CANADIAN ENVIRONMENTAL LAW RESEARCH FOUNDATION

Seminar on Environmental Effects of Biotechnology held at the Canadian Bar Association-Ontario Education and Meeting Centre, Suite 1000, 120 Adelaide Street West, Toronto, Ontario, on September 15, 1986, at 9.00 a.m.

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NETHERCUT & COMPANY LTD.
185 RICHMOND ST. W.,
TORONTO, ONT. M5V 1V3
TEL: 593-4802

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BEFORE:

Mr. Douglas Macdonald — Chairman

Dr. Bernard Glick

Ms. Yvonne Skof

Nethercut & Company Limited,
185 Richmond Street West,
Toronto, Ontario
M5V 1V3

Per: J. Henderson, C.S.R.

--- Upon Commencing at 9:15 a.m.

THE CHAIRMAN: Before we start with the agenda, perhaps I will make a few mechanical remarks about the way we hope the day will go. May name is Doug Macdonald, I am the Executive Director of the Canadian Environmental Law Research Foundation. Before I say anything else, I would like to thank you all very much for making the time and effort to be with us today.

We have with us today Joan Henderson, a Reporter, who will be making a transcript of today's proceedings and I will explain in a little more detail what that is going to be used for and how careful you should be about what you say since it will be held against you on the record.

Bernie Glick from the University of Waterloo, who, I think, a lot of you know, is working with us on this project. Yvonne Skof, Research Associate, is also working with us on the Biotechnology project. We are all wearing name tags, but I think it would be useful if each of you as we go around the table would introduce yourself and your affiliation.

Reporter's Note: All present so identified themself and their affiliation.

The Canadian Environmental Law Research Foundation is an environmental research organization which has recently published a book on toxic air polution. I should explain that until recently I smoked two packages of cigarettes a day and I quite like being

in a room with a smoker. It's the only chance I have to get a little "hit". But if you would wander out to the other room to have a smoke I think it would be easier -- we could allow a "grandfather" clause so that any grandfathering uses of tobacco can continue after this announcement.

What we hope to do is to run this session in a fairly informal way. The agenda and everything else about the day is up for discussion and if anyone has any thoughts about how we should do things differently, just say so.

I should explain something about the individuals involved and then I would like to spend a quick minute to tell you about the research foundation in general terms. Then I would like to talk about the particular biotechnology project we are doing, in which you are all participating today, and then I will turn things over to Bernie Glick, who will deal with the first item on the agenda.

I am the Executive Director of the Canadian Environmental Law Research Foundation. I am neither a lawyer nor a scientist. Usually at these kind of sessions I am dealing with a paper which has been produced by lawyers and which I find at least vaguely comprehensible. I am now in a meeting with scientists, for whom I have an enormous respect, if nothing else, and my job is simply to coordinate and keep things moving along. Substance will be provided by other people on the team.

Invitations for this forum were issued by the former Director of Research. She has since left the Foundation and will not be with us today. Working with us is Mr. Bernie Glick, who will handle things on the science side, and a lawyer, Ms. Irene Courage, who will, I believe, be with us today, will handle things on the policy side. We have with us Ms. Yvonne Skof, who has degrees both in law and in science, and who is working on both sides.

The Canadian Environmental Law Research Foundation is an independent organization. We share office space with the Canadian Environmental Law Association but have quite a different mandate. The association, CELA, as you may know, often provides legal services for people fighting environment battles and directly lobbies government. Our organization, on the other hand, does environmental law and policy research and we do not litigate or directly lobby.

We have sitting out on a table for anyone who is curious a copy of our Summer '86 Direct Activities Report and that just gives a listing of the kinds of things we are doing. The substantial function of our activities is toxic contamination of the environment, fairly broadly defined, and the varous processes which go along with that, assessment, standards setting, enforcement, compliance, what happens when we get into the Courts. We do not do scientific research ourselves. The work we do is based upon our understanding of the

science which is being done.

A good example of the kind of work we do is the study I just referred to on the regulation of toxic contamination and air polution in North America. That was done jointly with the Environmental Law Institution in Washington. It consists of an overview of all air polution, all forms of air polution, other than SO2, but then the substance of it gets into an analysis of the regulatory systems in both America and Canada.

Our interest is not in litigation and the action that the citizen can take using the legal system in Canada for environmental protection, but more on the side - we have a greater interest on the side of regulation and government activities.

We like to see ourselves as an independent organization standing between government, or perhaps not between, but amongst government, industry, environmental organizations and other sectors of society and we attempt to play a brokerage role of bringing together different sectors. We often hold these kinds of events.

We do not try to reach a consensus, but we try to get at least some exposure on the different perspectives of various organizations. Anyone who is curious about the other work we are doing can pick up a copy of the Current Activities Report or talk to me

at any time during the course of the day.

We have had an interest in biotechnology since 1984, since the beginning of 1984. This was brought to our attention largely through the litigation which was being undertaken in the United States at that time as the American government was trying to sort out its regulatory approach to the release of genetically altered organisms into the environment. We felt that this was an issue which inevitably was going to be addressed in Canada. We felt that it was an important issue given our limited understanding of the science.

We felt that inevitably there were going to be some environmental impliations. What intrigued us was the fact it was still coming in the future and this was an opportunity in Canada to spend time addressing the question of regulation before the fact rather than after the fact. In theory that is an ideal place to be. In practice, as you all know, it is a very difficult place to be because we are trying to regulate and we do not know exactly what it is we are regulating, and that causes problems.

We decided to initiate work in this area by holding a conference in 1984. During the planning stages of that conference, I had extensive discussions with David Shindler of the Ministry of State for Science & Technology who convinced us that the best service we could do would be to do substantive work on the regulatory side ourselves and to put some concrete proposals

on the table. He was worried we were going to do a quick in and out number and that other people were going to have to pick up the fall-out. We spent time for that reason getting an overview of the current regulatory procedure, or existing legislation which would be available for regulation, and based on an admittedly cursory overview, we then proceeded to advance a proposal for new legislation and new institutions.

Basically the idea was that the Federal government would pass new legislation, create a new institution, and that the Federal government would be the major regulatory body concerned with Provincial licensing powers. We put that forth in October of 1984. It was commented on by representatives from industry, governments, and environmental organizations. We brought up Mr. Rifken to talk about his perspective of biotechnology, which was a very valuable and interesting talk. By and large, I think, the conference was quite successful.

We then had our attention occupied with other things for about another year. We then started to become actively involved again in the fall of 1985. One of the spheres of our involvement was the seminar which the Vice-counsel on Occupational Health convened which we attended. I was at this point having talks with pople like John Evans and other people in terms of what Canada should be doing in terms of regulations. We decided we wanted to do more work ourselves in terms of developing our own proposal and we wanted to work

with other sectors in Canada that were involved.

As you know, it is a fairly small community. There are a limited number of people doing things. We thought that it was now the opportunity for us to make a contribution to the process.

Our policy on everything we do is very simple and straightforward. We are an environmental research organization. We place environmental protection at the top of the list of priorities and our perspective is clearly one which says that environmental protection should come first and other social goals such as industrial development should come second. Our mode of operation, given the realities of the world we work in, is to look at ways in which both can be accommodated. Usually that is the case in fact. I am convinced that in all cases of polution, that can be done.

We can have both environmental protection along with the other social goals of our society and every other society. We simply have to start going about things in a different way, pay a little more money and make a little more effort, in order to achieve those goals. In the case of biotechnology this combination of goals falls very clearly into place.

There is concern in Canada, particularly on the part of the Federal government, expressed through the Ministry of State for Science and Technology, that biotechnology be given impetus in development and assistance and that Canada's international position

in terms of pride is dependent on speedy development of the biotechnology industry.

