is made on a case-by-case basis. Their level of comfort with Aquatic Biotechnology is largely based on what the potential benefit will be. Acceptability will be assessed on each individual case.

It is fair to say that participants have the most comfort with those applications that have the potential to provide a larger benefit to society and most likely associate this with health applications. Indeed, few, if any, expressed any hesitation with using GM fish for any health-related research. They recognize that this type of research is regularly conducted and that it is more reasonable to conduct this type of research on fish rather than humans.

Those applications that are focused on health research and medical treatments for humans were seen as being more acceptable than in the past. It appears that there is a greater understanding of the rationale for exploring some of these areas of research than there might have been in the past. The applications, such

as the application to produce insulin, or to conduct research on fish instead of mice or rats, appear to make more intuitive sense to people as appropriate ways of developing health products. While they were equally concerned about risks of these applications, there was a clearer sense that these might have a potential upside.

Regulatory System – Aquatic Biotechnology

Attitudes and perceptions about the regulatory system that might govern Aquatic Biotechnology were generally consistent with the attitudes described above concerning biotechnology as a whole – namely, stringent management and containment procedures are essential to acceptability and there is a greater tendency to accept applications of Aquatic Biotechnology when health benefits are involved. That said, since Aquatic Biotechnology is a relatively new area of scientific research, there is a concern about whether appropriate and sufficiently sophisticated regulatory authorities and enforcement processes are in place to protect Canadians.

In terms of expected components of a regulatory/governance framework for Aquatic Biotechnology, there were a number of principles that consistently were raised by participants in the groups. These included:

- **Adequately and thoroughly resourced regulatory system**
 - The financial resources must be allocated to thoroughly test products, not just review the data provided by companies. This may not necessarily mean more financial resources than are currently allocated, but the reassurances that there are enough resources in place to sufficiently carry out their mandate.
 - Adequate human resources, specifically measured by the number of scientific experts (PhDs) involved in the analysis and testing of these products.
- **Arms-length from political influence/corporate influence**
 - There is an expectation that tight measures have to be in place to ensure that regulatory agencies are entirely insulated from the pressures of political and corporate interests.

- **Peer Review**
 - A means should be in place to ensure that results, both of reviews and scientific data, are looked over by impartial third parties, such as experts at universities, as this group was considered the most trustworthy. This is not limited to the experimental phase, but also includes a long-term monitoring component.
- **Transparency/Public Accessibility to Information**
 - All relevant information regarding the approval process, decisions, and science underlying decisions concerning products and applications of Aquatic Biotechnology should be available and *easily* accessible to any member of the public.
- **Long-term Testing**
 - Extensive time should be required to test products thoroughly before approval.
 - Resources should be provided to study the impact of products after approval.
- **Thorough enforcement of laws governing production and containment**
 - The idea that government authorities need to be more diligent in monitoring production practices and safety measures was very strongly expressed in these groups. There was a very strong view that this was an area that is significantly lacking in regulatory and governance systems of government right now.

"Don't compromise research. That is profiteering."

Ethical and Socio-Economic Considerations

The core objective of the research for DFO was to explore Canadians' interest in incorporating ethical and socio-economic factors in the regulatory governance approval framework for Aquatic Biotechnology. Other considerations, such as labelling, and public involvement, were also explored. The focus group participants provided very clear guidance on these questions.

1. **Socio-economic considerations.** On the question of socio-economic considerations, there was a near consensus across all groups in all regions of the country that socio-economic considerations ***should not*** be included as

factors within the regulatory approval system for products of Aquatic Biotechnology. There was a consistent view that the science on risk should be the only factor that should govern regulatory decisions. The reasons why this view was expressed were consistent as well:

- People would not want to trade-off risk for potential socio-economic benefit. In an area like Aquatic Biotechnology, where concerns about risk are already heightened, the idea of potentially making this trade off is disconcerting to many, and would not only exacerbate fears of risk, it would potentially undermine perceptions of regulatory authorities and the scientific grounding on which those authorities' efforts are predicated.
- People worry that decisions about socio-economic benefit are extremely subjective, and are often subject to political or corporate pressure/interference. As mentioned earlier, Canadians tend to be fearful of political pressure making its way into the current regulatory approval process, and if socio-economic considerations were incorporated, this would be seen by many as a further "loophole" for political and corporate influence to affect decisions.
- The idea of having socio-economic considerations playing a role in determining whether a product should or should not be approved was also explored and similarly rejected in the groups. First, it was seen as a process that should be insulated from those kinds of pressures, and should focus on science. Second, there were concerns that political and corporate influence could exploit socio-economic considerations to their own ends, which may or may not align with the true interests of Canadians.

2. Ethical considerations. On the question of incorporating ethical considerations into the regulatory approval process, there was a broad, if not unanimous point of view across the groups that this is not desirable on a case by case basis, but there remains a strong expectation that broad spectrum/overarching ethical governance be in place – such as in the banning of human cloning.

Aquatic Biotechnology is not an area that raises significant ethical concerns. Many feel trepidation about exploring research in Aquatic Biotechnology, but that trepidation is grounded in concern about risk of accidental release affecting natural populations of fish, and risk of the GM products making their way into the food system, rather than concerns that are ethical in nature. Concerns related to Aquatic Biotechnology tend to revolve around impacts to the environment or human health, rather than purely ethical concerns, which are more commonly associated with perceived direct impacts of biotechnology on humans. For Aquatic Biotechnology, there was no significant desire for ethical issues to be strongly addressed within the framework of a regulatory governance system.

In the broader context of biotechnology however, there is a feeling among some (particularly those who have the most concern about biotechnology), that ethical governance over biotechnology as a whole is lacking. Therefore, at first blush, there is an appetite among that group of people to introduce a new ethical framework.

Upon further discussion, it was revealed that the underlying driver of concern, and the resulting appetite for incorporating a new ethical framework, is as much the lack of knowledge or understanding of the existing ethical regime than of perceived failings, gaps or the absence of a sufficient ethical regime. None of the participants in these groups knew about the ethical provisions in the *Human Reproductive Technology Act*, and only a small handful (mostly those who worked at universities) knew about the ethical governance bodies that are active in the scientific research sphere.

So, lacking knowledge of what is currently in place, and with a concern that nothing is really in place to govern ethics, a significant number say that ethical provisions ought to be incorporated into the regulatory approval system.

However, even in that context, there are many that express strong reservations about taking this kind of step. The first point of resistance is the issue of “whose ethics” ought to govern decisions. Participants

typically cite the fact that different people, and different interest groups/politicians express different ethics, and they cannot imagine how it would be workable to build a system that would establish and apply a set of ethics that are broadly accepted. Further, they become quite concerned with the idea of government bureaucrats making ethical decisions on behalf of Canadians – many would rather make those decisions on their own, with the exception of areas like human cloning that need an overarching policy/legal framework. Therefore, they are resistant for the inclusion of an ethical component in the regulatory or governance framework at any level.

When the provisions of the *Human Reproductive Technology Act* and the ethics committee systems that govern research today are explained to participants, the level of interest in the idea of establishing an ethical set of criteria to incorporate into the regulatory system is advocated by relatively few people (about 10 of the 75 participants in these groups).

However, a much larger number of participants remained concerned about what they observe as a gap in the ethical governance of privately funded research. There is a sense that something should be done to appropriately address ethical considerations in private research, although for most, the regulatory system is not the right vehicle to do that.

