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FOCUS GROUPS ON PLANT MOLECULAR FARMING:

A Report to AAFC and CFIA

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INTRODUCTION

Plant molecular farming (PMF) is another phase in the on-going research and development of transgenic plants, offering possibilities of producing therapeutic and industrial proteins. At the same time, this innovation raises social, environmental, and regulatory challenges which need to be addressed when considering how these products might be commercialized successfully and responsibly. With this in mind, the Genome Prairie GE3LS group was approached to carry out some initial public consultations on the subject.

Since 2001, the GE3LS group has been carrying out studies on different aspects of commercialization of biotechnology and genomics. A major initiative to investigate various commercialization aspects of PMF's was begun in late 2003 so this project opportunity was viewed as one component of this larger ongoing initiative. The purpose of this larger PMF project was to investigate the policy and regulatory development in this area and to explore stakeholder views and perceptions. This series of focus groups was designed to understand early-stage consumer perceptions and policy preferences which could contribute to on-going policy development as well as provide a base for a larger-scale consumer study the GE3LS PMF project was expecting to carry out in 2004-2005.

The purpose of this focus group research was to examine the perceptions and reactions to PMF among lay Canadians. The discussions were structured around the following categories:

- General awareness of plant molecular farming
- Reaction to the principle of plant molecular farming
- Identification of key issue areas/questions that respondents brought to the discussion
- Awareness and reactions to specific PMF applications
- Reactions by type of plants used in the production process (food vs. non-food)
- Reactions to the various types of products being produced (medical vs. industrial)
- Comfort with various production approaches (open field versus greenhouse or underground)
- Reactions to some of the proposed approaches to regulatory treatment of PMF

METHODOLOGY

Approach

Because this technological application was quite new, a decision was made to modify the traditional focus group approach in two ways: by providing background information to participants so the discussion to be undertaken would be based on some understanding of the basics of PMF; and by providing more time for deliberation. The discussions were conducted by a research company in Vancouver, Toronto, Halifax, and Montreal between April 12-21, 2004[1].

Participants

In each city, one discussion group took place, involving between 12-15 respondents. A total of 48 respondents participated, chosen at random from their respective communities. The participants in each of the four cities were recruited randomly from the general populace, broadly representative of the population by age, gender, and education level.

The 48 participants included the following subgroups:

- 23 Females, 25 Males
- 14 aged Under 35, 20 aged 35-54, 14 aged 55+
- 13 HS or less, 17 College or some university, 18 University graduates
- 7 Visible Minorities

Briefing Document

Each respondent was sent a discussion paper (see Appendix A) in advance of the meeting, a 10 page document produced by GE3LS that provides a brief overview of the topic, an explanation of the technology, some typical applications, a regulatory overview, and a discussion of the benefits and risks involved with the technology. The briefing document was drafted as an introduction to the topic for a layperson who had never come across the technology before. The document was given to a PMF expert with extensive experience in the field to ensure scientific and factual validity. The briefing document was then tested on volunteers from various education levels (from less than high school education to university graduates) to ensure clarity and understanding as well as balance.

The finished product was a detailed overview of the technology in a question-and-answer format (What are PMF's?, Why use plants? etc.). The objective of this discussion paper was to provide background information on the topic of PMF's to encourage a more informed discussion of the issues raised by the technology. All facets of the PMF technology were included in the briefing document, both positive and negative.

Procedure

During the recruitment process, volunteer participants were invited to read the discussion paper and to bring with them to the focus groups three key issue areas or questions they have about

[1] The research was conducted by Earnscliffe Research and Communications. This report is an expanded and updated version of one produced by Earnscliffe.

PMF, and which they feel need to be addressed before decisions can be made about applications and research in this area. Each of the discussion groups was about 2.5 hours long.

The facilitator first explored levels of awareness among the participants prior to their having read the briefing document. This was followed by a discussion of issues participants considered important. A series of PMF applications were then discussed in turn, focusing on different products (industrial and pharmaceutical) and different host crops (food and non-food). Responses to different containment strategies were also explored. This was followed by a brief discussion on perceptions of regulatory capacities.

The discussion ended by providing participants with a sheet of paper which included the list of applications discussed and a rating scale labeled as an "acceptability spectrum". This was adopted from the ***Genetically Modified Food and Feed Dialogue Tool*** developed by the Canadian Biotechnology Advisory Committee as a framework for assessing GM foods.[2] The scale was on a continuum that ranged from "fully acceptable" to "acceptable with conditions", "unacceptable unless conditions were met" to "totally unacceptable". On the one-page rating sheets, participants were also asked to provide brief explanations for their ratings.

[2] See the CBAC web site for more information on the GMFF Dialogue Tool: http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/en/h_ah00350e.html

Awareness and Initial Reactions

As a subject, plant molecular farming has not yet entered into the domain of public awareness. Before reading the discussion paper, only one or two of the 48 participants had heard of plant molecular farming, either the concept or the practices or applications involved. Few were surprised that these types of technologies were being investigated by scientists, but specific awareness was almost nonexistent. In contrast, respondents revealed a high level of awareness of the subject of genetically modified foods, and about biotechnology applications generally. Most people viewed the field as a cousin of gm foods, falling under the broader umbrella of biotechnology.

First impressions of the technology 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. 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. People made references to other areas of biotechnology health applications like stem cell research to suggest that this could also be a very promising area, but were similarly fraught with potentially complex problems associated with risks.

Its closest "cousin" in the biotechnology sphere is GM food. Most initially see this area as very similar to GM food, which carried with it a level of initial trepidation that is not as evident when people initially talk about other applications in health or the environment.

ISSUE AREAS/ QUESTIONS

The first exercise of the discussion involved inviting group participants to voice the issue areas/questions that they felt needed to be taken into consideration regarding PMF and its potential introduction in Canada. Each participant was given a few minutes to discuss the issue areas that they felt were important, and these were listed by the moderator and discussed by the group as a whole.

Respondents tabled a wide range of issues/questions that they felt needed to be taken into consideration by decision makers, many of which revolved around 3-4 themes or topics. Some of these topics overlap, and are seen as cause or consequence of others, but for sake of clarity they are separated in this report. They are:

2. **The potential for cross-pollination and contamination of food crops.** 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. Many felt that contamination could happen relatively easily, certainly from food to food crops, but even from greenhouse environments to field environments, and from non food to food crops. Women tended to harbour the deepest concerns about this set of issues. These concerns were fuelled by several underlying drivers.

    - 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. Many made direct reference to the Schmeiser case as evidence of this possibility.

    - Some, particularly those who were relatively less sophisticated, had a lot of difficulty with the idea that the PMF versions of plants and crop or other agricultural versions of plants would be separated entirely from each other.

    - A secondary concern regarding contamination focused on humans, the idea that humans might contaminate food crops either by error (through accidentally taking plant material from a greenhouse and it dropping into a field) or malicious intent (someone seeking to benefit by stealing the technology to try and use it for their own gain and then the technology running wild). A related concern regarded the potential for bioterrorism, that people who learn how these technologies work could modify a plant to produce a toxic substance and then introduce that plant to food crops.