It has become apparent to us watching events in the United States that the regulations is key to the question of the development of the industry. The Americans have spent quite some time trying to - perhaps I will interrupt myself for a second. We have had two people join us, Dr. David Rokosh of the Ministry of the Environment and Ms. Irene Courage of CELA.

As you know, the Americans are spending quite a bit of time trying to sort out how they are going to regulate. They have a different way of going about it because they have a different society. It is a more open society. It is also much more ameniable to litigation. So when they do things in a public way and litigate,that may be good or bad, I don't know, but that is the way they are doing it.

I was at the conference in Washington at the beginning of summer. Almost all industry people were there and very few government or environment people and the complaint over and over again was that "We in America are going to lose our competitive benefits unless we decide this very, very quickly because we are spending all this time just trying to sort out how to regulate".

All of this led us to design this program at the beginning of this year, these two goals of trying to ensure environmental protection and trying

to clarify the regulatory framework in order to allow industrial development and to allow the achievement of the benefits which biotechnology has to offer. We have, in consultation with the Ontario Ministry of the Environment, which is funding that project and for which we are very greatful - we are working with people like Goff Jenkins, people in the policy planning branch - and the idea was to see what consequences we could find in this country, on the one hand, on the possible ill-effects which regulations intended to guard against and, on the other hand, on the political issues which regulations have to take into account.

We decided we could do this by preparing two background papers, one with Bernie and one with Irene, on the science and on the regulation side, and by holding two seminars. This is the first. There will be a second one on October 15th which will be on the policy side.

We are having a transcript made for both seminars which will assist us in the preparation of procedures which will go into the final report. It is not our intention to attribute any individual remarks to any individual speaker, nor to publish the transcript. What we intend to publish is the paper, then a summary of the discussion of the paper, and the same thing will hold true for the policy side.

Our idea is to hold the second seminar in the middle of October. We will then go on and write

a report and present it to our founder, the Minister, and anyone else interested - we will provide copies to everyone who attended this seminar and the second seminar automatically - saying that this is a consensus and we have been able to identify the effects on the environment which this regulation is intending to prevent, or the problems which regulations - the physical and empirical problems which regulation has to cope with, and on the other side, there are the policy issues which regulations have to address.

We are then hoping to fit in with the timetable the Federal government is following. It at the moment is developing its own proposals for regulation which, as I understand, are about to go through. I should explain that it has done an overview of existing legislation similar to the work we do but in a slightly expanded version. It is now developing its options for regulation and taking those to the provinces.

We are going to do further work on our proposals for regulation and we are hoping to convince other people in other countries to also turn their minds to this question. The Federal government, as I understand, will be putting something on the table publicly early next year and we then intend to hold a major conference in the spring of - sometime in the spring of 1987, at which time the Federal and Provincial governments will be given an opportunity to say how they

intend to regulate. Other organizations and all other interested parties will also be given an opportunity to give their thoughts on how regulations should go. There will be a public discussion which, hopefully, will lead to action from that.

So that is who we are and that is what we are doing, and that is the purpose of today's seminar. It is one step in this process which is going to carry through to the spring of next year.

I am going to stop now and turn things over to Bernie. Are there any questions about the organization or about what is happening today? Is there anything about what I have said today that anyone would like to have clarified? If not, I would like to now turn things over to Bernie who, using the method of other scientists, is going to use slides to illucidate the subject for us.

SLIDE PRESENTATION

DR.BERNARD GLICK: I think the first thing I would like to comment on is that, as Doug mentioned, there are two reports, and the two reports, we hope, will not be two solitudes, that is, the science report and the policy report we hope will impact on one another and in fact we are going to try to get some of the people with a scientific background to be attendees at the policy discussion as well.

The other thing is that the report is

just a starting point. The report is not intended to cover all of biotechnology. It is not intended to go into tremendous detail about any particular aspect of biotechnology. It is intended very much to be an overview and it is intended also to elicit comments, discussions, and suggestions from you.

Having said that - and I want to give credit on the first slide, biotechnology. It has been suggested that there is a continuum, but there is a break in the continuum. The continuum is, in a sense, from old biotechnology, BBC, that is before Boyer and Cohen, and ABC biotechnology, after Boyer and Cohen, since 1973, and let me give credit for the BBC/ABC to Jack Pasternak, and I gather that BBC and ABC has since been copied by others without giving credit.

Certainly, the experiments of Boyer and Cohen, the ability to splice DNA to generate recombinant DNA molecules is a bit of a watershed and really to some extent is it why we are here. To some extent again it all started not with Boyer and Cohen but with Watson and Crick. This is just a copy of their original paper. This is their entire paper.

In any event, the technology we are talking about, we are talking about being able to take - and again, just before I say anything about this, I think we are trying to point it out in the report that we have - and we are talking not just about micro-organisms, although largely about micro-organisms - that we have a continuum,

that is, we have micro-organisms which have traditionally been used to do particular things. We now have the ability to develop those micro-organisms in particular ways.

There are applications of those micro-organisms that we need to consider which are more traditional applications - or less traditional applications but without using genetically manipulated organisms, and then we get into the newer applications using genetically manipulated organisms, and I think one of the questions that arises - the very first questions - is in fact is there a difference between genetically manipulated organisms and those that are selected - mutagenized and selected in traditional ways. I do not intend to answer that at this point.

Using this technology, Cohen and Boyer were able to basically excise pieces of DNA, cut pieces of DNA, specifically with restriction endonucleases, enzymes that recognize specific sequences on the DNA molecule and to join these up with other pieces of DNA, generally vectors that carry that DNA into a bacterial cell, or sometimes a plant or an animal cell, and specifically select for the piece of DNA that they are interested in and then manipulate that in some way.

What that does, that creates an organism carrying the unique genetic complement - a complement, if you like, that has never existed before, or may have

never existed before in nature.

Obviously, with this technology there has been an enormous amount of concern expressed and that concern has taken a number of different forms, and the concern has taken the form of people calling for a halt to genetic manipulation. People have been concerned about not just environmental release but from the very beginning, that we are going to create strains that will - well, andromenous strains, if you like, strains that we will not be able to contain, that will have untold consequences.

Some of the concerns have been concerns that have not been well articulated, but people are very nervous about how it is going to impact on them. In a sense this cartoon suggests really that the public is wary in ways they have trouble articulating, but it is wary of the entire technology. It really doesn't know what it is getting into.

Another concern is schematosized in this cartoon and really again I think most of you - except those sitting at the very back - can read it. The idea is - and of course this is quite fanciful. We realize very well that we are not going to create organisms of this type. Nevertheless, I think in the public's mind, and to some extent reinforced by the press, this type of possibility still exists, and I think it is something that scientists have to deal with and address in terms of educating the public. That is not necessarily the issue

that is before us today.

This I have to think my son for. I don't know if everyone can read it. Basically, there is now a comic book called "DNAgents" and "DNAgents" are genetically programmed and I think people are concerned that we are getting into a - if you want to call it a "brave new world" type of scenario where we manipulate people in specific ways, program them and make them drones.

Obviously, again, this is a fanciful and gross exageration of the kinds of things that people are doing. This is not the only view of recombinant DNA technology. Another view and a more positive view - and this is taken from someone's advertisement - is that what we are doing, really, is building the future. I think to some extent, maybe not all of us but many of us here would take this kind of perspective, that in fact the technology has opened a window of opportunity for us and it is a very large window. Right now we are looking in and we are trying to see how to use that technology.

It is a technology that has had an enormous amount of scrutiny already. From 1973 to now is not a very long time. Yet the Episcopal Church - and this is last year - found it worth its while to discuss it at its general convention and to officially give it its backing. So it is a technology that is not going to be ignored and it is a technology that has probably had more

scrutiny than any other technology we have ever dealt with, including the computor industry and other such technologies.