"If I am having heart surgery, am I going to ask the public or a heart surgeon? We are trying to micro-manage something we know nothing about."

- 3. Public Involvement in Regulatory Decision-making and Transparency.** These focus groups included a segment of the population called involved Canadians. These are individuals that tend to be more aware and engaged in public affairs issues than most members of the population. One might typically expect that among this segment, there would be higher than average levels of interest in public involvement.

However, on the question of how to involve the public in decisions about Aquatic Biotechnology, the preferred approach of the majority was to make a much more significant commitment to transparency, but not necessarily direct public involvement in regulatory decision-making. There were some who felt that there should be a "seat" at the decision-

making table for ordinary citizens. While they want to be made aware of research, applications and the commercial developments being undertaken, most don't necessarily feel the need to be involved in the process. The main reason was that they do not feel they are qualified to assess the science that informs decisions.

4. **Labelling.** On the question of labelling, there was a full consensus. All participants in all groups feel that information about the genetic modification of a product is necessary on the product label, over and above labelling provisions for health and safety. This relates back to the issue of public awareness. By labelling products "GM", participants feel they are able to make an informed decision about products they would use based on all the information available to them.

Exemptions to the New Substances Notification Regulations

Participants were not comfortable with the current Contained Research and Development Exemption to the New Substances Notification Regulations whereby the Government has no regulatory mechanism to gather knowledge of research activities being conducted in containment using genetically modified animals. Their opinion is based on two key considerations:

1. **Knowledge of releases.** At issue is the potential of these organisms to be released, either unintentionally or unauthorized, and the government having no knowledge of these occurrences or their potential effects.
2. **Verification of containment.** A key concern is the verification that these products are being created in a contained facility. There is no reassurance of a mechanism in place to validate and enforce containment measures.

Despite the above, participants recognized the intensity of contained research involving genetically modified animals and the consequent magnitude of the regulatory burden if researchers were required to notify every single time they imported or developed a genetically modified animal. Primarily, they anticipate that government would be burdened by paperwork and this in turn would limit their ability to prioritize other regulatory functions.

Participants suggested that an acceptable solution might be site certification. They suggested individual certification of contained facilities that import or develop organisms as a mechanism to ensure appropriate containment. A certification system would serve two-fold: first, it would ensure that those sites would be properly equipped for containment. Second, it would provide a sense of the types of organisms being imported or created. Ultimately participants wanted to be reassured that the government knows what research is being done and that appropriate safety mechanisms are in place to mitigate any foreseeable potential risks.

Plant Molecular Farming

Like Aquatic Biotechnology, plant molecular farming is not an area of biotechnology where there is any significant level of awareness among the Canadian public. Most were not surprised that these types of technologies were being investigated by scientists, but specific awareness was minimal. In contrast, respondents revealed a high level of awareness of the subject of genetically modified foods, and about other biotechnology applications in the crop sphere, such as biofuels and ethanol. Most people viewed the field as a cousin of GM foods.

To shape the discussion, participants were presented with the following examples of PMF:

- ***The genetic modification of tobacco plants to produce interleukin.*** Interleukin is an enzyme used in health treatments for diseases like Crohn's disease. Fast-growth plants like canola/tobacco are used to grow interleukin because that allows interleukin to be produced in high volumes.
- ***The genetic modification of corn plants to produce bioplastics.*** Bioplastics are biodegradable plastic products that come from certain proteins in those plants, such as corn/safflower. This method is used to produce these bioplastic products on a scale to make it effective as a substitute for synthetic plastic products currently in use.
- ***Edible vaccines.*** Genetic modification of potatoes to, for example, produce a vaccine against the Norwalk virus (currently in human clinical trials). These potatoes could be of use in developing nations where refrigeration of vaccines and sterilization of needles makes it difficult to immunize all those who need it. It should be noted, however, that if edible vaccines come into general use, the whole potato will not be administered (the potato will be freeze dried to control for dose amounts and the dried powder will be administered orally).
- ***An enzyme used in the treatment of cystic fibrosis, called Gastric lipase.*** This enzyme, found in pigs, can also be produced from plants using safflower/corn/tobacco. The company developing the corn version claims that it will be safer and more effective and will also provide treatment to the 15% of

patients who currently have no effective treatment options). Current treatment involves ingestion of a pancreatic extract from pigs.

- ***An enzyme called Trypsin, traditionally isolated from cow or pig pancreatic sources and used in large volumes in the detergent and leather industries as a catalyst.*** Involved in the process of creating cleansing products, Trypsin is being produced in genetically modified corn. It can be created by inserting the animal gene into a plant or by creating that gene synthetically in a lab and inserting it into the plant.

“Very positive for developing country ...from a Canadian standpoint, we heavily subsidize farmers and can diversify economy and set precedent for it.”

Impressions of these technologies were mixed, but with an emphasis on the positive. As a concept, PMF is a field of research that was described by most as being fascinating, promising, and exciting but also potentially very risky, particularly with regard to PMF in open fields.

The main reason why it was initially viewed as positive involved the potential for developing new treatments for diseases, and/or cheaper and simpler treatment of diseases. All of the applications that were discussed garnered a significant level of positive interest from participants.

The main area of concern regards the potential for cross-pollination and contamination of food crops, when PMF crops are grown outside. This tended to be the most dominant issue that was raised. People were extremely concerned that contamination of food crops could occur following the acceptance of PMF applications in fields. Many felt that contamination could happen relatively easily, certainly from food to food crops, and from non-food to food crops.

While there were some differences between the risks of PMF grown in food and non-food crops, there were more concerns raised about food crops, but concerns were fairly high for non-food crops as well.

The main concern about cross contamination was that “the modified product” would get into the food chain through direct cross pollination, through wind, animals or insects/birds.

Issues of safety, regulations and enforcement were also a concern. The point of departure on this set of issues is that people believe that with any new

technology, there are many unknowns, and as such, those in charge of safety have great difficulty managing those unknowns. People accept that having unknowns is inevitable in any new area of technology, but fear that safety measures are not at a level commensurate with the level of uncertainty and the level of risk involved.

Finally, there were concerns on the regulatory side as well that appropriate time might not be taken to study how these technologies impact health and the environment over time. People talked about the idea of testing these applications over generations of humans or other potentially impacted organisms, and doubted whether that would actually be done before the technologies would be introduced.

The subsequent discussion focused on two key issues: the regulatory framework and conditions under which PMF plants are being managed today, and the potential to allow those who are growing PMF plants to grow in larger areas.

The moderator provided a summary of the conditions that those who grow PMF products in test plots must fulfill, outlined below.

Conditions placed on developers are intended to segregate PMF plants from the surrounding environment and from points of contact with related food or feed commodities safeguarding human, animal, and environmental health.

The conditions include:

- *Limited to 1 hectare = 2.5 acres*
- *Isolation distances from other plants (distance varies in accordance with known plant dispersal, e.g., corn is 400 meters from other corn)*
- *Removal of the plant's reproductive organ (flower) prior to seed setting*
- *Restrictions on use of the field following PMF use*
- *Controlled use of harvested material (direct transport to processing plant with no stops, no contact points with grain elevators)*
- *No livestock grazing within 50 meters of PMF fields*
- *Disposal of leftover biomass (plant) must be witnessed by CFIA inspector*
- *Restrictions on post-harvest use of land, no species can be planted for a period of 1-5 years depending on plant type*

"Okay with it. Would like to think there is someone analyzing what this hectare has produced in its off years."