    - Some were also concerned about the safe disposal of waste material, and whether disposal systems would be able to entirely eliminate any chance of modified plants entering the ecosystem. There were broadly held fears in a number of groups about modified material making its way into soil and eventually contaminating other crops.

    All of the above views were fuelled by concerns about the idea of some of these technologies "running wild" and taking over food crops. This is a concept that many can

grasp, as people have seen more and more evidence of this type of event occurring with foreign species (zebra mussels, asian ladybugs). Few had a clear sense of how this contamination might occur, and were not able to discriminate between different types of contamination risks, so they tended to assign a similar risk "value" to a range of potential contamination risks (from bugs or microbes passing the PMF version of a product to food crops, to having these wind-blown, or contaminating the soil).

3. **Issues of safety, regulations and policing.** 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. There were a number of secondary drivers associated with this set of issues:

   - The ability of regulators to police these technologies. There was a fairly widespread perception that there weren't enough resources to appropriately "police" the research to ensure that all safety measures were being followed to the letter. Moreover, there were concerns voiced about "who" the people responsible to police these technologies would be, specifically whether those people had the appropriate level of scientific experience to be able to accurately measure the risks involved.

   - The scope of the existing rules and regulations. Given that this is a new field of endeavour, some were of the view that there might not be appropriate guidelines and standards in place, and an enhancement of such standards might be appropriate. Of note, in some groups, there was a strong belief that there were likely plenty of rules and regulations in place, but that resource limitations for government scientists/enforcement officers made it impossible to appropriately police those doing the research.

   Overall the concern about adequate policing capacity tended to be greater than the concern about insufficient standards/regulations.

   For most, achieving zero risk was not necessary, but minimizing risk to its absolute minimum was the most important.

4. **The potential long term side-effects, specifically impacts on human health or the environment.** Although not as widely mentioned by respondents, this was actually the most important factor/issue raised, because this issue of long term risk was ultimately the concern that flowed from questions about contamination and safety measures. These considerations were of significant concern, particularly among those that tended to voice the strongest trepidation about the technology at the outset of the discussion. People suggested that these technologies might reveal impacts that won't be able to be detected for years, even decades, after they are introduced. Two major points of discussion associated with this topic were:

   - 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.

- That appropriate and stringent safety/regulatory measures weren't in place to monitor or provide surveillance about these technologies over time.

5. **The interests of those growing/farming/researching these applications not being consonant with the "public interest".** There were many questions raised about the role of the profit motive in developing these applications, and the potential of the profit motive to ultimately supercede the public interest in terms of safety. For example, participants did not feel that it would be necessarily in the best interest of growers/farmers – "who would only look out for their own wallet" - to follow the rules that governments set out stringently, and they didn't believe that there would be enough enforcement staff to ensure that the rules were followed. Similarly, people do not assign very much credibility to preservation of the public interest to the companies that might be involved in developing these technologies – a few cited Monsanto as an example of a corporation that works in a related area that works "against the public interest".

   - This, coupled with concerns about the efficacy of enforcement mechanisms discussed above, fostered very deep concern among some participants about whether it was worthwhile to go ahead with the technology.

   - A related point on this question had to do with whether this technology was really necessary to take the risks to pursue. Some asked whether there might be safer (but less profitable for "big companies") ways of achieving the same goals, such as using natural products like those found in health food stores to achieve the same goals or using conventional technologies already in use.

6. **The purpose of the application.** Related to the point about the profit motive in developing these types of applications was a core question that people asked in every case -- what the purpose of the application is. The issue of whether an application had a worthwhile purpose or not had a substantial influence on peoples' perceptions about whether it would be worthwhile to go forward with it.

   - Many suggested that if an application had a "useful" or important purpose, that it would be more worthwhile to allow. Useful purposes generally involved significant health or environmental benefits, such as providing new treatments or remedies for health or environmental problems. Less useful purposes involved producing existing products at lower prices.

Ultimately, this "purpose" test was really a surrogate for assessing the "benefits" of an application, which proved to be the most important arbiter of how respondents viewed the specific applications that were discussed in the group. Indeed, in several cases, this test "trumped" the various other risk considerations that were tabled in the discussion.

Overall, the issues/questions that were raised revolved primarily around perceptions of risk, and whether the risks associated with these technologies are seen as worth taking in order to achieve the benefits. When asked directly whether these technologies raised moral/ethical concerns, a handful suggested that there were moral/ethical dimensions to these issues that would be a significant consideration. For example, one or two suggested that access to these technologies by developing countries was a moral issue. Some noted that if the discussion were about molecular farming with animals, they might have a different view, but as long as the discussion was about plants, moral and ethical issues did not come into play.

APPLICATIONS

The participants read about a number of potential applications of PMF in the discussion paper. As part of the discussion, five potential applications were explained and the participants were invited to indicate whether they generally supported or opposed it, what they saw as potential risks and benefits, and why.

This discussion acted as a catalyst for deconstructing the core drivers of acceptability, because it enabled respondents to have a discussion about specific applications (which have real-world implications) rather than about the topic in general (which tended to be more of a theoretical discussion).

The five different applications were chosen strategically to incorporate a number of different combinations of both medical/industrial use and food/non-food use. The varying permutations were used to help cross-reference various issues and triangulate responses to individual elements. One of each medical and industrial product was combined with both a food crop and a non-food crop. This reads out as:

1. Medical product in a Food crop
2. Medical product in a Non-Food crop
3. Industrial product in a Food crop
4. Industrial product in a Non-Food crop

After discussing the applications, participants rated these applications on a four point "acceptability spectrum":

Fully acceptable ***More acceptable*** ***Less acceptable*** ***Unacceptable***

In addition, respondents were asked to comment on each in written form. Finally, the participants were asked to rate each one on the Acceptability Spectrum and comment on their overall impressions of PMF's. Major findings:

1. **Overall, people tended toward the middle two points on the spectrum, either "more acceptable" or "less acceptable" than at the poles of outright acceptability or unacceptability.** Men and those with higher levels of education tended to be more likely to situate themselves on the "acceptable" side of the ledge, while women and those with lower levels of education tended to situate themselves on the "unacceptable" side.

2. **The groups revealed that most people indeed hold a mix of views on these applications, and tend to lean toward acceptability or unacceptability on a case-by-case basis, depending on the application, and the benefits and risks involved.** As a result, not all applications get the same level of acceptability – indeed there is some fairly wide variation in acceptability across PMF applications.

Our overall assessment is that people tend to engage in a risk-benefit analysis about each application, assigning weight to a number of factors associated with both benefits and risks. Indeed, the analysis can be broken down into something of a mathematical equation, which has a benefits side and a risk side to the ledger, with weights assigned to variables within each category.