This is actually just the front - or it is not the front - it is the front page of the Living Section of the Kitchener-Waterloo Record of about six months to a year ago, I cannot read the date from here, and actually this type of thing is fairly common in the popular press. I think to some extent that if people actually read this and paid attention to it, we wouldn't have any problems. The problem is that the newspapers and magazines as well publish this but I do not think it is often read. I think what people pay attention to are headlines and they pay attention to the "Jeremy Rifkin's".

Why it is that the technology is of concern and why it is anything more than a laboratory exercise is because we expect an enormous amount of impact on our society in terms of economic impact. We expect the technology to have enormous economic benefit and we will look in just a moment at some of the areas that would impact, but already it has been estimated that more than $4 Billion dollars - and most of this is in the United States - has been spent developing biotechnology.

This is again just a fanciful view of some positive experiments in terms of genetic manipulation of plants. The man is shown at full size.

We can go down the list briefly. We can

anticipate currently - and the list is not meant to be all-inclusive, but largely inclusive of the kinds of activities that we see people engaged in now. We see the development of both subunit and synthetic vaccines, live vaccines - in that case I am thinking at this point of vaccinia virus although there is some discussion of live vaccines based on adno virus, DNA diagnostics, of course, and this was originally developed for prenatal diagnosis. It is being used now in a very large way for diagnosing and detecting the existence of viruses and specific micro-organisms in a variety of ways.

Specific drug delivery, here we are talking more about the use of monoclonal antibodies. Pharmaceuticals, we have heard a lot over the last number of years of synthetic insulin and Interferon and many, many other pharmaceuticals. In fact, both of these; insulin, Interferon and growth hormone have been approved and are in fact on the market at the present time.

We are going to see from recombinant DNA a tremendous growth in the use of recombinant, as well as non-recombinant, use of enzymes as biocatalysts. Antibiotics, we know, have been produced for years from micro-organisms. People are just beginning to manipulate those organisms not just to increase the yield, but to manipulate the organisms to a point where they can create new antibiotics.

There are a variety of chemicals that one

can produce. I should say at this point that I am not distinquishing between applications that will be strictly laboratory, that is, contained applications and released applications. Biomass utilization is something that may or may not ever come to fruition. I think those people who work in this area will tell you that there are lots of problems to be solved and the problems may be more economic than biological.

Single cell protein is likely to be the same sort of thing, in fact. We have other sources of protein and in fact for the developed world single cell protein may not ever be a going concern.

Microbial fertilizers and microbial pesticides is something we are going to talk about a little bit today and, hopefully, we will address some of the specifics and specific applications. Hybrid plants and engineered plants, well, of course, we have had hybrid plants for years. We are just developing the hybrids differently now through self-fusion. Genetically engineered plants are coming around faster than one would have expected - at least, that I would have expected a couple of years ago.

Microbial waste treatment, microbial oil leaching and microbial oil recovery are all examples of where one would use, and where microorganisms are being used in the environment. Right now those organisms are not necessarily genetically engineered organisms,

but they are likely to be. So we have a whole continuum. Some of these things, as I say, are on line now. Some of these things are likely to come on line within the next ten to fifteen years. It is very difficult to put a timeframe on all of this.

As I implied before, we can break down the environmental implications of biotechnology into roughly three categories. And we can talk about contained applications, and by that I mean where we grow the organism in some sort of fermentation vessel - it might be a small fermentation vessel, it could be a rather large one - but where we have no intention of releasing the organism to the environment and the only release of the organism to the environment is unintentional.

The next stage, the next category, if you like, is where we use killed microorganisms that form the product. An example of this might be, for example, in the use of single cell protein or, in some instances, where microorganisms are used for oil leaching or oil recovery the organism need not be viable and, in some instances, killed microorganisms will work just as well. So a killed microorganism may form the product in that case.

The area of most concern - what we think is of most concern - will be the area of the use

of genetically modified organisms which we deliberately release to the environment. These are living organisms and are, to some extent, distinct from the contained applications which the organisms might escape. These are organisms which can live and replicate in the environment, possibly pass on their genetic information to other organisms and, in fact, these are organisms which we will specifically select to be competitive in the environment.

What I am going to propose, and we do not necessarily have to do it, but of the discussion in terms of how to deal with gentically manipulated organisms, or any organisms, for that matter, in the environment, it seems to me the schemes which have been proposed, largely by Martin Alexander in the United States, seem to be a reasonable framework, at least for discussion. I am not going to suggest that his equation is at all meaningful, but I will suggest that the categories are meaningful.

He talks about the probability of a deleterious environmental affect from releasing genetically manipulated organisms. I would not like to say that it is P-1 times P-2 times P-3. I think that is a little bit simplistic. But let us just run through what the categories are.

The first thing to consider is the probability that the organism will be released. In

the case of a contained application, that probability, we hope, is quite low. That is because we have physical containment and we have back-up systems. Should the first level of physical containment fail, we have a second level of physical containment, at least. The probability that an organism will be released is, of course, one in terms of an organism that we are going to release into the environment.

The next question is will the organism survive once it is released. To a large extent, again, organisms will have different probabilities of survival. An organism which, for example, is intended for a contained application is likely to be an organism that is severely debilitated and is unlikely to survive for very long outside of the special conditions we can provide for it in the laboratory or in the contained environment.

Other organisms, again, we want them to survive because if they do not survive they will not do their job. Along that continuum there is room for organisms which will survive for a certain period of time and because they are only needed to be around for a certain period of time and after that, they also will not survive, they will die. In a sense, connected with survival is, will the organism not only survive, but will it multiply? Can the organism grow in the environment?

Again, I would argue that this is becoming - as we go down the list, it becomes harder and

harder to predict ahead of time because we do not know - at least, I do not think we know very much about what makes one organism competitive in the environment. I think part of the problem in predicting ahead of time is the knowledge base which we are operating from.

Again, with following up on multiplication, we ask what is the probability that an organism will be disseminated throughout the environment? What is the probability that it will transfer its genes to other organisms? We know that microorganisms, for example, can travel often great distances whether in water, whether through soil, whether attached to specific animal vectors or carried by the wind. We know also, in terms of transfer, microorganisms normally exchange genetic information and they do this perhaps in ways that - some of the ways are obvious to us - through conjugation, for example. Some of the ways, perhaps, not so obvious to us, in that organisms that contain plasmids, for example, may eventually die but still yet transfer their DNA or use their DNA to introduce that DNA into other micro-organisms.

But all of P-1 to P-5, it is possible for us to test it and for us to measure it. P-6 is a tough one. The question is, what is the probabilty of harm in releasing that organism? That is easy to say if the organism is pathogenic, if the organism encodes a

toxin, for example. It is not so easy to say if the organism is there performing a fuction in the environment. It is very difficult for us to predict what might be the consequences of that introduction.

Just a couple of examples of some environmental concerns. I mentioned before that the first one is the live vaccinia viruses. We know that vaccinia has been used in the past with enormous success in the eradication of small pox. It is now proposed that vaccinia be used to carry antigenic determinants or the genes for those antigenic determinants, rather, for things like rabies, herpes and hepatitus, and that specifically for rabies we use this, for example, to help eradicate rabies in the wild. So we have to ask the question now, what is going to be the potential consequences of releasing that genetically altered vaccinia virus to the natural environment? What is going to be the consequences of treating wildlife in that way?

There is quite a lot of work going on right now, and I am not suggesting that it has reached fruition, in terms of looking at the potential of Rhizobia, Rhizobia being microorganisms which can fix nitrogen in a symbiotic relationship with specific plants. The most important of these is Rhizobia Cheponicom (sp?) which forms nodules with soybean. A lot of work in the recent couple of years has stressed the nodulation genes, specifically. The work before

his looked at the nitrogen-fixing genes specifically. There already is a small market for improved strains of Rhizobia, specifically Rhizobium Cheponicom. I think the market is about $15 million in the United States. This is likely to grow.