- Books showing detailed log of all activities must be kept and shown to CFIA inspector
- On site surprise inspections

Participant reaction to this set of conditions generally conveyed a sense of pleasant surprise. It conveyed a sense that CFIA was taking the right issues into account, and that they were taking appropriate care to keep a close watch on what was happening in the field. The elements which had the strongest positive reaction:

- Restrictions on use following PMF use
- Controlled use of harvested material
- Disposal has to be witnessed by an inspector
- On site surprise inspections
- The removal of the reproductive organs from the plants

The discussion then turned to the idea of allowing PMF crops to grow in larger tracts of territory. The moderator outlined the rationale for why this might be considered, as well as provisions/conditions in terms of regulation which involved a scalar expansion of isolation distances.

Overall reaction to the idea of expansion was caution, if not resistance. There was a broad acceptance that in order to make these products commercially viable, they would need to be grown in larger plot areas. There was also acknowledgement that since they had been looking at test plots for 13 years, this should provide a level of knowledge about what works and what doesn't.

However, the concerns that applied to test plots carried over to these expanded plot areas. When the new regulatory approach was tabled (such as a scalar expansion), most raised questions about it, not because they challenged it but because they would expect that there would be a science/research basis behind the decisions. The described new set of provisions was not perceived to be based sufficiently on science and analysis from the first 13 years of test plots.

Key concerns/issues with allowing larger plots for PMF:

- Participants wanted to know more about the rationale for some of the changes, such as expanded isolation distances.
- They also wanted to know more about studies that have been done on the test plots, and what they say about the potential for cross-pollination between plots of land.
- In particular, the issue of how far seeds have been found from the plots is extremely important, as is what impacts occurred as a result of rain carrying seed/plants/DNA outside the test plot areas.

In addition to these concerns, the other issues that participants raised about PMF regulation were consistent with those raised regarding the regulation of Aquatic Biotechnology. Their sentiments tended to reflect a mix of negative and positive, with a fairly high level of resistance to the idea of expanding the application and growth of GM products, which in the case of PMF is expansion of allowable plot areas. For those who accepted the idea of expanding plot areas, there were a series of expected provisions from a regulatory perspective. These included many that were also tabled as expectations for regulation of Aquatic Biotechnology:

- **Adequately and thoroughly resourced**
 - The financial resources necessary to thoroughly test products, and not just review the data provided by companies. This may not necessarily mean more financial resources that are currently allocated, but the reassurances that there are enough resources in place to sufficiently carry out their mandate.
 - Adequate human resources, specifically measured by the number of scientific experts (PhDs) involved in the analysis and testing of these products to sufficiently carry out their mandate.
- **Arms-length from political influence/corporate influence**
 - Expectation is that there are air-tight measures in place to ensure that regulatory agencies are entirely insulated from those pressures.

- **Peer Review**
 - A means of having results, both of reviews and scientific data looked over by impartial third parties, such as experts at universities.
- **Transparency/Public Availability**
 - The provision of all relevant information regarding the approval process, decision, and science underlying decisions to be made public, *easily* accessible to any member of the public.
- **Long-term testing**
 - The allowance of extensive time to test products before their approval.
 - The provision of resources to study the impact of products after they have been approved.
- **Thorough enforcement of laws governing production**
 - The idea that government authorities need to be more diligent in monitoring production practices and safety measures was very strongly expressed in these groups. There was a very strong view that this was an area that is significantly lacking in regulatory and governance systems of government right now. While participants were initially surprised that the government had regulations in place, the overriding concern was how they are enforced. In their view, there can be all the regulations in the world, but it is their enforcement that makes regulations and governance strong.

Appendix A: Moderator's Guide (English and French)

DFO/AG focus groups on Biotechnology

Final

1. Warm up (5)

The moderator will take a few minutes to introduce himself and to go around the table and ask respondents to introduce themselves, and will outline a few ground rules for the discussion:

- Want to ensure that people share their views openly and honestly.
- Want people to talk about their views, not "other people's views".
- No right or wrong answers.
- Everyone's views are valid.
- The moderator's job is to ensure that we stay on topic.
- Reinforce the message that the moderator has no stake in the results.

The moderator will also point out that there is a one-way mirror, observers in the back, and audio/video taping, but ensure that all discussion is entirely confidential.

Note: As this is a guide, all questions will not be asked of respondents verbatim.

2. Introduction (15)

Tonight we are going to talk about new technologies. To start things off, I would like you to talk to me about some of the new technologies that you know of / are aware of.

- 1 ▪ How are they changing our world, the things we do, the treatments for our health, the products we use?
- 2 ▪ Have you heard of the word biotechnology?
- 3 ▪ What does it mean? What does it encompass?
- 4 ▪ Is it a subject you know a lot about, a little about, or not much about?

Handwritten notes and signatures:

#0605
DFO / DMO

Transition
Instruction

Now I'd like to get more specific and talk about biotechnology.

- 5. ■ Biotechnology has applications in a number of fields. Can you recall any that you have heard of?
- 6. ■ Is it a subject you know a lot about, a little about, or not much about?
- 7ab. ■ Where do you get your information about it? How did you learn about it?

7a

7b

Just so we are all on the same page, here is a definition of biotechnology:

Common
Definition

8a

Biotechnology Definition: a term that encompasses a broad spectrum of scientific applications used in many sectors, such as health, natural resources, agriculture, and fish. It involves the use of living organisms, or parts of living organisms, to provide new methods of production and make new products. Related to biotechnology are the areas of life sciences, genetic modification, and genomics.

8a → f

- 8b. ■ Is it a subject you know a lot about, a little about, or not much about?
- 8c. ■ Where do you get your information about it? How did you learn about it?

8c

8d

Common
Definition

8e

GM Definition: An organism (plant, animal, and bacterium) is considered genetically modified if its genetic material has been altered through any method, including conventional breeding, resulting in a novel trait (ex. Insect resistance, modified nutritional content, etc.).

Common
Definition

8f

(DO NOT MENTION FOR THE PMF GROUPS) GE Definition: An organism is considered genetically engineered if it was genetically modified using techniques that permit the direct transfer or removal of genes in that organism. Such techniques are also called recombinant DNA or DNA techniques.

info

There is also another element of biotechnology, which involves the use of living organisms to serve new purposes ie. catfish used to clean out drainage ditches.

9a → d

What are the major benefits/drawbacks of these technologies? In health/crops/fish? In other areas? Why is that?

9c

9d

FG 1

DFO SECTION ONLY

3. Key Applications: GM Fish

(30)

Transition

I'd like to talk about an area of biotechnology you may or may not have heard of, genetically modified fish.

of Qs
DFO / PMF

14

Biotechnology applications are being explored in fish. Work in this area remains at the early research stage, no such applications or products have been approved in Canada at this time.

- Fish are being genetically modified for a number of reasons, such as to improve the growth rate of fish, or for production of drugs or cells for the treatment of human disease.
- Genetically modified fish are also being used increasingly in laboratory research to study such fields as developmental biology and medical research in much the same way that mice and rats have been used for decades.
- Fish make excellent models because of the ease with which the DNA in their eggs can be manipulated and because their short life cycle allows for the study of multiple generations in a relatively short period of time.
- These fish are created by taking DNA from one source – the same or a different kind of fish, a different animal, or a bacterium – and putting it into a fish to give it a new or altered trait.
- These applications are carried out in contained facilities or laboratories.