Table 1: Acceptability of PMF Applications

Application	Fully Acceptable	More Acceptable	Less Acceptable	Unacceptable
Interleukin in tobacco	8	25	13	2
Edible vaccines (Norwalk in potatoes)	10	25	11	2
Gastric lipase in corn for cystic fibrosis	6	26	15	1
Trypsin grown in corn for industrial uses	1	14	21	11
Bioplastics grown from corn	6	21	14	6
Overall Impression of PMF	3	29	10	6

3. **In virtually every case, acceptability is predicated on the idea that there are stringent approval processes and long-term measures in place to ensure safety.** This is essentially a quid pro quo for willingness to go forth with any PMF application.

4. **The perceived level of risk was the first factor that people employed when considering acceptability.** Risk of contamination, and risk of impacts on humans/the environment/wildlife were the major elements that were considered. The groups suggested that people tend to assign a similar level of risk to all PMF applications, with minor variations.

    - If the PMF application is grown in a food crop, it is likely to be assigned a higher level of risk than if grown in a non-food crop

    - If the PMF application is grown in an outdoor context, it is likely to be assigned a higher level of risk than if it is grown in an indoor context

    - If the PMF application retains properties of being able to seed/flower, it is likely to be

assigned a higher level of risk than if it is not able to seed/flower

The purpose (or benefit) of the application was actually the most important factor in determining whether it was acceptable or not. The reason is that people tended to assign widely differing values to the benefit factor, depending on the application involved. In some cases a very high value was assigned to it, in others a very low value was assigned to it.

- If the purpose was seen to provide a significant potential benefit to human health or the environment, ***greater than existing products or applications***, people tended to be more supportive of it, assigning a higher value to the application

- If the application were going to provide economic benefits (ie lower cost) but ***not*** significant new benefits to human health (ie not a new treatment, but a better way of producing an existing treatment) the weight that people assigned to the purpose variable would be lower. If the benefits were entirely economic (ie lower cost industrial products) the benefit value people assigned to it was quite low.

In other words, the risk side of the equation tends to be relatively constant (and relatively high) for all applications, whereas the benefit side tends to vary significantly. In cases where the benefits are seen to be substantial, they can overcome concerns about risk, but if the benefits are minimal or even somewhat beneficial, the risks will tend to outweigh them.

Application 1: Interleukin in Tobacco

The genetic modification of tobacco plants to produce interleukin, an enzyme used in treatments for diseases such as Crohn's disease. *Fast-growth plants are used to grow interleukin because that allows interleukin to be produced in high volumes.*

As the data suggests, this application created something of a divide among respondents.

At first blush, several respondents suggested that this was an interesting and potentially beneficial application, especially if interleukin were a relatively scarce enzyme and this might enable more people to have access to treatment. But not all were convinced that this was necessarily the case, so they were not certain of what the "marginal benefit" that the application would provide to people.

In addition, some indicated that the idea of using tobacco for a socially useful purpose would be a great idea, not only to reduce production of tobacco but also to potentially move tobacco farmers away from their dependence on tobacco farming

The idea of using tobacco as the medium to produce interleukin (instead of corn) also gave some people greater comfort about reducing potential food crop contamination risks.

Others were less certain about it, for a number of reasons, primarily revolving around risks. There were a sizeable number of respondents that suggested that cross-contamination into the

food supply was possible – indeed in some groups people felt that it was equally likely that contamination could occur between tobacco and food crops as it might be between two like food products (such as corn).

In addition, from an emotional standpoint it was a strange idea to some that tobacco, a product that has such a socially undesirable purpose could be utilized in this way.

Several respondents wondered whether smokers would bear the greatest potential risks, and wondered whether that was a socially acceptable situation

Overall, because the purpose of the application was perceived to revolve around cost savings rather than other more compelling health benefits, there was a rough split between the "more acceptable" and "less acceptable" sides of the spectrum.

Application 2: Bioplastics in Corn

The genetic modification of corn plants to produce bioplastics, which are biodegradable plastic products that come from certain proteins in those plants. *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.*

This application also generated a fairly clear split in opinion. Most people found the principle behind this application to be compelling and appealing, primarily because the idea that synthetic plastics could be reduced or eliminated was seen to be an important step in reducing waste and pressure on landfill sites.

But there were clearly and widely articulated concerns about the contamination risks of growing these PMF crops in corn plants. The risks of contamination were seen to be of significant concern, as people wondered what might the impact on health or the environment be if this type of application made its way into the food system.

Ultimately the environmental goals were not universally lauded, as several people in each group suggested that taking a measure like this is like a band aid - that encouraging people to reduce waste was a more appropriate step and that this kind of an approach missed the core point. As a result, for many, the benefits side of the equation was not compelling enough to overcome concerns about the risks.

Application 3: Edible Vaccines

Edible vaccines, such as genetic modification of potatoes to produce a vaccine against the Norwalk virus. *These types of vaccines 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 was explained that a dried version of the potato would be administered, rather than a whole potato, to control for dose amounts and for ease of distribution and administration.*

This was the most widely acceptable of the applications tested, for a number of important reasons on both the benefit and risk side of the ledger.

First, most saw it as an effective way to administer a vaccine, and people imagined that there would be demonstrable benefits to being able to deliver vaccines in this type of form to developing countries in particular. In that sense, the application was seen as providing a "new" benefit to health treatment, over and above cost savings. However, cost savings was seen to be of particular benefit in this case, because the importance of low cost is perceived to be crucial to the ability to distribute treatments in developing countries. People could imagine that this kind of vaccine could be produced cheaply, and probably distributed cheaply within developing countries.

The other compelling element of this application was that it would or could be utilized as a preventative measure as well as a treatment.

The risks of contamination were viewed to be significant on this application, but they tended not to weigh as heavily in assessments of the application, for a couple of reasons. First, because the worst that could happen is that more people would get a vaccine, which was not seen to be as severe as risks associated with some of the other applications. Second, the idea of turning the product into a powder form was seen as posing less risk of contamination than utilizing the product in its natural form. So in spite of the fact that this application involved a food crop, respondents appeared to weigh the risks from this application as slightly less severe.

Application 4: Trypsin in Corn

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, 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. It would be able to simplify the production of many products in these in sectors, and likely reduce costs of production.*

People did not see how they or society would benefit from this application, Rather, they tended to view the benefits as accruing mainly to companies, in the form of higher profits – this was not seen as a positive.

One or two respondents suggested that by introducing lower cost inputs that consumers would benefit by lower prices.

However, this argument did not resonate. Many others did not believe that money would be saved (because of all the safety measures that would be required to use the PMF version of trypsin) and even if they did, they were very skeptical that consumers would actually benefit, and that whatever cost savings might be achieved would not be worth taking the risks.

A number of people suggested that going forth with an application like this was also less desirable since it was an existing product which should not have a priority over developing

something new that cannot be made with conventional methods.

The risks of this application were seen as being similar to other applications, the idea of contamination being the most important risk.

Overall, there were few reasons that were seen to warrant engaging in research for this type of PMF technology.