These are not yet genetically manipulated strains. These are just normally selected and improved strains. But as we increase our ability, as the development of these strains is facilitated through genetic manipulation, we are likely to see an increased use of this type of organism as well as other nitrogen-fixing organisms. But I suggest that the use of other nitrogen-fixing organisms is much further down the road so I do not know if we need to discuss that necessarily today.

An application has already been made in the United States for approval to field-test so-called "ice-minus" bacteria. These are Pseudomonads which have a so-called ice-nucleation gene and this ice-nucleation gene has been - or a deletion mutant of this gene has been engineered, and an application to spray this deletion mutant on, I think it is, strawberries and potatoes, has been made with the idea that the ice-minus bacteria would protect these crops against frost damage.

Again, there is also an application in the United States to test a Pseudomonad that has been engineered to produce the bacillus thuringiensis

toxin. Many of you know that the bacillus thuringiensis or B.t toxin has been used as a bacterial insecticide for quite some time, but this is a new application, It is a new application and it represents a significant, if you like, escalation in terms of use and it represents also possibly a different type of use. Seeds would be treated before planting.

Very recently there have been - or at least there has been one report about insects developing resistance to B.t. B.t is normally degraded very rapidly in the environment but when something was used to treat stored grain, there was some incidents of resistance developing. So the question here, or one of the many questions here, is if we disseminate the B.t toxin in large amounts, within which it doesn't break down as rapidly as it normally does, will we be defeating our own purposes to some extent?

In addition, probably most of you are aware of the work being done in identifying microorganisms which break down. There has been a lot of research done in terms of using these organisms in more specific ways trying to develop organisms to degrade specific pollutants, trying to develop organisms which will function at different temperatures, trying to modify the existing specificity, temperature and other specificity.

Before I finish, let me make, and these may be obvious suggestions or conclusions - from the

amount of knowledge we have, it seems that, first of all, we cannot come to any - I would think it is difficult to come to a lot of general conclusions. I would recommend that rather we proceed, at least for the time-being, and the time-being may be quite a long time, on a case by case basis. Each specific application for a while is going to have to be dealt with on an individual basis and as we gain experience, then the process will be speeded up.

Obviously, the first few approvals are going to take some time. The second thing that is very clear to me is that as far as the microbial ecology specifically, there is an enormous amount of work which remains to be done. There is an enormous amount we do not know about the behaviour of microorganisms in the natural environment. I think a lot of basic information is needed in this area and I think that we should target this area specifically and provide funds for research specifically directed towards understanding something about the competitive nature of microorganisms in a natural environment.

The third suggestion, and again I have borrowed this and adapted it from Martin Alexander - I do not want to take credit for it - is to institute tier testing. That is, if we first assess the survival of a microorganism, if an organism is not going to survive, if the probability is zero it will survive, then we do

not need to test it any further. If it is going to survive, then let us test can it multiply? Will it be disseminated? Will it transfer? If we test in stages in this way, the suggestion is - and it is not the necessity for testing for detrimental effects may never arise - we may find the organism cannot survive or cannot multiply or cannot be transferred or cannot disseminate to other organisms, therefore, it is not a concern that it is going to cause detrimental effects in the environment.

Only if the answer to all of these is "yes, yes, yes" should we then begin the much more complicated process and the much more expensive process of going through that extensive testing for detrimental environmental effects.

I think in this way we can improve lots of things we know something about or that we can get an easy handle on without the cost in terms of actual cost and without the cost in terms of time. I think what we want to do is, I think there is a balance here of protecting the environment. Also what we want to do is facilitate the development of this technology and the dissemination of it. I do not think we want to unnecessarily impede that.

I am going to stop just about here and turn things back to Doug. Without commenting very much

on it what I would like to do is just give you a one-page handout. This is from the latest issue of Biotechnology. It is the commentary by the editor, Bernard Dixon, in which he is talking about the development of AIDS vaccines, and the problems he sees in the kind of society we are getting into or that we have the pendulum swung towards developing what might be call a "no-risk society". I think he is arguing - and I will let you read the argument for yourselves - that the pendulum may have swung too far towards that "no-risk society" and maybe now is the time to reconsider how exactly where we want that division to be made.

So I will just pass these out, turn on the lights and turn things back to Doug.

--- Article by Bernard Dixon distributed.

THE CHAIRMAN: What we are thinking of doing is at least beginning the discussion which, on the agenda, is slotted for eleven o'clock. I will talk about that in a moment, but, first, does anyone have any questions they would like to ask Bernie, or any comments they would like to make on anything generally coming out of his presentation?

DR. BOB WATSON: I would like to ask, will we be having a discussion on some of the concepts just talked about or is there enough time?

THE CHAIRMAN: Perhaps we should talk about that, then, just the agenda for the day. As both Bernie and I have mentioned, we are quite open to any changes which might be suggested. What we are looking for, as you know, is what sort of consensus or agreement might exist amongst this group which is then fed into the policy development process. So it is not a discussion of science per se, but to provide the foundation for development of regulatory policy.

Our thought was to, first of all, discuss potential applications and our interest, of course, is in release to the environment either deliberate or accidental, but we are trying to make a distinction between that and purely contained applications.

I think what we would like is to get your comments, or feelings or predictions on which applications are most likely to be coming on stream first and in the greatest numbers and which, therefore, require the initial attention of the regulatory bodies.

That you can see on the agenda is the discussion slated for eleven o'clock, so that will get us back. Bernie has given us his overview of applications. We will now run through that and then go into the whole question of the environmental effects associated with those applications. Our thought was to make a distinction between the conceptual approach, how you go about

conceptualising, and that will get us back to the Alexander technique, and then again talk in more detail about the applications and possible effects associated with them.

So the answer to your question is, yes, we are going to spend the rest of the day talking about what Bernie has given us, his overview. I should mention just a couple of other things. We are having a transcript made of the proceedings which will help us. Normally in these cases we would have large name tags in front of everyone. We were remiss in not doing that. It would help the court reporter a lot if you would say your name prior to your remarks. Anyone who insists on anonymity, of course, can simply speak without saying their name.

I would like to welcome Don Lush who joined us during Bernie's presentation. Mr. Lush is with Beak Analytical Services Ltd. which has done work for the Minister of State for Science and Technology on biotechnology.

We will probably just get going and then break for coffee but at least we can start on a discussion of potential applications. Perhaps the easiest thing to do is, Bernie has listed five applications.--

DR. BERNARD GLICK: Yes, those were just examples. There really is a whole list of areas of application and I think what Doug is looking for

is really other examples. He is also asking the question, as I understand it, what people think are going to be the more immediate concerns.

THE CHAIRMAN: I guess those are the two questions. What else would you add to Bernie's list and in what order should we place them?

DR. V.N. IYER: My name is Bob Iyer. The issue was raised in your presentation. Are we going to address the question of any release of any organism or are we focussing only on organisms that have been constructed using modern biotechnology? I think that question should be first addressed and resolved.

DR. BERNARD GLICK: All right. I think that is probably a question we should throw open to the floor rather than us trying to answer it.

DR. V.N. IYER: I am just saying that that question should probably be answered before we categorize different experiments.

DR. BERNARD GLICK: I think you are absolutely right. So really the question is should we treat genetically manipulated organisms as part of all microorganisms or separately from other microorganisms?

DR. VERN SELIGY: Just following up with what Dr. Iyer has said, in hearing your presentation there are about four or five things that sort of got my attention. One of them right away was I think what the

real problem is, is not right now with respect to recombinant DNA because actually we are still going through - which amazes me a little bit - we are still going through this anxiety assessment that a great deal of effort and energy has gone into in the past, going back to 1973 and after that point, but I think the real problem is going to come when recombinant DNA aspects sort of come around and link up with the old technology, the one that, in some respects, is what I think is probably the more critical issue to deal with and not whether or not we are going to release a recombinant organism. Because quite often we are only still dealing with one gene and you know how fragile that system is.