Some of these applications involve the genetic modification of fish, where single genes are inserted or modified to obtain desired traits such as improved growth or disease tolerance.

Other applications involve genetic selection, where fish that have certain traits are identified, selected and reproduced using conventional breeding techniques.

10b How familiar would you say you are with genetic modification/selection of fish?

There are numerous ways in which genetically modified fish can be used. Some examples:

- **The development of genetically modified fish that can produce human insulin to treat diabetes.** Conventional injection of insulin by type I diabetics can produce circulatory problems over time. The use of genetically engineered fish cells for transplants could relieve the symptoms of diabetes without the need for insulin injection. These fish would be grown in contained laboratory facilities.
- **The development of genetically modified algae for the production of pharmaceutical drugs or dietary applications.** One example of this is GM algae, producing a human protein to protect against infection by a variant of the herpes simplex virus. These algae are grown in contained, land-based manufacturing facilities.
- **The development of genetically modified tropical fish for use in the aquarium and retail pet industry.** Zebra fish, genetically modified by adding a fluorescence gene so that the fish absorb light and then re-emit it, creating the perception that they are glowing. These fish are currently developed in other countries and could be imported into Canada.

- **The development of genetically modified tropical fish for use in medical research, similar to how laboratory mice and rats are used.** For example, embryonic development can be studied by adding a fluorescence gene to Zebra fish so that their blood vessel development can be continuously observed with a time-lapse camera. This kind of fish may be used in many useful applications for medical research. This research is conducted in a contained facility.
- **The development of genetically modified fish for use in the food industry.**

11b

I would like to understand the extent to which you think GM fish might benefit our society. What are the benefits of this kind of research?

11c

And what do you see as the major risks involved?

11d

What are the main considerations that you think should be taken when we consider introducing these products?

4. Regulation of GM Products

(45)

transition

Moving on now, I would like to discuss your perceptions and preferences about how these products are regulated by government.

12

Do you think there are safety regulations / processes in place for applications like this?

13

What about for GM/biotechnology products in general?

14

What do you imagine are the central elements of these processes?

15

And from what you know, do you think that the government of Canada processes / regulations are fairly stringent or not all that stringent?

16a

What should the core elements of regulatory approvals for products like this be? What other measures should governments/regulators take to help ensure that its actions are a good reflection of the interests of Canadians? -16b

17a → 2g

What about ethical considerations? In your view, should part of the regulatory approval process for products like this? Why? Why Not? If yes, how might that be done? Should it be done on an application by application basis? On a category by category basis (health apps/food apps/crop apps)? -17e

18a → 2e

What about socio-economic considerations, such as the potential economic benefit to Canadian communities? Rural communities? In your view, should part of the regulatory approval process for products like this? Why? Why Not? -18e

19ab

What about labeling of these products (beyond the standard food and drug labeling that is used now)? Do you want to implement labeling for exotics/selectively bred fish to the same extent as transgenic fish? -19a

#805
DFO/DND
10

20 ▪ To what extent would you like to see the general public involved in making decisions about the approval or denial of use of these products?

21ab ▪ What about giving public notice when proponents are notifying authorities that they are doing work in this area, as well as when they are approved for use? If so, how to best give this notice? — 21b 21a

22a → c ▪ Who are trusted/credible sources of information on this issue? On the socio-economic dimension? On the ethical dimension? 22a 22b 22c

Common
Info.

23a { When the existing regulations were established in 1997, a decision was made to exempt research and development involving organisms from the notification and risk assessment requirements of the new substance notification regulations. This exemption is conditional on the organisms being produced in, or imported directly into a contained facility, and being held in containment such that there was no release into the environment, as it was assumed that organisms kept in containment were not expected to pose significant risks to human health or the environment.

23a → d ▪ How do you feel about scientists conducting research without being required to notify the government if it is conducted in a secure facility? Is this acceptable to you, or not? Why? 23b 23c

DFO | DMD
1 | 0

FG 2

PMF SECTION

3. Key Applications: Plant Molecular Farming

(30)

transition

I'd like to talk about an area of biotechnology you may or may not have heard of, plant molecular farming.

Common Definition

The term "plant molecular farming" describes a process of *farming genetically modified plants* to produce commercially valuable *molecules*. What is novel about the process is the nature of the *molecules* produced: they are compounds that are useful in medicine or industry. For example, in the medical realm, plants have been modified to produce vaccines and drugs to treat a host of diseases such as diabetes, cancer and cystic fibrosis. On the industrial side, plants have produced raw materials for plastics, detergents and cosmetic products.

10ab2

- PMF has a wide range of potential applications. Can you recall any that you have heard of? - 10b

There are numerous ways in which genetically modified plants can be used. Some examples:

- The genetic modification of tobacco plants to produce interleukin**, which is an enzyme used in health treatments for diseases like crohn's disease. Fast-growth plants like canola/tobacco are used to grow interleukin because that allows interleukin to be produced in high volumes.
- The genetic modification of corn plants to produce bioplastics**, which are biodegradable plastic products that come from certain proteins in those plants, such as corn/safflower. This method is used to produce these bioplastic products on a scale to make it effective as a substitute for synthetic plastic products currently in use.
- Edible vaccines**, such as Genetic modification of potatoes to produce a vaccine against the Norwalk virus (currently in human clinical trials). These could be of use in developing nations where refrigeration of vaccines and sterilization of needles makes it difficult to immunize all those who need it. It should be noted, however, that if edible vaccines come into general use, the whole potato will not be administered (the potato will be freeze dried to control for dose amounts and the dried powder will be administered orally).
- An enzyme used in the treatment of cystic fibrosis, called Gastric lipase**. This enzyme is an enzyme found in pigs, which would be produced using safflower/corn/ tobacco. The company developing the corn version claims that it will be safer and more effective and will also provide treatment to the 15% of patients who currently have no effective treatment options). Current treatment involves ingestion of a pancreatic extract from pigs.
- An enzyme called Trypsin, traditionally isolated from cow or pig pancreatic sources and used in large volumes in the detergent and leather industries as a catalyst** (it is involved in the process of creating cleansing products), is being produced in genetically modified corn. It can be created by inserting the animal gene into a plant, or by creating that gene synthetically in a lab and inserted into the plant

11a-f

Common Info

11a

#06 Qs

DFO DMO

0

8

info (There are a number of different types of plants that might be used to produce these applications. In all cases, the plant would not be part of the food system in any way, it would be specifically used for molecular farming. Do you have concerns about certain types of plants being used in this area?

- 11b
- 11c • Corn
 - 11d • Rice
 - 11e • Tobacco
 - 11f • Safflower

12 I would like to understand the extent to which you think Plant Molecular Farming might benefit our society. What are the benefits of this kind of research?

13a-7d And what do you see as the major risks involved? 13g

32 (For moderator) Probe to grasp whether there are attitudinal differences between food and non-food crops used for molecular farming 13b

33 At this juncture it might be useful to probe whether there are attitudinal issues in other areas:

13c • Comfort with different sites where these types of plants could be grown

13d • Whether there are other measures, such as modifying the plants so they won't flower, that would increase comfort with these applications

14 What are the main considerations that you think should be taken when we consider introducing these products?

4. Regulation of GM Products

(45)

transition Moving on now, I would like to discuss your perceptions and preferences about how these products might be regulated by government.