Application 5: Gastric Lipase in corn

The development of *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 corn.* *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*

This application generated mixed views. The drivers of acceptability tended to revolve around a couple of factors. First among these was the potential of that this application to treat the 15% of patients that do not have effective treatment options – the principle of the application being "new" was compelling to many people. The secondary driver of acceptability was the idea that this treatment will be safer for patients – people need to have more proof that it is truly safer, but if so, then this would contribute to acceptability.
The drivers of unacceptability again revolved around the idea of contamination of food crops, and concerns that the benefits will primarily be about cost savings, which consumers are unlikely to gain by.

GOVERNANCE AND THE REGULATORY REGIME

Perceptions and priorities in terms of governance were remarkably consistent across the groups. A regulatory overview was provided in the briefing document giving participants a good grasp on the regime in Canada.

Most did not possess a very high level of confidence in regulators to ensure that these applications and methods are safe before they are introduced. Some drew upon experience or perceptions of regulatory stringency in other areas, and in general those experiences or perceptions lend to perceived credibility of regulatory systems on these issues.

To a person, most felt that government regulators would have to add resources and qualified staff in order to manage the technology.

One of the specific issues that was tested in the groups is the issue of comfort with different settings where PMF products could be grown.

- There was almost complete unanimity that using open fields with buffer zones around it was not seen as acceptable at all. The reason why was they felt that contamination could easily occur – in fact many people mocked the "400 meter" buffer distance as being far too little to provide comfort. People felt that the product could easily contaminate other crops by birds or insects taking pollen and leaving it on other crops, or through the soil.

- Above-ground greenhouses gave many more people comfort, although there were a sizeable number (about one third) that remained just as uncomfortable about this method as they did about open fields.

- Underground sealed facilities or bio-domes in places where the utilized crop was not naturally grown were seen as acceptable to almost all respondents.

However, some asked the question about whether the PMF plants could be modified to become sterile or in other words, not flower, and that led to a discussion of whether people would have a different view of the acceptable growth environment under those circumstances. While about half of respondents overall remained uncomfortable about PMF in fields, the other half were much more comfortable with this method if the plant were modified not to flower. More importantly, there was almost universal consensus that growing in greenhouses would be acceptable if this additional measure of eliminating the ability of the PMF plant to reproduce were initiated.

FAULT LINES AND CONSENSUS POSITIONS

Throughout many of the discussions, respondents consistently sought to find ways to find consensus about PMF and how to deal with it, what are the broadest areas of acceptable and unacceptable elements, in terms of applications, types of crops, types of growth settings, and regulatory measures.

To crystallize those discussions around building consensus, participants were asked a series of "forced choices" on a series of core issues associated with PMF that were raised over the course of the discussion, to determine under what circumstances there would be more or less acceptability of these applications. These fault lines or consensus points boil down to five main dimensions:

- **Food versus non-food crops.** In general, the level of risk assigned to growing PMF applications was believed by a majority of participants to be higher in the case of food crops (like corn) than non-food crops (like cotton). However, some participants suggested that the risks with non-food crops could also be similar, owing in part to an expectation that insects or birds could still fly everywhere and take pollen with them into food crop areas. Having said that, edible vaccines appeared to be an exception. That is, this was seen to be acceptable likely because of the perceived benefit to developing countries.

- **Flowering versus non-flowering plants.** Flowing from the discussion of risks associated with food and non-food crops, people in a number of the groups raised the prospect of developing non-flowering versions of the plants that would be used for PMF. In many ways, the idea of producing non-flowering plants as PMF designated plants was very appealing – indeed, there was a broader consensus that the risks of non-flowering plants was much lower than the risks of growing only in non-food crops.

- **Health and Environmental Applications versus Industrial Applications.** Health/Medical applications were consistently seen as being more acceptable than industrial applications. The articulated view is that the purpose of health and environmental applications is deemed more beneficial to society, and therefore more worthwhile to pursue. While this may seem to be an untenable position from a scientific point of view, this was arguably one of the most important areas of consensus about PMF – if industrial applications were being judged and if the benefit was primarily to industry, the level of acceptability would be significantly lower.

- **Producing new applications that serve a demonstrably new purpose, versus applications that improve or reduce cost of existing processes.** People assigned a much higher value to applications that were seen as providing a benefit above and beyond that provided by existing products or treatments that were going to be created in a less costly or more efficient way. In some significant part the reason for this is that they will not reap any benefits from the cost savings, and they aren't even really

sure that with all of the expected measures taken, that the companies that develop the products will actually save money – so the rationale for taking the risk is tenuous.

- **Enclosed versus outdoor growth settings.** People tended to believe that growing these products in enclosed settings like a greenhouse would reduce the risks to a point where most applications would be acceptable (again assuming appropriate regulatory provisions were in place).

Ultimately, the consensus position was that it was acceptable to go forward with health or environmental applications of PMF, with the following provisos:

- Greenhouse only until thorough testing complete
- Non-flowering versions of plants
- Strong preference for non-food over food crops, with the exception of edible vaccines
- More resources, independence assigned to regulators
- Assurance that surveillance for long term impacts is being done

CONCLUSION

This exercise yielded a number of important findings. Not only were people able to weigh in thoughtfully on Plant Molecular Farming; it suggests that Canadians were able to weigh in constructively on an issue that is relatively scientific in nature, and relatively unknown to them.

Initial awareness of the technology was very low, but the use of the PMF briefing document generated an educated group of citizens that were able to debate this complex topic. They brought with them to the focus group a list of three concerns they had after reading the briefing document and were able to crystallize their opinions through a discussion with other participants in the various groups. They were able to identify the key issues that Canadian citizens in general have with PMF technology and suggest solutions to those issues. Deliberations were held on the use of food and non-food crops, the use of open field, greenhouses or under ground production for containment, the preference of medical applications over industrial, and the potential issues associated with Canada's regulatory regime now and in the future.

The key concern most often identified by participants was the potential for contamination of food crops (whether the product was grown in a food or a non-food crop). Other concerns included issues of safety, regulation and adequate policing, and the possible long-term side human health and environmental side effects. Distinctions in risk determinations were made in the following areas:

- PMF products grown in food crops were seen as riskier than non-food crops
- PMF products grown in the outdoors were perceived as riskier than those grown indoors
- If the plant host is able to go to seed/flower, it is seen as riskier

These concerns weighed heavily in evaluating the various PMF applications. However, it was the nature of the perceived benefits that ultimately determined the level of acceptability of each application, i.e. were the benefits considerable enough to warrant taking a substantial risk? The "purpose" of the product being made via PMF was a major factor in answering this question. Medical applications were preferred over industrial applications, and within the industrial realm, producing environmentally friendly products was preferred over the ability to produce products at a lower cost.

While people spent a lot of time talking about issues and questions associated with risks, the preponderance of opinion at the end of the discussions suggest that Canada should "proceed with caution" on PMF, while "erring on the side of caution" along the way. What that means in practice is mandating that only certain types of plants should be used, and certain types of growing contexts utilized, as well as ensuring that the science on safety is sound, that approval systems and policing are stringent, and that more resources are dedicated to this purpose.