Any of you benchworkers here know you cannot really make it work very well. So what I think - and I am going to be bold about this, but as far as I am concerned, what I think is probably the most serious threat in biotechnology is that of the release of either the organic waste or some debris,or whatever have you by-products, coming from biotechnology industries, or any industry which is dealing with living matter in its processing.

That could be a detergent industry. It could be a pesticide industry, anything like that.

DR. BERNARD GLICK: You have not dealt with Bob's point specifically, but let me just answer

your point. I think to some extent what you are talking about is in contained applications, the by-products of biotechnology. I think those by-products, that is not unique to biotechnology, per se, or to using organisms or even genetically manipulated organisms.

DR. VERN SELIGY: But there is one implication and that is that when you release a spectrum of substrains you automatically, to some extent, are challenging the natural environment for certain organisms to reach levels that they never did before.

DR. BERNARD GLICK: All right. You are changing the spectrum of organisms that are selected for so you are talking really about the treatment of the waste in some way or appreciation that a new form of waste exists.

DR. VERN SELIGY: Well, in the case of just where the ordinary public is concerned, I think they are going to be much more affected by whatever is released and enhanced by industries in that way than there will be probably in any other encounter.

In other words, the only other area which is exceptional, I think, is the medical area where we really cannot control some of the experimentation which is going on on a clinical basis with fertility because all those experiments - and you can call them experiments - are being done by a transaction with the

public who agree they are willing to have certain things done to them in order to have offspring. This is done sort of after the fact. Society has really no opportunity to make a decision whether or not they want it.

DR. BERNARD GLICK: Maybe we can just go back to Dr. Iyer's point for a moment because I think it is central to our discussion. Should we be treating organisms that are manipulated by recombinant DNA technology any differently from any other microorganisms?

THE CHAIRMAN: There is a comment over here and then I would like to say something about where the Foundation would like to go.

MR. DAVID SHINDLER: I will start by addressing a topic and I think it is a base-line for our discussion, and that is, what about protecting the environment? What is the aspect of environmental damage we are worried about? Because when we talk about organisms and their damage to the environment we have to know what we mean by "damage". Is the Love Canal the existing environment we are trying to protect? Or is Manhattan the environment we are trying to protect? Are we primarily concerned with preserving our agricultural environment, which has a great deal to do with Canada's productivity? Or are we talking about virgin forests?

There is a tremendous difference there

and in some cases one would want an organism to survive and in other cases one would not.

And if all these issues - if we make a general rule over issues like this, we will just be running in circles all day long, so we are going to have to define things like what do we mean by the "environment" before we start talking about preserving things and worrying about things.

THE CHAIRMAN: Your point is well-taken. That is the same debate, of course, which is going on throughout all areas of environmental contamination, the question of risk assessment and how safe is safe, and neither this society nor any other has come up with an answer yet, and I do not think we will be able to do that today.

By the same token, when we are considering any particular, you are absolutely right, that is what we have to be looking at. Going back to this absolutely essential question, what are we talking about, that, I think, is going to be one of the major things which on the policy seminar is going to be discussed and which I assume David and his colleagues are wrestling with in terms of how to regulate, whether you separate out or not.

Our interest is more on the side of we would not want to be all inclusive here today. The

more we can focus it, the better for our interests.

MR. DAVID SHINDLER: I want to add to that that if you do not use precision and make your definitions at the outset, you run into the situation which exists in the United States today, that biotechnology has been defined very, very broadly and the Congress, as a result of the publicity about biotechnology and the investment, demands that biotechnology be regulated and asks the regulators to regulate, therefore, everything.

And I think that if we fall into exactly the same situation, we are just going to spin our wheels here in Canada. I think we have to be very precise and define what we are talking about at the outset. I would encourage this group to do that with its membership from industry, provincial government and the federal government, to perhaps take a more narrow definition at this point. Throw away the word "biotechnology" as useful in this particular symposium and take a narrower view of what we want to talk about. I think we would get far further doing that than we would if we concentrate on "biotechnology".

THE CHAIRMAN: I think maybe that would fit our purposes very much.

MR. DAVID SHINDLER: Therefore, the energy right now could be confined to that point.

DR. BERNARD GLICK: I am certainly happy with that. In fact, originally I tried to limit my definition of biotechnology to A, B, C biotechnology, you know, after Boyer and Cohen, and specifically using the so-called enabling technologies and largely the enabling technology of recombinant DNA for this discussion, anyway. I think that is really where the major concern is.

DR. FRANCIS ROLLESTON: We have a problem here because in your opening remarks you said that this was not just a case of protection of the environment, this is also protection and encouragement of the economy. I think if we become too ivory tower and too restrictive in our definition, how much use are we with respect to encouraging industry to settle in this country, which is the other side of the coin we cannot lose sight of.

THE CHAIRMAN: I am sorry, I do not understand the point you are making.

DR. FRANCIS ROLLESTON: The point I am making is we become too restrictive in our definitions. The side we really have to look at is what is industry -- the other side we have to look at is what does industry need because we can set up a thicket, in fact there is already a thicket of regulations and rules, et cetera, at provincial and federal levels, and I have

a feeling today that there is an enormous amount of wasted time in the industrial side of things as they struggle their way through this maze of regulations, and so on. So I have a feeling that if anything is to be valuable in the two-sided picture that you have introduced, we must recognize the needs of the industry because this is a target of this country.

THE CHAIRMAN: Well, I am working on the assumption that what industry needs more than anything else in any regulatory situation is clarity and the best way to get clarity here -- well, I do not know what the answer is, but it seems to me, as David has suggested, that the more you can define clearly what it is you are regulating and what you are not regulating, the better off industry will be.

Again, I am certain that in the policy discussion this question is going to be central. I like the idea for our purposes today to try to limit but I do not know whether that can be done and I am in the hands of the group.

MS. PENNY CHAN: I do not really want to throw a spanner in the worksbut if you intend to try to limit it to genetically engineered, which I guess is where you're going if you are taking biotechnology out, how can you really decide whether it has been using an enhancement technology or a naturally -- or using a

non-specific technology to cause mutations and selection? Are you going to draw the line at the technique of producing the organism or what?

DR. BERNARD GLICK: I do not have a good answer for you. I think what we have -- and this is really a comment addressed to some people from the government -- we have existing legislation to deal with, to some extent, at least, the traditional uses of micro-organisms in the environment, or either intended or unintended release of those organisms. It seems to me the question we are dealing with is the use of genetically manipulated micro-organisms rather than non-manipulated organisms.

For example, we already use micro-organisms, bacillus thuringiensis, for spreading for spruce budworm. We already use thiobacillus in microbial mining and there are examples of other organisms. Are the people in the government, for example, satisfied that we have adequate legislation to deal with this? That is really a question. And if so, do we need to consider that separately or should we still consider them together.

AN UNIDENTIFIED VOICE: I think we have sort of slipped into talking about micro-organisms all of a sudden. We talk about it a lot. Of course, there are a lot of other organisms that can be genetically

engineered, plants in particular. We may feed our animals in terms of having things in the fields which have been genetically engineered. Transformed tobacco has been successful, from what I hear. So here is a plant for the field. It seems to me we have a macro-organism and a micro-organism. That may be an easy line to distinguish. You can always go over that with a chain saw or a lawn mower and wipe out the, I think, macro-organism quite rapidly. The micro-organism is a little more difficult, in that case. But we sort of slipped into talking about micro-organisms and I would hate to see macro-organisms valuated in the same way.

MS. PENNY CHAN: Well, hasn't the need for water curing of macro-organisms to a great extent been spreading, and cured tobacco plants have been spreading all over the country. That would make it much more difficult. Not being a scientist, I can envisage a plant having been grown for ten years and the seeds have been blown away and new plants spreading.