- 15 • Do you think there are safety regulations / processes in place for applications like this?
- 16 • What about for GM/biotechnology products in general?
- 17 • What do you imagine are the central elements of these processes?
- 18 • And from what you know, do you think that the government of Canada processes / regulations are fairly stringent or not all that stringent?

19a
19ab • What should the core elements of regulatory approvals for products like this be? What other measures should governments/regulators take to help ensure that its actions are a good reflection of the interests of Canadians?

119b

of Qs
DFO / DMO
0

- 20a → e
- 200 20b
20c 20d
What about ethical considerations? In your view, should part of the regulatory approval process for products like this? Why? Why Not? If yes, how might that be done?
- 21a → e
- 21a 21b
21c 21d 21e
What about socio-economic considerations, such as the potential economic benefit to Canadian communities? Rural communities? In your view, should part of the regulatory approval process for products like this? Why? Why Not?
- 22
- 22 To what extent would you like to see the general public involved in making decisions about the approval or denial of use of these products?

Transition

I'm going to give you a brief summary of the regulatory system that currently governs Plant Molecular Farming.

The CFIA has regulated outdoor growth of PMF plants since 1994. This has been done for research purposes.

Conditions placed on developers are intended to segregate PMF plant from the surrounding environment and from points of contact with related food or feed commodities safeguarding human, animal, and environmental health.

The conditions include:

- Limited to 1 hectare = 2.5 acres
- isolation distances from other plants (distance varies in accordance with known plant dispersal, e.g., corn is 400 meters from other corn)
- removal of the plant's reproductive organ (flower) prior to seed setting
- restrictions on use of the field following PMF use
- controlled use of harvested material (direct transport to processing plant with no stops, no contact points with grain elevators)
- no livestock grazing within 50 meters of PMF fields
- disposal of leftover biomass (plant) must be witnessed by CFIA inspector
- restrictions on post-harvest use of land, no species can be planted for a period of 1-5 years depending on plant type
- books showing detailed log of all activities must be kept and shown to CFIA inspector
- on site surprise inspections

Common Info.
23a

- 23b
- 23c 23d
23e 23f
23g 23h
What are your overall impressions?
 - 23 From what you read, what do you think of the regulation process? Does it give you comfort, or concern? Do you think the process is stringent or lax?
 - 23 How confident would you say you are in the safety and regulatory approval systems governing these crops? Why do you say that?
 - 23 What steps could be taken to increase your confidence?

(If issue of accidentally mixing GM and non-GM crops is raised) From what sources did you hear about this issue? Is this a concern to others? Do you think that there would be differences between the US and Canada in dealing with this issue?

22

of Qs 24a → c

DFO	DMD
0	8

There are some proposed potential changes to the regulatory system that governs Plant Molecular Farming. The changes that are being proposed have to do with making this kind of crop development economically feasible. I'd like to read it for you and then discuss.

Regulators are currently developing guidelines for outdoor growth of PMF plants on a larger scale. This increased scale would enable developers to develop their products, with a view down the road to commercialization. From a safety perspective, the regulations would increase in proportion to the size that the allowed growth area has.

- Size of allowable plot would be XYZ
- Isolation distances from other plants (distance varies in accordance with known plant dispersal, e.g., corn is 400 meters from other corn)
- removal of the plant's reproductive organ (flower) prior to seed setting
- restrictions on use of the field following PMF use
- controlled use of harvested material (direct transport to processing plant with no stops, no contact points with grain elevators)
- no livestock grazing within 50 meters of PMF fields
- disposal of leftover biomass (plant) must be witnessed by CFIA inspector
- restrictions on post-harvest use of land, no species can be planted for a period of 1-5 years depending on plant type
- books showing detailed log of all activities must be kept and shown to CFIA inspector
- on site surprise inspections

Developers must submit a lengthy application to prove that their plants are unlikely to pose an environmental hazard before receiving approval to grow them outdoors, outside of a greenhouse. The process is significant and includes CFIA visiting the site. Once the developers have approval, they have to prove that they have followed the conditions provided by CFIA, or their license is revoked. CFIA looks at their books and witnesses plant biomass disposal.

Common
info on
proposed
change to
regs

25a

25a-7h

- 25b
- What are your overall impressions of this approach? 25c
 - From what you read, what do you think of this idea? Does it give you comfort, or concern? Do you think the process is stringent or lax? 25d
 - If these were introduced, how confident would you say you would be in the idea of changing the approach to safety and regulatory approval systems governing these crops in Canada? Why do you say that? 25e

25f What steps could be taken to increase your confidence?

26 (For those who raise concerns/reject the new scenario) If you knew that the PMF industry would just move to US and other countries who allow outdoor growth of larger scale fields, would that affect your views? It is possible that some pharmaceutical products could be grown in greenhouses, high value products that can be grown as satisfactory concentrations in a small number of plants. However, for the majority of PMF products, PMF plants would likely need to be grown at greater numbers (scale) than is currently permitted.

#8125
DFO | DMO
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9

27ab

- Who are the most appropriate sources of information about this kind of subject? Are there organizations/groups that would be credible to you if they were to speak about this issue?

27a

27b

Both

6. Conclusions / wrap-up

(10)

//

Before wrapping up the group, the moderator will come back to the viewing room and check to see if there are any questions or areas the client(s) would like asked or explored further.

DFO	DMO
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2

Ministère des Pêches et des Océans (MPO)/Vérificateur général (VG) - groupes de discussion sur la biotechnologie**Finale****1. Introduction (5)**

Le modérateur prendra quelques minutes pour se présenter, faire un tour de table et demander aux participants de se présenter. Il mentionnera ensuite quelques règles de bases pour la discussion :

- Il doit faire en sorte que tous puissent exprimer leurs points de vue ouvertement et en toute honnêteté.
- Il faut que chacun exprime son point de vue personnel et non celui « des autres ».
- Il n'y a pas de bonnes ou de mauvaises réponses.
- Tous les points de vue sont valables.
- Le rôle du modérateur est de faire en sorte que l'on ne s'égare pas dans des discussions futiles.
- Le modérateur est indépendant et n'a aucun parti pris.

Le modérateur souligne également les points suivants : le miroir d'observation, les observateurs, l'enregistrement audiovisuel et le caractère confidentiel de la discussion.

Note : Puisqu'il s'agit d'un guide, les questions ne seront pas toutes posées mot à mot aux participants.

2. Entrée en matière (15)

Ce soir, nous discuterons de nouvelles technologies. Pour commencer, j'aimerais que vous me parliez des nouvelles technologies que vous connaissez ou dont vous avez déjà entendu parler.

- Comment ces nouvelles technologies changent-elles la société, ce que nous faisons, les traitements médicaux, les produits que nous utilisons?
- Avez-vous déjà entendu le mot biotechnologie?
- Pouvez-vous m'en donner une définition? Qu'est-ce que la biotechnologie englobe?
- Est-ce un sujet que vous connaissez très bien, un peu ou pas vraiment?

J'aimerais maintenant entrer dans le vif du sujet et parler de biotechnologie.

- La biotechnologie a des applications dans de nombreux domaines. De quelles applications avez-vous déjà entendu parler?
- Est-ce un sujet que vous connaissez très bien, un peu ou pas vraiment?
- Où obtenez-vous de l'information sur le sujet? Comment en avez-vous entendu parler?