Most people feel that this type of technology has the potential to offer some important and useful benefits to Canadians, and as such can be pursued, but with extreme care, as long as those provisions outlined above are put in place.

APPENDIX A: PMF BRIEFING DOCUMENT

What is Plant Molecular Farming (PMF)?

The term "plant molecular farming" describes a process of *farming plant crops* 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.

What kinds of plants are being used in PMF?

Corn and tobacco have been used for most experiments in PMF, but many other crops have also been successful, such as safflower, rice, alfalfa and canola. It is important to note that the plants used in PMF are grown solely to isolate the compound of medical or industrial interest. After the compound is isolated, the remaining plant material is disposed of and is not used for any other purpose.

Newer research is adopting lesser-known, lesser-used plants (non-commodity crops) such as alfalfa, safflower, duckweed, and algae, and these will most likely make up the second phase of products.

How are PMF products made?

PMF crops are made up of plants genetically engineered by the same method used to genetically modify food crops (the technique is called ***recombinant DNA***[3] technology). See Figure 1 for an explanation of recombinant DNA.

[3] Expressions that are bold and italicized can be found in the glossary at the end of the document

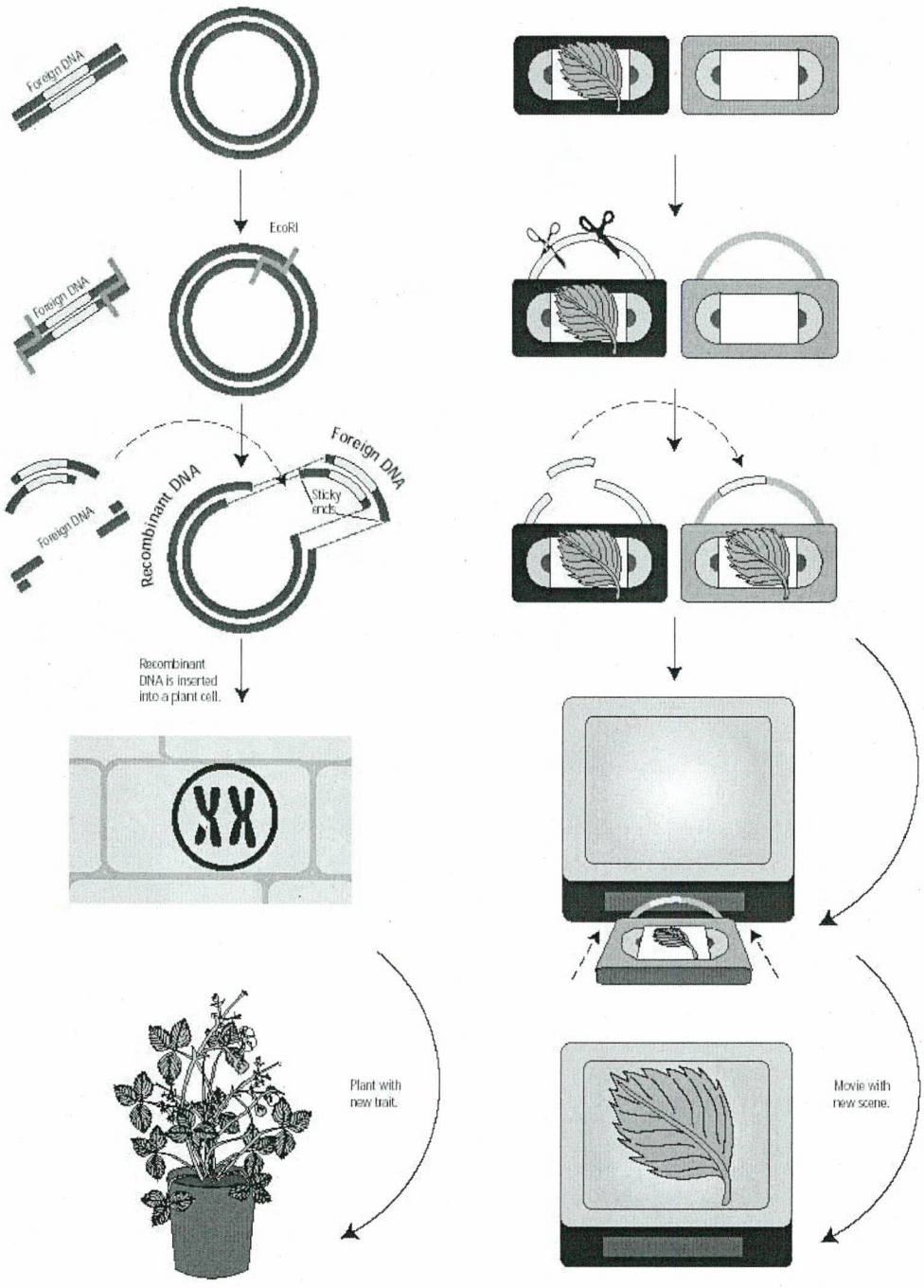


Figure 1: Recombinant DNA is analogous to videotape editing. DNA sequence information encodes genes that determine the characteristics of an organism just as videotape contains the information that can be used by a VCR to display a movie on the screen. Recombinant DNA methods allow a segment of DNA to be transferred from one organism to another, thereby transferring the trait that the gene encodes. Similarly, a section of videotape containing a specific scene can be cut and spliced into a second tape, which will then display the transferred scene.

EXAMPLE: PRODUCING INSULIN IN CORN

For an illustration of PMF, take the case of producing insulin to treat diabetes (see Figure 2). Scientists will locate and then isolate the specific gene that creates insulin (alternatively, they also have techniques to chemically synthesize this gene). This piece of DNA, or ***transgene,*** is then inserted into a plant host such as corn. The resulting corn crop would then produce the insulin as if it were one of its own naturally occurring genes. The corn plant may be modified to have the insulin accumulate in the seeds or leaves or corn kernels. Once the crop has matured, it would be harvested and the insulin extracted, refined and used in pharmaceutical production. In this process, plants themselves become "factories" for producing insulin.

PMF crops are not grown in the same way as crops intended for the food system, but instead are grown under highly regulated conditions in confined growing environments and are strictly regulated by the Canadian Food Inspection Agency (CFIA) and Health Canada. After the plants are harvested, they go through a series of processing steps that extract, separate, purify and package the active protein for industrial or medical use.