AN UNIDENTIFIED VOICE: Here is a point I had intended to bring up talking about plants and engineered plants. It seems to me various departments of agriculture have to be included in any kind of procedural evaluation because many times the question there is -- the important question is not so much whether the environment is being threatened as the

agricultural strategy is being threatened, whether or not a plant can hibernize very rapidly with a weed variety. And strategy of use of a transformed plant. So that may be quite different from what would happen with a micro-organism.

DR. DAVID SHINDLER: I think, Mr. Chairman, we are very much in the realm of speculation. When we talk about our farm plants we could speculate on all sorts of things happening but in practice most of the crops I can think of we use in the country are not genetically engineered and do not really spread like weeds. As a matter of fact, there is a lot of effort going into keeping them growing against all odds. I suspect down the pipeline the kinds of things that you might be looking at are analogous. Even if there were a new gene introduced, rather than thinking of these things as spreading like wildfire, we may have to do the same thing to really intensively farm them, to keep them growing, and that is the problem. I think that is our conundrum right here. We can speculate on what might happen but we are not doing it from a solid base. I think it is not a good idea to do that. Rather than do that, perhaps we might go to the other end of things, say what we do now and what the next step is in the genetic engineering revolution and what that may likely imply, and then identify the key problem areas.

Now, it is obvious that viruses introduced in plants as pathogens is an area -- there is a history of pathogenicity. There is a probability of spread in the environment. There are all sorts of things. Maybe that is an area we could discuss, where the problems are more likely to come at us much faster than discussing the revolution in terms of crop plants. I think it is up to groups like this to really pinpoint where problems are going to occur soon so we know where our regulatory challenges are going to be, rather than speculating on what might happen. I think Bernie's talk was in that direction, but I think we are going to have to be more precise than that.

Let's go from the concrete where we are now to where we think the next step will occur rather than looking way into the future. That would be most useful.

DR. V.N. IYER: Since the question I raised has not really been addressed, I want to sort of perhaps propose for discussion that we try and help this group here to focus on -- not so much on the procedure by which a biotechnological product, a live product, is made. We ignore that aspect and focus more on the use of the product, or the way that product is going to be used. That is what we are talking about when we talk the dispersal or releasing organisms, micro-organisms or

macro-organisms. We focus on those two issues and that would really imply, then, that we do not treat A, B, C differently from BBC or CBC, I forget.

In other words, not treating organisms that have been manipulated any differently from organisms which have been mutated.

DR. BERNARD GLICK: I think that is a good suggestion and actually for the sake of the discussion today, if that is more or less acceptable to people, I think maybe we should operate under that umbrella.

THE CHAIRMAN: So we do not exclude anything from the discussion but we discuss, if we are looking at use, which use presents the greatest potential problems and would require the more immediate attention.

DR. BERNARD GLICK: Sure, but look at all organisms, including plants.

DR. FRANCIS ROLLESTON: With the macro-organism, the sweet corn I buy off the roadside stands are a highly selective creature. It is BBC, that is for damned sure. Are we going to regulate it?

DR. BERNARD GLICK: In response to that, Francis ---

DR. FRANCIS ROLLESTON: It applies to recombinant pets as well. Just think of the trouble you could get into.

AN UNIDENTIFIED VOICE: I don't think the process is to regulate everything. I think we should try to find out if the new technology is going to require new regulations or will they follow the old regulations? Are we dealing in an environment we do not know? In other words, are we going to potentially create a hazard? I don't want to get into the scenario of doomsday or things like that but what we have to do with the new forms of life that we are going to be releasing into the environment with respect to touching up existing regulations, or whether they require brand new regulations? We are not obviously dealing with the regulation part, which is another conference and another paper, but I think with respect to the uses of that component, that becomes a bit -- maybe everyone can cite a little scenario, a little history or a little research that they are working on that may have a potential use.

I do not really think that is productive to what we are getting at here. If we all, one way or another, do feel that regardless of how the living product is generated, there is going to be a release of biological organisms in one way or another, what I think we should try to do is ascertain what people would be looking for in developing those organisms with respect to keeping the environment safe as possible.

If you look at elements with respect to

helping guidelines for people who are developing these organisms, where do they go, how do they go about preliminary testing, what are the requirements for preliminary testing, what are the criteria that we would establish for a hypothetical deliberately released organism? In other words, we should look at areas of pathogenicity and various things like that, the ecology and ecological impact. That might be more meaningful because it does not allow us to get into these sort of hair-brained scenarios which we may or may not quibble about but it deals with, I think, the areas in the broadest sense. I think that is the best you can hope for from such a diverse group. That is the way I am thinking, anyway.

I know Krimsky -- I think most of you have probably seen or read it -- prepared a paper called "Regulatory Policies on Biotechnology in Canada" and includes "Survey Uses of New Technology: Are There Any Problem Areas or No Problem Areas". I think that is where you want us to focus. I am not personally too concerned about focusing on that level. I think there will be uses, and I think we should go beyond that level in the context of what we are doing with the organisms to make that organism as potentially safe as possible, what are those features we would want to build into the organism.

We can genetically engineer it, anyway. That is where I am coming from. Everyone is throwing in their two cents before coffee. That is my two cetns.

THE CHAIRMAN: We are coming up to the time for coffee. I do not think we are going to be able to draw an exact box around the subject of today's iscussion. What I am hearing people say, though, is that difficult as it may be to define "genetically engineered", that we are looking at that and we are looking at the use and at the most immediate use applications, the most immediate problems, which have to be dealt with but that we will not exclude other subjects from discussion. With that sort of vague approach, my suggestion is that we continue on. I do not think it is going to pose a great problem, but I think, Penny, you are about to tell me that it is.

MS. PENNY CHAN: What I can see is this difficulty in distinguishing between genetically engineered organisms and the definition, but if you pursue the use problem, thinking genetically engineered, and then apply it to all organisms that come within that use, because what you will find is that you are defining uses by the areas that are going to be most stressed by genetically engineered organisms.

So once you get into that area of use, then you determine whether you have to distinguish

between genetically engineered by the A, B, C or the BBC method. And I think that is one way of focusing the discussion without getting too hung up on your definition before you start.

AN UNIDENTIFIED VOICE: Well, there may be others but what would be the type of characteristics you would want in a genetically engineered micro-organism that is deliberately released, or any organism? I just put these down while Bernie was talking -- I have heard Bernie talking before. Obviously, what you would want is a non-pathogenic organism, I would think. You would want an organism, if you are using it to replace an existing organism, without affecting its ecological impact but bringing in a new property without offending anything. You would want that organism that you were introducing into the environment to be restricted to that particular niche and not to invade other niches or other organisms and from the genetic engineering point -- and this is debatable, I am sure -- one of the things you seem to stress in your report is the non-transferability of the DNA either into or out of that released organism.

And I think these are properties that you would look for in any deliberately released organism for any use. That is where I'm coming from.

AN UNIDENTIFIED VOICE: We are going to have some problems. I do not think we can stop nature

from passing genes around. It happens all the time to those of us who have exposure to natural bacteria. Good luck, if you put an organism into the environment that things won't be passed around.

MR. BERNARD GLICK: We may be able to limit the extent that genes are passed around.

AN UNIDENTIFIED VOICE: The problem is how many years and how many hours, I would ask, non-pathogenicity, pathogenic to what? Humans? How? Trees? Insects? Sometimes you want pathogenicity. That's why you put it in there in the first place. B.t is the best example. Going back to what was said, the function of what you are producing is quite important because in some cases you want it to survive in the environment and in other cases you do not. In some cases you want it to be pathogenic and in other cases you do not. So it seems to me the first point he made about the function of the organism, what functions it may do, is perhaps the first thing that has to be addressed. Otherwise, one gets into contradictory arguments.

The general rule about a released bug that is not supposed to survive after a certain point is foolish.