Pour que nous parlions tous de la même chose, voici une définition de la biotechnologie :

Biotechnologie : terme qui comprend un vaste éventail d'applications scientifiques utilisées dans de nombreux domaines comme la santé, les ressources naturelles, l'agriculture et l'élevage de poissons. La biotechnologie fait appel à l'utilisation d'organismes vivants, ou de certaines parties de ces organismes, dans le but de mettre au point de nouveaux procédés et de créer de nouveaux produits. La biotechnologie regroupe notamment les sciences de la vie, la génétique et la génomique.

- Est-ce un sujet que vous connaissez très bien, un peu ou pas vraiment?
- Où obtenez-vous de l'information sur le sujet? Comment en avez-vous entendu parler?

Génétiquement modifié : Un organisme, comme un végétal, un animal ou une bactérie, est dit génétiquement modifié si son matériel génétique a été altéré par quelque méthode que ce soit, y compris la sélection classique, pour lui conférer de nouveaux traits (ex. résistance aux insectes, valeur nutritive modifiée, etc.).

(NE LISEZ PAS POUR LES GROUPES MOLÉCULE VÉGÉTALE (MV))

Génie génétique (GG) : Un organisme est considéré comme produit de génie génétique s'il a été génétiquement modifié à l'aide de techniques qui permettent le transfert direct ou le retrait de gènes dans cet organisme. Ces techniques sont également connues sous les noms de techniques de l'ADN recombinant ou ADNr.

La biotechnologie comprend également l'utilisation d'organismes vivants à de nouvelles fins, par exemple les poissons-chats utilisés dans le nettoyage des tranchées de drainage.

Quels sont les principaux avantages/inconvénients de ces technologies? Dans le domaine de la santé/de l'agriculture/des poissons? Dans d'autres domaines? Pourquoi?

SECTION MINISTÈRE DES PÊCHES ET DES OCÉANS

3. Applications clés : les poissons génétiquement modifiés (30)

J'aimerais que nous parlions d'un domaine de la biotechnologie dont vous avez peut-être déjà entendu parler, soit la modification génétique des poissons.

La biotechnologie a de nombreuses applications possibles, notamment dans l'élevage de poissons. La recherche dans ce domaine demeure cependant à un

stade précoce. À ce jour, aucune application et aucun produit n'ont été approuvés au Canada.

- Il existe de nombreuses raisons pour modifier génétiquement les poissons, notamment l'amélioration du taux de croissance des poissons et la production de médicaments ou de cellules utilisés dans le traitement de maladies humaines.
- Les poissons génétiquement modifiés sont de plus en plus utilisés dans les laboratoires de recherche dans des domaines tels que la biologie du développement et la recherche médicale, à peu près comme les souris et les rats sont utilisés depuis des décennies.
- Les poissons sont d'excellents cobayes parce qu'il est facile de manipuler l'ADN contenu dans leurs œufs et parce que la brièveté de leur cycle de vie permet l'étude de plusieurs générations dans une période de temps relativement courte.
- Pour créer des poissons génétiquement modifiés, on insère de l'ADN provenant d'un poisson (qu'il soit de la même variété ou non), d'un autre animal ou d'une bactérie dans l'ADN d'un autre poisson pour lui donner une nouvelle caractéristique ou un nouveau trait.
- Ces applications se déroulent dans des installations étanches ou en laboratoire.

Certaines de ces applications comprennent la modification génétique des poissons, où un seul gène est inséré ou modifié pour obtenir la caractéristique ou le trait désiré, par exemple un meilleur taux de croissance ou une meilleure tolérance à la maladie.

D'autres applications comprennent la sélection génétique, où les poissons qui présentent certains traits définis sont sélectionnés et se reproduisent par les techniques de reproduction traditionnelles.

Dans quelle mesure la modification génétique/sélection génétique des poissons vous est-elle familière?

Il existe plusieurs façons d'utiliser les poissons génétiquement modifiés. En voici des exemples :

- ***Le développement de poissons génétiquement modifiés dans le but de produire de l'insuline pour traiter le diabète.*** L'injection conventionnelle d'insuline chez les personnes souffrant de diabète de type I peut entraîner des problèmes circulatoires. La transplantation de cellules de poissons génétiquement modifiés pourrait contrôler les symptômes du diabète sans nécessiter l'injection d'insuline. Ces poissons seraient élevés dans des installations de laboratoires étanches.
- ***Le développement d'une algue génétiquement modifiée pour la production de médicaments et de produits diététiques.*** Par exemple, une algue génétiquement modifiée produit une protéine humaine qui protège contre les infections d'une variante du virus de l'herpès simplex. Cette variété d'algues est produite dans des installations terrestres étanches.

- ***Le développement de poissons d'aquarium tropicaux génétiquement modifiés pour l'industrie des animaux de compagnie.*** Des poissons-zèbres sont génétiquement modifiés en leur ajoutant un gène de fluorescence qui confère au poisson la capacité d'absorber de la lumière pour ensuite la réémettre, donnant ainsi l'illusion que le poisson brille. Ces poissons sont actuellement développés dans d'autres pays et pourraient être importés au Canada.
- ***Le développement de poissons tropicaux génétiquement modifiés pour être utilisés en recherche médicale, un peu comme le sont les rats et les souris de laboratoire.*** Par exemple, le développement embryonnaire peut être étudié en ajoutant un gène de fluorescence aux poissons-zèbres de façon à ce que le développement des vaisseaux sanguins puisse être observé de façon continue au moyen d'un appareil de photographie chronologique. Ce type de travail a de nombreuses applications en recherche médicale. Cette recherche se déroule dans des installations étanches.
- ***Le développement de poissons tropicaux génétiquement modifiés pour être utilisés dans l'industrie alimentaire.***

J'aimerais savoir dans quelle mesure vous croyez que les poissons génétiquement modifiés seront profitables pour la société. Quels avantages tire-t-on de ces recherches?

Et quels sont les principaux risques associés à ces recherches, selon vous?

À votre avis, de quoi devrait-on surtout tenir compte lorsque l'on pense à mettre ces produits sur le marché?

4. Réglementation des produits génétiquement modifiés (45)

Passons à un autre sujet. J'aimerais maintenant connaître vos perceptions et vos préférences concernant la façon dont le gouvernement devrait réglementer ces produits.

- Croyez-vous qu'il existe des règlements/des processus de sécurité pour ce genre d'applications?
- Qu'en est-il des produits génétiquement modifiés/des produits de la biotechnologie en général?
- Selon vous, quels sont les éléments au cœur de ces processus?
- Et à votre connaissance, les processus / règlements du gouvernement du Canada sont-ils assez rigoureux ou pas si rigoureux?
- Quels éléments devraient être au cœur des approbations réglementaires pour ce genre de produits? Quelles autres mesures les gouvernements/organismes de réglementation devraient-ils adopter pour veiller à ce que leurs actions soient bien à l'image des intérêts des Canadiens?
- Qu'en est-il des considérations éthiques? Selon vous, devraient-elles faire partie du processus d'approbation réglementaire pour ce genre de produits? Pourquoi? Pourquoi pas? Si oui, comment devrait-on procéder? Devrait-on procéder application

par application? Ou catégorie par catégorie (applications en santé/en alimentation/en agriculture)?