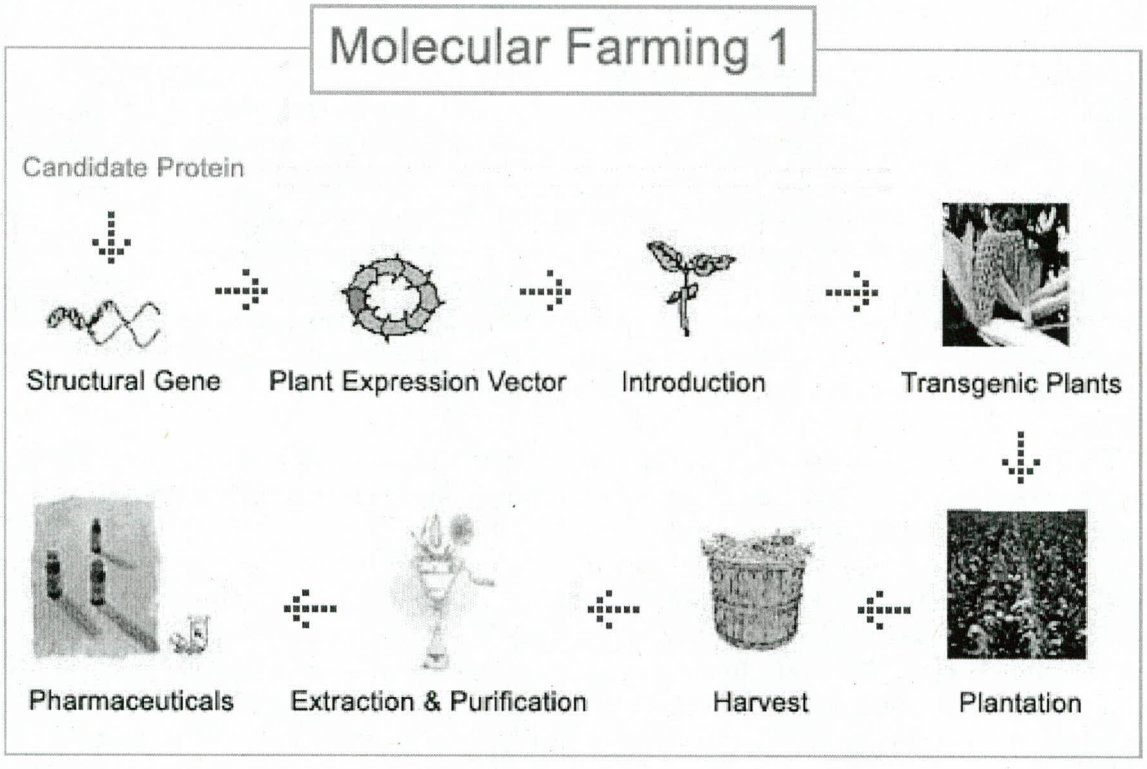
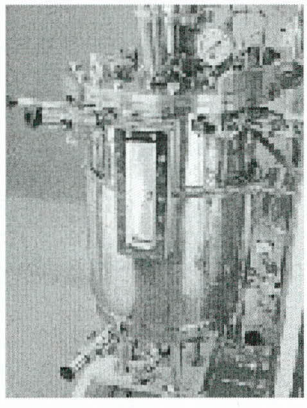


Figure 2: A hypothetical case of producing insulin in corn

What other ways might these products be produced?



A typical bioreactor

Prior to the development of recombinant DNA technology in the 1970s, protein products were available in extremely limited supplies; for example, human cadavers were the source for human growth hormone, and insulin to treat diabetes was collected from slaughtered pigs. Chymosin, a protein used in cheese production, was originally extracted from calf stomachs, but is now being produced in genetically engineered microorganisms. In fact, since 1990 over 90% of the cheeses produced in North America have been produced using chymosin from microorganisms.

Currently, a great number of drugs and industrial products are grown using genetically modified microorganisms such as bacteria and yeast. Also commonly used are ovary cells from Chinese hamsters. These cells are grown in fermentation chambers known as bioreactors. Bioreactors are used because they are able to maintain specific environmental growing conditions (i.e. specific temperatures, humidity levels and pressure). An example of a bioreactor is shown in Figure Two.

Why plants?

If bacteria and yeast bioreactors have been successful in creating medical and industrial products, why would companies consider using plants? Advocates of PMF cite the following advantages:

LOWER COST: Bioreactors are expensive and can take 5-7 years to build and get running. Plant crops need neither that length of ramp-up time nor the same level of investment in infrastructure. Companies producing PMF crops predict drug prices could be 10 to 100 times lower by using plants rather than bacteria or yeast. Lower production costs also mean that proteins that could not be produced cheaply enough at high volume through conventional methods might become economically viable using genetically engineered crops.

EASY TO SCALE UP: Because PMF growth is not limited by construction of expensive, limited capacity bioreactors, it would be easier to scale up production to meet increased and varied demand for products.

INEXPENSIVE, EASILY DELIVERED VACCINES: Food plants engineered to contain pieces of inactive disease agents can function as orally administered vaccines, avoiding the need for injection and syringes. Currently, tomatoes and other vegetables are under development for that purpose. The vegetables would most likely be freeze-dried with a known concentration of active ingredient in order to produce a standardized dose. The developers hope that the lower production costs and the convenience of avoiding refrigeration and sterilized needles would make the products attractive to the developing world.

Why use plants that also can be used for food crops?

Farmers have extensive agricultural knowledge of and familiarity with breeding and growing food and feed crops. As well, scientists have a broad understanding of the genetic modification

of plants, agronomics and the environmental impact the plants may have. This base of information allows PMF researchers to more easily modify plants to produce a desired protein as well as control weeds and grow the crop on a large scale.

However, current research is also focussing on lesser-known, lesser-used crops such as safflower and duckweed as an alternative to food crops. As well, tobacco has been used in many PMF experiments.

What kinds of diseases will be treated through PMF?

Therapeutic protein drugs may be produced by PMF for diseases such as cancer, HIV, heart disease, chronic obstructive pulmonary disease (COPD), diabetes, Alzheimer's disease, kidney disease, Crohn's disease, cystic fibrosis, multiple sclerosis, spinal cord injuries, Hepatitis C, obesity, rheumatoid arthritis, iron deficiency and many others. In the U.S., some PMF crop products have reached human clinical trials (see Table 2).

Table 2: Drugs in human clinical trials

Company	Host	Product/Indication
Meristem	Corn	Gastric lipase for Cystic fibrosis Expected market launch 2004-2005.
Monsanto*	Corn	Avicidin, IgG for colorectal cancer
Planet Biotechnology	Tobacco	1) IgGs for the prevention of tooth decay 2) Prevention of common cold
LSBC	Tobacco	Cancer vaccine for non-Hodgkin's lymphoma
Meristem	Corn	Lactoferrin for prevention of infection
Prodigene	Corn	Lt-B vaccine (Traveler's disease)
Arizona State University	Potatoes (Tomatoes)	Edible vaccines (E. Coli, Norwalk Virus and Hepatitis B)

What kind of industrial products will be produced by PMF?

Industrial chemicals, compounds used in the manufacture of products like paper, plastics, personal care items, and laundry detergents, can be produced using PMF. The first commercialized industrial crop incorporated a gene from the California bay tree into canola in order to produce more lauric acid, a key raw material in the manufacture of soap, detergents, and cosmetic products. Conventional canola does not contain lauric acid. Other examples of industrial products from PMF include:

Trypsin: An enzyme traditionally isolated from bovine sources and used in large volumes in the detergent and leather industries. It is being produced in transgenic corn.