THE CHAIRMAN: So you are getting back to the case-by-case and the use arguments. There is a comment here and a comment there and then I think perhaps

we should think about coffee.

AN UNIDENTIFIED VOICE: I think we are going back to MRC guidelines by the sounds of it right now. I am just sort of curious as to how many people are very familiar with the MRC guidelines for the recombinant DNA technology, to begin with.

Actually, Francis, you should be telling us a little bit more about how it is being updated. It seems to me that the 1980 guidelines which are used quite a bit still today are fairly stringent and have most of the attributes of what you are talking about.

AN UNIDENTIFIED VOICE: But the MRC guidelines from the very beginning were aimed at - inaudible. They did not even include fungi. Even the updates to the original guidelines. What we are talking about here is an area which was not really addressed, and that is the environment, and we come back to the environment protection, and what the environment is is a broad question. That is where the confusion comes in, what we are going to do with the organism. Sometimes it is contradictory and we end up with contradictory guidelines.

AN UNIDENTIFIED VOICE: One of the definitions which is used for assessment now is the number of cells per, another is giving a density factor more than anything else in the area. Although it sounds silly at the beginning, it makes a heck of a lot of sense

because, for example, in a plant all the cells, although they are very confined, the numbers are contained in one spot, the density is extremely high, therefore, it would fit the same definition as any micro-organism or its product being released, you know, if it reaches the same kind of levels , it could be a serious matter.

So it is a good one to look at. And I gather what you are really trying to focus on is release. In other words, we are not going to really deal with or interfere with any policy of the use of any component in that technology but rather the responsibility of how does one manage to release it, or components of it. My original fear is that I think it is the by-products of that, and how it impacts on the environment, that is really the one the industry really has to get the most harassment for or take more responsibility for.

DR. FRANCIS ROLLESTON: My problem is that someone did comment on the point about no pathogenicity, et cetera. The Delaney amendment in the United States was a fantastic amendment in the 1950s.. It said there should be no carcinogenicity or no toxicity, and with the levels of chemistry capable then, that was a perfectly reasonable thing to say. Now, with our capability of measuring things now in terms of minus 50 and in terms of minus 20, it no longer makes sense. I think the problem of any categorical statements of that type becomes all

the more -- (inaudible).

We have to recognize that there is going to be a release. We cannot get away from it. What we are trying to do is minimize risk to an acceptable societal level within our present technology. We cannot destroy it. Otherwise, we stay in bed and we get bedsores.

THE CHAIRMAN: I think perhaps on that note we will close this part of the discussion. This has been very useful and it is going to be central throughout the day. I have asked Bernie to sort the whole thing out over the coffee break. He will explain to us exactly what the focus and parameter of the discussion will be.

I would like to introduce Don Hart from Beak Analytical Services Limited who has joined us.

--- Short Adjournment

--- Upon Resuming:

THE CHAIRMAN: We are going to talk in the dark for a moment. That is not to suggest that we have not been in the dark. We promised you before the coffee break that we would sort out the whole question of what it was we were gathered to discuss here today. Bernie has done a fine job of that. The general consensus or the feeling is that any definition is better than no definition and that there is a crying need for an

arbitrary hand, so again Bernie has provided it.

What we are going to talk about is genetic engineering as opposed to more traditional methods of changing genetic makeup. And we are going to focus the discussion by means of use or application. What we would like to do is to spend a very short time -- we have gone back to the slide which provides a very comprehensive list of potential applications and we are going to adopt a suggestion advanced by Jack Pasternak that we basically vote as a quick decision-making method for deciding which particular applications are the ones which are going to be coming onstream fastest and providing the greatest environmental problems and, therefore, requiring a more immediate regulatory response.

What we would like to do is spend five or ten minutes and, as a group, decide which are the applications which deserve attention more than any others in terms of release to the environment, deliberate, accidental or otherwise, and then we are going to run through the rest of the day talking about those things. The way we are going to do that is, as indicated on the agenda, to talk again about the conceptual approach and to then talk in detail about the applications we have chosen and the environmental effects associated with each.

If you are willing to do this, I am hoping that Bernie can run us through this list and act as the facilitator so that in a very short time we will have agreement on the applications we are talking about.

DR. BERNARD GLICK: Before we recognize Vern ---

DR. VERN SELIGY: Is it just Canada , or the United States, when we start to go through this little vote, because the emphasis is different in the two countries.

THE CHAIRMAN: We are talking about regulation in Canada.

MS. IRENE COURAGE: It could be relevant that applications in the United States can lead to contamination in Canada.

DR. BERNARD GLICK: Is that really what you had in mind, Vern?

DR. VERN SELIGY: It is not just that, but some of these things do not really exist in Canada in the industries so in a way it's difficult to ...

DR. BERNARD GLICK: Now we can get into another whole issue. Some of these industries do not even exist in Canada.

MS. YVONNE SCOFF: I think what we are interested in is what would be meaningful in Canada.

DR. BERNARD GLICK: As Yvonne says, it

is what applications of biotechnology are likely to be used in Canada.

DR. VERN SELIGY: Using genetics.

DR. BERNARD GLICK: Yes. That does not necessarily mean developed here, but used here. They are different. I am not trying to be facetious, but a large number of these are obviously contained applications and, again, as I indicated, some of them are already onstream. I think alpha interferon has been approved in Canada for treating, what is it, haricell leukemia, and a human growth hormone has been approved in Canada as well.

DR. FRANCIS ROLLESTON: In some areas, yes.

DR. BERNARD GLICK: All right. Is there a sense, then, and I think that we are particularly interested in the environmental applications, is there a sense that anyone has as far as Canada is concerned that any of these, or other applications that we may have left out, are imminent, that we are going to see them within the next two or three years, for example?

AN UNIDENTIFIED VOICE: You just want to leave it at three years, Bernie?

DR. BERNARD GLICK: Well, expand your time frame, if you like. If you want to say two to five years.

AN UNIDENTIFIED VOICE: Or fourteen.

THE CHAIRMAN: Do you want to comment, Don?

MR. DON LUSH: Well, people have been talking about genetically engineered B.t. That is one potential application that may be coming down the road in the next few years, and you can expand that, but its potential application, that is one.

DR. EARL NESTMANN: Since our focus is on the environment, I think 1 through 12, I believe, we just do not need to consider, really, at all, because they are not intended for deliberate release into the environment.

DR. BERNARD GLICK: That is right.

THE CHAIRMAN: Excuse me. I should mention again, for the benefit of our reporter, that it would help quite a bit if we could just say our names. So your suggestion is to knock out 1 to 12 and go from there?

DR. BERNARD GLICK: With the exception of No. 3.

AN UNIDENTIFIED VOICE: The Ministry of the Environment is looking at situations now on the application of wild rabies vaccine in the environment from one form or another so I think that that is an issue before us at the current time and, obviously, has to be left in in our current considerations.

DR. BERNARD GLICK: Just apropos to that comment, I do not know if it is in the report or not but there was a report, I think it is in Science again, within the last couple of weeks, of a vaccinia vaccine against rabies that was effective by oral administration in protecting foxes against rabies so that would be very important in terms of that program.

MR. GOFF JENKINS: We are trying to get some more information on what the actual wild vaccine innoculation program is being conducted at the moment but we do have information that they basically are conducting one in Ontario. We do not have the information yet on the actual virus they use or how they produce it but we know they will be looking at these aspects of the new vaccine in the wild.

DR. FRANCIS ROLLESTON: Vern made a point this morning about the chemicals that go into the environment. When one talks about the pharmaceuticals, hormones or these kinds of things, feed to animals in large quantities and then get into the streams, the water systems and start affecting fish and so on, are we disregarding that, are we dealing only with agents which can reproduce themselves? We never really answered Vern's question.

THE CHAIRMAN: The decision has been made that we are dealing with agents which reproduce.