- Qu'en est-il des considérations socio-économiques, par exemple les retombées économiques possibles pour les collectivités canadiennes? Pour les collectivités rurales? Selon vous, devraient-elles faire partie du processus d'approbation réglementaire pour ce genre de produits? Pourquoi? Pourquoi pas?
- Qu'en est-il de l'étiquetage de ces produits (au-delà de l'étiquetage standard des aliments et des médicaments utilisé actuellement)? Voulez-vous que le même étiquetage particulier soit instauré pour les poissons exotiques/issus de la reproduction sélective que pour les poissons transgéniques?
- Dans quelle mesure aimeriez-vous que le grand public participe aux décisions concernant l'approbation ou le refus pour l'utilisation de ces produits?
- Croyez-vous que le public devrait être avisé lorsque des promoteurs informent les autorités qu'ils font du travail dans ce domaine et lorsque l'utilisation de leurs produits est approuvée? Si oui, comment devrait-on rendre cet avis public?
- Quelles sont les sources d'information fiables/crédibles à ce sujet? Du point de vue socio-économique? Du point de vue éthique?

Lorsque le Règlement concernant les substances nouvelles a été adopté en 1997, il avait été décidé de soustraire les projets de recherche et développement sur des organismes de l'obligation de déclarer et d'évaluer les risques de substances nouvelles. Cette exemption était possible à condition que ces organismes soient fabriqués ou importés directement dans une installation étanche et s'ils étaient gardés en confinement de telle sorte qu'ils ne soient pas rejetés dans l'environnement, car on avait alors supposé que les organismes gardés en confinement ne devraient pas poser de risques importants pour la santé humaine ou l'environnement.

- Que pensez-vous des scientifiques qui mènent des recherches sans devoir d'abord aviser le gouvernement qu'ils travaillent dans un environnement sécuritaire? Trouvez-vous cela acceptable, ou inacceptable? Pourquoi?

SECTION MOLÉCULTURE VÉGÉTALE

3. Applications clés : la moléculture végétale

(30)

J'aimerais que nous parlions d'un domaine de la biotechnologie dont vous avez peut-être déjà entendu parler, la moléculture végétale.

Le terme « moléculture végétale » décrit un processus de *culture de plantes génétiquement modifiées* pour produire des *molécules* fort en demande sur le marché. La nouveauté de ce processus est la nature des *molécules* produites : il s'agit de composés utiles en médecine et pour l'industrie. Par exemple, dans le domaine médical, des plantes ont été modifiées pour produire des vaccins et des médicaments pour traiter plusieurs maladies comme le diabète, le cancer et la fibrose kystique. Dans le domaine industriel, des plantes ont produit des substances brutes utilisées dans la fabrication de plastiques, de détergents et de produits cosmétiques.

- Il existe un vaste éventail d'applications possibles pour la moléculture végétale. De quelles applications avez-vous déjà entendu parler?

Il existe plusieurs utilisations pour les plantes génétiquement modifiées. En voici des exemples :

- **La modification génétique du tabac pour produire de l'interleukine**, une enzyme utilisée dans le traitement de certaines maladies comme la maladie de Crohn. Les plantes à croissance rapide comme le canola/le tabac sont utilisées dans la production d'interleukine parce qu'elles permettent la production en grande quantité.
- **La modification génétique du maïs pour produire des bioplastiques**, des produits de plastique biodégradable issus de certaines protéines des plantes comme le maïs et le carthame. Cette méthode est utilisée pour produire ces produits de plastique biologique à grande échelle afin d'en faire une alternative efficace aux produits de plastique synthétiques qui sont présentement utilisés.
- **Les vaccins comestibles**, par exemple la modification génétique des pommes de terre pour produire un vaccin contre le virus Norwalk (actuellement en essai clinique chez les humains). Ces vaccins pourraient être utilisés dans les pays en développement, où la réfrigération des vaccins et la stérilisation des aiguilles rendent l'immunisation difficile pour tous ceux qui en ont besoin. Toutefois, il importe de noter que si les vaccins comestibles deviennent d'utilisation courante, la pomme de terre transgénique ne serait pas administrée en entier (la pomme de terre serait d'abord lyophilisée pour contrôler les doses et ensuite, la poudre séchée serait administrée par voie orale).
- **Une enzyme qu'on appelle la lipase gastrique, utilisée dans le traitement de la fibrose kystique**. On retrouve cette enzyme chez le porc, mais elle pourrait être produite à partir du carthame, du maïs ou du tabac. La société qui travaille sur la lipase gastrique produite par du maïs génétiquement modifié estime que cette enzyme sera plus sécuritaire que celle d'origine animale et qu'elle permettra de traiter les 15 % des patients

pour qui il n'existe actuellement aucun traitement efficace). Le traitement actuel consiste en l'ingestion d'extraits pancréatiques de porc.

- ***Une enzyme qu'on appelle trypsine, traditionnellement isolée à partir de sources pancréatiques bovines ou porcines et utilisée en grande quantité comme catalyseur dans la fabrication de détergent et l'industrie du cuir*** (on utilise la trypsine dans la fabrication de produits nettoyants), est maintenant produite à partir de maïs génétiquement modifié. On crée la trypsine végétale en insérant le gène d'origine animale dans la plante ou en le créant synthétiquement en laboratoire pour ensuite l'insérer dans la plante.

Plusieurs types de plantes pourraient être utilisés dans la production de telles applications. Dans ces cas-là, la plante ne ferait aucunement partie de la production alimentaire, elle serait utilisée uniquement pour la moléculture. Avez-vous des préoccupations concernant l'utilisation de certains types de plantes dans ce domaine?

- Le maïs
- Le riz
- Le tabac
- Le carthame

J'aimerais savoir dans quelle mesure vous croyez que la société profiterait de la moléculture végétale. Quels avantages tire-t-on de ces recherches?

Et quels sont les principaux risques associés à ces recherches, selon vous?

(Modérateur) Sondez pour savoir s'il existe des différences attitudinales face aux cultures alimentaires et aux cultures non alimentaires utilisées en moléculture.

Dans les circonstances actuelles, il est peut-être utile de demander aux participants si d'autres domaines leur posent des problèmes :

- *Êtes-vous à l'aise concernant les endroits où l'on pourrait cultiver ces types de plantes?*
- *Existe-t-il d'autres mesures qui vous rendraient plus à l'aise à l'égard de ces applications, par exemple, modifier les plantes pour les empêcher de fleurir?*

À votre avis, de quoi devrait-on surtout tenir compte lorsque l'on pense à mettre ces produits sur le marché?

4. Réglementation des produits génétiquement modifiés (45)

Passons à un autre sujet. J'aimerais maintenant connaître vos perceptions et vos préférences concernant la façon dont le gouvernement devrait réglementer ces produits.

- Croyez-vous qu'il existe des règlements / des processus de sécurité en place pour ce genre d'applications?
- Qu'en est-il des produits génétiquement modifiés/des produits de la biotechnologie en général?
- Selon vous, quels sont les éléments au cœur de ces processus?
- Et à votre connaissance, les processus/règlements du gouvernement du Canada sont-ils assez rigoureux ou pas si rigoureux?

- Quels éléments devraient être au cœur des approbations réglementaires pour ce genre de produits? Quelles autres mesures les gouvernements/organismes de réglementation devraient-ils adopter pour veiller à ce que leurs actions soient bien à l'image des intérêts des Canadiens?