Laccase: Another enzyme used in making detergents but also in the manufacture of fiberboard, is being produced in transgenic corn.

What are the potential risks of PMF?

HUMAN AND ANIMAL HEALTH RISK: Pharmaceutical and industrial proteins produced in

plants (or by conventional methods such as using bioreactors), can cause adverse side effects when humans or animals are exposed to them. However, the magnitude of the risk posed by a PMF crop is dependent on the type of compound being produced. Some industrial and medical proteins may be very harmful at very low exposure while others may be relatively benign even at high exposure (this would be true regardless of whether they were produced in plants or by other methods). Some PMF compounds have been created so that they do not become "active" until after they have been extracted from the plant host. In other words, the compound needs to be removed from the plant and chemically treated before it becomes active, thus reducing the risk of accidental human or animal exposure. Other PMF compounds will be active when still in the plant tissue.

CONTAMINATION OF FOOD SUPPLY: Since PMF plants may also be crops that are used to provide food for people and feed for livestock, a major concern is the contamination of the food and feed supplies. PMF plants have two major routes into the food and feed system:
Seed mixing: Physical mixing of seeds can occur during seed production, on the farm as a result of using the same machinery to plant or harvest both food crops and PMF crops, during seed storage or transport, or at the grain elevator or mill. Canadian regulations require producers not to use the same machinery at the same time for both food crops and PMF crops (there is more on regulation later in this document).
Pollen flow: Pollen flow is a more indirect way of introducing new genes into non-PMF crops. Wind-borne pollen from corn, currently the most popular PMF crop, can travel more than 50 metres, making possible fertilization of nearby corn, intended for food, by PMF plants. As a result, farmers who did not plant PMF corn could wind up with food and feed crops contaminated with medical or industrial products. To reduce this risk, the Canadian Food Inspection Agency requires a minimum isolation distance from other corn plants (in 2003 this distance was 400 metres).

CROP CONFINEMENT: With open-air crops, there are ways that a PMF product could potentially escape:
Grazing wildlife: Even if all the pollen, as well as the seeds and other plant material, associated with every PMF crop remained within the fields in which they were planted, wildlife could still be exposed. As anyone who has attempted to keep deer out of a vegetable garden or birds from fruit trees can attest, animal consumption of field crops is essentially unavoidable.
Insects and microbes: Pollinators and herbivorous insects will frequent PMF crop fields as well. Microbes and other animals present in the soils of PMF crop fields will also be exposed to the compounds produced in these plants.
Weedy relatives: Although corn and soybeans do not have wild and weedy relatives in the Canada, canola and other important plants do. Its pollen flow could create a wild mustard weed capable of producing a PMF compound, and such a weed would need less human intervention, as compared to a crop plant, to perpetuate itself. For this reason, canola is no longer being considered for PMF.

Strategies to deal with this risk: To reduce this risk, some PMF producers are choosing to grow their crops contained in greenhouses. Greenhouses may have different levels of ***containment*** and ***confinement***, from a construction that prevents rodents and small animals from

entering to ensuring fine screening that will not allow pollen or insects to gain access, to building a structure that forces people to pass through an air lock upon entering. For an even higher level of containment, experiments are being done in underground mines to ensure complete physical isolation.

Is there PMF going on now in Canada?

There has been no commercial plant molecular farming in Canada to date. However, a number of organizations have been conducting research on molecular farming in laboratories and greenhouses as well as in a limited number of approved confined field research trials since 1994. It is estimated that in 2002, PMF used 1.25 acres of land and 0.6 acres in 2003.

How is PMF regulated in Canada?

The Government of Canada is currently conducting a broad policy review of plant molecular farming. Until this consultation and analysis are complete, applications for confined research field trials will be addressed on a case-by-case basis by the Canadian Food Inspection Agency (CFIA). No permission for commercial planting is being granted at this stage, only for confined field trials. Authorizations are granted according to the Regulatory Directive 2000-07. This directive oversees all ***"plants with novel traits"*** (PNTs, or plants that have had a specific trait added to them through ***genetic engineering*** or other techniques). All GM foods are PNTs and therefore fall within this directive.

An amendment to the directive was created to add (stricter) interim recommendations specifically for PMF crops until the policy review is complete. These include:

Developers are encouraged to consider fibre crops, crops with only minor food or feed use, or small-acreage specialty food or feed crops as production platforms. The use of major food or feed crop species for plant molecular farming is not recommended by CFIA at this time;
No livestock grazing or food production within 50 metres of the PMF crop;
For traditional food species crops, the minimum isolation distance from other crops is doubled for PMF trials compared with GM food trials;
Disposal and destruction of plant materials must be witnessed by a CFIA inspector;
Restrictions have been placed on post-harvest use of the land – for example, no species related to the test crop can be planted for a period of 1-5 years (depending on the crop type); and,
Developers must submit hazard and exposure data for human and livestock health effect assessments.

TIMELINE FOR REGULATORY ACTIVITY: As mentioned above, the CFIA is currently examining policy options for the commercial release of PMF crops. The structure of the approval process and the time required to complete the process is thus not yet determined. Analysts have predicted, however, that the time period from approval for a first field test to approval for full market release is approximately 5 to 10 years. The CFIA expects to receive applications for commercial release PMF crops in the next three to five years.

Glossary of Terms

Bioreactor — An apparatus, such as a large fermentation chamber, for growing organisms such as bacteria or yeast that are used in the biotechnological production of substances such as pharmaceuticals, antibodies, or vaccines, or for the bioconversion of organic waste.

Confinement — In this paper, confinement refers to biological and genetic mechanisms that isolate a PNT from its environment, including other sexually compatible plants. Isolation distances and male sterility are examples of confinement.

Containment — In this paper, containment refers to physical isolation of a PNT from its environment. Containment is provided by physical structures such as secure greenhouses, indoor growth facilities or laboratories, and ensures that there is no release from the facility to the environment of the organism, the genetic material of the organism, or material from the organism involved in toxicity.

DNA — Deoxyribonucleic acid; the material of which genes are made. DNA consists of a linear sequence of subunits called bases. DNA is the carrier of genetic information, which is encoded in the sequence of bases. It is present in chromosomes in the cell nucleus, and also in chromosomal material of subcellular units such as mitochondria and chloroplasts.

Genetic Engineering — The process of modifying the genetic makeup of an organism, usually by insertion of one or more genes. The genes may come from the same or another organism, even from an unrelated organism such as from another phylum.

Plant expression vector — A DNA construct that allows for the introduction of foreign DNA into host plant cells.

Plant Molecular Farming — The use of plants in agriculture to produce biomolecules instead of food, feed and fibre; i.e. PNTs grown as crops are harvested for scientifically, medically or industrially useful biomolecules.

Plants with Novel Traits (PNTs) — PNTs are plant varieties/genotypes that are not considered substantially equivalent, in terms of their specific use and safety both for environment and for human health, to plants of the same species, having regard to weediness potential, gene flow, plant pest potential, impact on non-target organisms and impact on biodiversity. PNTs may be produced by conventional breeding, mutagenesis, or more commonly, by recombinant DNA techniques.

Promoter — A DNA sequence associated with a gene that determines under what conditions the gene is expressed. Promoters may be *tissue-specific* (e.g.

	they may determine that the gene will be expressed only in seeds, or leaves); or *inducible* (e.g. they may determine that the gene will be expressed only in response to an environmental trigger such as exposure to heat, or a chemical); or *developmentally-specific*, or specific to a developmental stage (e.g. they may determine that the gene will be expressed only in embryos, or in senescing organs); or *constitutive*, meaning the gene will be expressed under virtually all conditions.
Recombinant DNA	DNA that has been cut and respliced. "Recombinant DNA" and "recombinant techniques" generally refers to genetic engineering.
Transformation	The insertion of a gene into an organism by genetic engineering.
Transgene	The gene which has been introduced into a genetically engineered, or transformed organism.
Transgenic	Refers to the introduction of a gene into an organism by genetic engineering. A transgenic plant is one in which a gene ("transgene") has been inserted.

Sources for Further Information

Biotechnology Industry Organization
http://www.bio.org/pmp/

Canadian Food Inspection Agency
http://www.inspection.gc.ca/english/plaveg/bio/mf/mf_disde.shtml

MA, J. K-C., P. M. W. DRAKE AND P. CHRISTOU. (2003) The production of recombinant pharmaceutical proteins in plants. *Nature Genetics* **4**, 794-805.

Pew Initiative on Food and Biotechnology: Conference on Plant-made Pharmaceuticals:
http://pewagbiotech.org/events/0717/
Conference Report: http://pewagbiotech.org/events/0717/ConferenceReport.pdf

Union of Concerned Scientists
http://www.ucsusa.org/pharm/pharm_open.html

APPENDIX B: MODERATOR'S GUIDE

PMF Public Engagement Dialogue
Moderator's Guide

Introduction and Warm-up (5 min)

- The moderator will take a few minutes to go around the table and ask respondents to introduce themselves, talk about the process, and outline a few ground rules: want to ensure that people share their views openly, let everyone participate, want people to talk about their views, not "other people's views", ensure that we don't want people to "debate" each other – everyone's views are valid, there are no right or wrong answers
- This process is different from a focus group as you know, because we have provided you with a background discussion document, and asked you to bring some issues/questions to the discussion. We look forward to a rich and dynamic discussion.
- The reason we are here is to consult Canadians about some of these technologies, to gather feedback about how Canadians feel about this particular field of technology, and the major issues and considerations that they expect in terms of governance
- Remind them that none of these applications are currently in use in Canada, they are 5-7 years from commercial use
    - The moderator will also point out that there is a one-way mirror, observers in the back, and audio and video taping, but ensure that all discussion is confidential

Awareness/Initial Reactions to plant molecular farming (20 min)

- Before reading the discussion paper that was forwarded to you, had you ever heard about plant molecular farming?
    - What had you heard about it?
    - What were your initial impressions/feelings about it?
- Now you have read something about this topic, what was your initial impression of the idea or principle behind molecular farming? Was it a positive or a negative impression?
    - Why is that?

Issue areas/Areas of Concern (30 min)

- Let's discuss the 2-3 key issue areas/questions that you brought to the discussion based on your reading of the discussion paper, and feel need to be addressed before decisions about PMF applications can be made.
- Id like each of you to tell me what they are, and why those are the most important to you, and once everyone has tabled their issues, lets see if we can organize/priorize them in some way
- For moderator:
- *What do these issues tend to revolve around? Is it about the health/environmental risks involved? Is it about the ethical issues involved?*
- *What are the underlying drivers?*
- *Is there consensus? Are there major differences of opinion?*
    - Are your concerns mostly about moral and ethical issues, or are they mostly about risks and benefits?
        - What are the major moral and ethical issues that you see in this area?
    - Now that we have talked about concerns, lets talk for a few minutes about potential benefits. What are the benefits that this field might yield?

PMF Applications (40 min)

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

For each of the following, *please tell me if you are generally supportive or opposed to the application*. For Each:

- What are some of the risks associated with these products? Who takes those risks?
- What are some of the benefits? Who benefits?
- Why do you say that?

- 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 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. 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 immunize all those who need it. It should be noted, however, that if edible vaccines come intogeneral use, the whole potato will not be adminstered (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 corn. 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*

12a→f

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?

13a→j

13a

- Corn 13b
- Rice 13c
- Tobacco 13d
- Cotton 13e

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

At this juncture it might be useful to probe whether there are attitudinal fault lines in two or three other areas:

- *Comfort with different sites where these types of plants could be grown: Field with 400 metre buffers, above ground greenhouse, or bio-dome/underground facility* 13g
- *Whether there is greater willingness to allow applications in health, environment, or industrial areas* 13h
- *Whether there is greater willingness to allow applications that do something new in treating problems, as opposed to improving the volume (reducing cost) of existing applications* 13i
- *Whether there are other measures, such as modifying the plants so they wont flower, that would increase comfort with these applications* 13j

14

- So can we come up with a set of measures that would satisfy your concerns, or is it your view that we simply shouldn't pursue research in this area?
- Take top priorities, have group discuss and work toward a consensus if possible *(Note: The consensus in Vancouver revolved around the idea of modifying the plants so they would not flower, and only producing them for the first few years in greenhouses (not fields)*

Attitudes - Roles and Responsibilities of The Federal Government (15 min)

15ab

- From what you know, what role does the government of Canada play with regard to these areas? What department/departments are involved? 15b 15a

16

- Do you feel that government is relatively stringent when it comes to regulating these areas, or relatively lax?

17ab

- Do you feel that government agencies responsible are able to manage the risks involved? What factor/factors contribute most to you having a level of confidence/not a very high level of confidence about this? 17a 17b

18ab

- Did you notice the interim set of provisions that were tabled in the discussion paper? Do they give you a level of 18a

24

comfort about the government's likely regulatory role?

- Do you think government is actively involved in carrying out/supporting research in this area, or not? Would it be a good or bad thing if it were?
- What role(s) should it play?
- Can it do both? Should it do both regulating safety and supporting research?

Next steps/expectations (30 min)

- Id like to give you a hand out that has the 5 applications we discussed tonight, plus an "overall" category. I would like you to fill out the hand out, you will see that there are 4 potential categories that you can assign to each application as well as overall, ranging from completely supportive to completely opposed. For each, I"d like you to make a note in the appropriate box, regarding the provisions you expect to be put in place in order to make it acceptable to you
  - Ask respondents to talk to the answers they filled in, identify what are the reasons are that were driving the choices, specifically why some might be preferable to others?
- Now that we have discussed this topic for a couple of hours, are the areas of concern similar to/different from the ones you came with? How so?

(10)