- Qu'en est-il des considérations éthiques? Selon vous, devraient-elles faire partie du processus d'approbation réglementaire pour ce genre de produits? Pourquoi? Pourquoi pas? Si oui, comment devrait-on procéder? Devrait-on procéder application par application? Ou catégorie par catégorie (applications en santé/en alimentation/en agriculture)?

- Qu'en est-il des considérations socio-économiques, par exemple les retombées économiques possibles pour les collectivités canadiennes? Pour les collectivités rurales? Selon vous, devraient-elles faire partie du processus d'approbation réglementaire pour ce genre de produits? Pourquoi? Pourquoi pas?

- Dans quelle mesure aimeriez-vous que le grand public participe aux décisions concernant l'approbation ou le refus pour l'utilisation de ces produits?

Je vais maintenant vous résumer brièvement le système de réglementation qui régit actuellement la moléculture végétale.

L'ACIA réglemente la culture extérieure de plantes issues de la MV depuis 1994. Cette forme d'agriculture sert à la recherche.

Les conditions imposées aux concepteurs visent le confinement des plantes issues de la MV de sorte qu'elles soient coupées de l'environnement et des points de contact avec les denrées alimentaires, de façon à protéger la santé humaine, animale et environnementale.

Les conditions comprennent :

- *La culture est limitée à un hectare = 2,5 acres*
- *La culture doit être isolée par rapport à celle d'autres plantes (la distance varie en fonction du mode de dissémination de la plante, p. ex., le maïs génétiquement modifié doit être planté à 400 mètres des autres espèces de maïs)*
- *L'organe reproducteur de la plante doit être coupé (fleur) avant la formation de graines*
- *Des restrictions encadrent l'utilisation des champs qui ont servi à la moléculture végétale*

- *L'utilisation des récoltes est contrôlée (transport direct à l'usine de transformation sans aucun arrêt, sans points de contact avec les silos à grain)*
- *Les champs destinés à la moléculaire végétale doivent être situés à au moins 50 mètres des pâturages*
- *Un inspecteur de l'ACIA doit être témoin de l'élimination des résidus de la biomasse (plante)*
- *Il existe des restrictions sur l'utilisation du terrain qui a servi à la moléculaire, aucune espèce ne peut y être semée pendant une période d'un à cinq ans, en fonction du type de plante*
- *Le concepteur doit tenir un livre de bord, y inscrire toutes les activités et le présenter à l'inspecteur de l'ACIA*
- *Des inspections-surprises peuvent avoir lieu sur le site*

- Quelles sont vos impressions globales?
- D'après ce que vous avez lu, que pensez-vous du processus d'approbation réglementaire? Êtes-vous rassuré(e) ou inquiet(ète)? Croyez-vous que le processus est rigoureux ou laxiste?
- Quelle confiance avez-vous dans les systèmes d'approbation et de sécurité réglementaire auxquels est assujettie l'agriculture au Canada? Pourquoi dites-vous cela?
- Quelles mesures pourrait-on prendre pour que vous ayez davantage confiance?

(Si on soulève le problème du croisement accidentel des cultures GM avec des cultures non-GM) De qui en avez-vous entendu parler? Est-ce que le croisement accidentel inquiète d'autres personnes ici? Croyez-vous que cette question serait traitée différemment aux États-Unis et au Canada?

Certaines modifications ont été proposées au système de réglementation qui régit la moléculaire végétale. Les modifications proposées visent à rendre ce type de développement végétatif économiquement viable. Je vais vous les lire et nous en discuterons par la suite.

Les organismes de réglementation élaborent des lignes directrices pour la culture extérieure à plus grande échelle de plantes issues de la MV. La production à plus grande échelle permettra aux concepteurs de créer des produits en vue de les commercialiser. Du point de vue de la sécurité, les règlements augmenteraient proportionnellement à l'augmentation de la superficie de la zone cultivée permise.

- *La superficie du lot serait de XYZ*
- *La culture doit être isolée par rapport à celle d'autres plantes (la distance varie en fonction du mode de dissémination de la plante, p. ex., le maïs génétiquement modifié doit être planté à 400 mètres des autres espèces de maïs)*
- *L'organe reproducteur de la plante doit être coupé (fleur) avant la formation de graines*
- *Des restrictions encadrent l'utilisation des champs qui ont servi à la moléculaire végétale*
- *L'utilisation des récoltes est contrôlée (transport direct à l'usine de transformation sans aucun arrêt, sans points de contact avec les silos à grain)*

- *Les champs destinés à la moléculature végétale doivent être situés à au moins 50 mètres des pâturages*
- *Un inspecteur de l'ACIA doit être témoin de l'élimination des résidus de la biomasse (plante)*
- *Il existe des restrictions sur l'utilisation du terrain qui a servi à la moléculature, aucune espèce ne peut y être semée pendant une période d'un à cinq ans, en fonction du type de plante*
- *Le concepteur doit tenir un livre de bord, y inscrire toutes les activités et le présenter à l'inspecteur de l'ACIA*
- *Des inspections-surprises peuvent avoir lieu sur le site*

Les concepteurs sont tenus de soumettre une demande détaillée pour prouver l'improbabilité que leurs plantes présentent des risques environnementaux avant d'avoir le droit de les cultiver à l'extérieur, en dehors des serres. Le processus est considérable et il comprend une visite de l'ACIA sur le site. Une fois l'approbation reçue, les concepteurs doivent prouver qu'ils ont suivi les conditions de l'ACIA, à défaut de quoi ils perdront leur licence. L'ACIA vérifie leurs livres de bord et assiste à l'élimination des résidus de la biomasse.

- Dans l'ensemble, que pensez-vous de cette approche?
- D'après ce que vous avez lu, que pensez-vous de cette idée? Êtes-vous rassuré(e) ou inquiet(ète)? Croyez-vous que le processus est rigoureux ou laxiste?
- Si cette approche était mise en œuvre, quelle confiance auriez-vous dans l'idée de changer l'approche actuelle en matière de systèmes d'approbation et de sécurité réglementaire auxquels est assujettie l'agriculture au Canada? Pourquoi dites-vous cela?
- Quelles mesures pourrait-on prendre pour que vous ayez davantage confiance?

(Posez à ceux qui ont soulevé des inquiétudes/qui rejettent le nouveau scénario) Si vous saviez que l'industrie de la moléculature végétale pourrait simplement déménager aux États-Unis ou dans d'autres pays où la culture extérieure dans des champs est autorisée à plus grande échelle, est-ce que cela aurait un effet sur votre point de vue? Il est possible de cultiver certains produits pharmaceutiques dans des serres, des produits de grande valeur que l'on peut cultiver dans des concentrations satisfaisantes à partir d'un petit nombre de plantes. Cependant, la majorité des produits issus de la moléculature végétale devront probablement être cultivés en plus grand nombre (à plus grande échelle) que ce qui est actuellement permis.

- Quelles sont les sources d'information les plus appropriées pour ce genre de sujet? Y a-t-il des organismes/des groupes que vous trouveriez crédibles s'ils en parlaient?

6. Conclusion

(10)

Avant de clore le groupe de discussion, le modérateur ira dans la salle d'observation pour vérifier si les clients ont d'autres questions ou s'ils souhaitent approfondir certains points.