MR. TERRY McINTYRE: I agree with Earl up to a point, assuming none of those involved are produced in Canada. One of the faults -- inaudible -- largely reflected in a recent PA study consisting of biotechnological production facilities in the United States. It indicated the two problem areas were in the waste characteristics and the adequacy of the existing pollution control devices dealing with biological detection of the waste systems.

AN UNIDENTIFIED VOICE: Could you say that again? Did you say none or always?

MR. TERRY McINTYRE: Inaudible.

DR. BERNARD GLICK: Doug has suggested I try to focus things a little bit. I think we are more focused but he has asked me to just run through, to some extent, the list, so I will try and do that.

No. 3, we have identified a vaccine against rabies as the most likely candidate for use of live vaccines. Are people happy with that? Are there other anticipated uses in the near future that people can see?

DR. V.N. IYER: It is possible that animal vaccines are used but I guess there is nobody here --

DR. BERNARD GLICK:

The people from Canought were invited but they are not here.

DR. VERN SELIGY: Would it not seem reasonable that live vaccines are going to be used in one way or another for release in the test situation within the next five years?

DR. BERNARD GLICK: Yes.

DR. VERN SELIGY: I don't know what they are. I am just taking a guess. But it seems reasonable that that is the way things are going. I might not know the specific virus, but ---

DR. BERNARD GLICK: Vaccinia viruses ---

DR. VERN SELIGY: But I can make an uneducated guess.

DR. BERNARD GLICK: --- have tacit approval from the World Health Organization if that, Vern, is at all useful.

DR. VERN SELIGY: Did we start with No. 1? What do we not start with No. 1?

DR. BERNARD GLICK: All right.

DR. VERN SELIGY: Yes, there is at least one industry that is involved with that, or in the planning stages.

DR. FRANCIS ROLLESTON: But in the sense of environmental problems.

DR. VERN SELIGY: Very well. I thought you were asking me to identify -- first of all, if that is going on in Canada, therefore, it is relevant, and the

answer is yes, within five years.

DR. BERNARD GLICK: Subunit vaccines to what?

DR. VERN SELIGY: I can't tell you. But, you know, there is an industry that is definitely moving into it.

DR. BERNARD GLICK: Canaught and Vido. And CAL? All right. I am going to move down all the way to ---

DR. VERN SELIGY: No, let's just walk down the list.

DR. BERNARD GLICK: All right. No. 2. By synthetic vaccines, what I meant there is peptide vaccines that mimic the antigenic determinant generally of viruses and, as far as I am aware, this is far from fruition in Canada.

DR. VERN SELIGY: It is being considered right now.

DR. BERNARD GLICK: All right. It is being considered.

DR. VERN SELIGY: With the university and industry and the hospital.

DR. BERNARD GLICK: So there is an industry interested in this? I would suggest in that case this presents very low risk because we are not dealing with organisms of any type whatsoever. We are

dealing with peptide chemistry. All right. No. 3.

THE CHAIRMAN: Is there anything else to be said about No. 3? No. 4?

DR. NEIL GRAY: Yes. There is at least two companies that are interested in diagnostics -- inaudible.

DR. BERNARD GLICK: Five? Six?

AN UNIDENTIFIED VOICE: Well, sort of.

THE CHAIRMAN: We will go with the "sort of". Seven?

DR. BERNARD GLICK: No. 7 is all over the place.

THE CHAIRMAN: No. 8?

DR. FRANCIS ROLLESTON: I think, gentlemen, what we are going to come up with is an answer of "yes" to all of these. What we need to do is to identify two or three on which we can focus from the point of view of environmental aspects.

THE CHAIRMAN: I am assuming we will do that when we get further down the list.

DR. FRANCIS ROLLESTON: Then expect to get a "yes" to all of them.

DR. BERNARD GLICK: All right. We can save time going through the list.

AN UNIDENTIFIED VOICE: They are either being researched or commercialized at some stage of the

process right now, all of them.

MR. GOFF JENKINS: Basically, you see, yes, all of them are going to be in the industry. As for the first twelve, I think the first aspect of concern we would have is in the waste stream characteristics as was mentioned a few moments ago. None of those would really be in the category of immediate deliberate release, with the exception of the live vaccines.

This is the very topic which is the only aspect of the first twelve, but which is really planned for deliberate release where we will have that type of problem. The other twelve, or the first twelve, is more waste stream characteristics that we would have to discuss from that aspect.

THE CHAIRMAN: Thank you, Goff. Is there agreement with that, that No. 12 will only be considered in terms of waste stream, other than the No. 3?

MR. GOFF JENKINS: The first twelve.

THE CHAIRMAN: The first twelve, I am sorry. Why do we not then continue on going down the list from there and in terms of applications with environmental implications?

DR. BERNARD GLICK: No. 13.

DR. BOB WATSON: I think this is one which will be applied very soon. There are certainly

pseudomonads used a lot and it is a very simple matter to modify them -- inaudible.

DR. BERNARD GLICK: Two questions in that regard. What sorts of modifications would you see being made to the strains of Rhizobia to improve them and what sort of time frame are you talking about?

MR. BOB WATSON: I think that modifications could be made right away. Simple modifications would simply to market the strain. One could add certain antibiotics -- inaudible. As it is now, one cannot tell one Rhizobian strain from another -- inaudible. And that is the simplest and can increase in complexity up to putting in genes to make bacterios to make it more susceptible to soil, to increasing the dosage of -- inaudible. And any one of them can be done now.

DR. BERNARD GLICK: So you would see, for example, marking strains as something, certainly within the next couple of years, and the other applications that you mentioned, a little bit further along?

MR. BOB WATSON: Any one of those things could be introduced and I am surprised it is not right now.

DR. BERNARD GLICK: You describe it as imminent?

MR. BOB WATSON: We have marked strains and could give them tomorrow to anyone who wanted to use them.

DR. FRANCIS ROLLESTON: Did I hear you say the institution of this activity is pending some certainty of the legislation?

DR. BERNARD GLICK: I am sorry. Could you say that again?

DR. FRANCIS ROLLESTON: I think I heard in your opening comments just now that they were waiting regulatory provisions before they went ahead, is that correct?

MR. BOB WATSON: I guess I couldn't say that. I'm not familiar with the companies involved. I believe, Bernie, that you mentioned there has been applications in the states for Rhizobium. That's not the type of information that would come to me, but I know there has been mention of improvements to be made to Rhizobiums which have been made now and will be made, supposedly, by industry, and I think many companies would want to introduce them if they were able to.

DR. FRANCIS ROLLESTON: I lost the last words.

MR. BOB WATSON: There are many mechanisms of using them.

DR. FRANCIS ROLLESTON: So they are

waiting for the kind of things that we are discussing. That's very important, I think.

MS. IRENE COURAGE: Would anyone know whether the current Fertilizers Act would apply, and if so, is it sufficient?

MR. BOB WATSON: If I may answer that, the Fertilizers Act I do not think applies because it does not handle genetically engineered micro-organisms. The people at Agriculture Canada would shy away from approving micro-organisms because it was giving us fertilizers not ---

DR. BERNARD GLICK: I am sure they would pass the ball on to someone else.

MS. IRENE COURAGE: That is not due to the Act as opposed to the legislation itself? They could do so if they felt confident.

AN UNIDENTIFIED VOICE: I don't know if it is in their mandate to do it or not. It would certainly come to them. All bacteria used as fertilizers has to go through Agriculture Canada. They would have to go through them/and those people would make some type of decision. I do not know whether there is a mandate to release these things or not. I don't think so.

DR. NEIL GRAY: Bernie, there is an application going on right now using --- inaudible.

DR. BERNARD GLICK: That is fair enough.

DR. V.N. IYER: Concerning the Rhizobium, are they only talking about DNA procedure or are they also talking about genetically marked strains? I think there are probably many people who have used genetically marked strains - inaudible.

DR. BERNARD GLICK: DNA as designed now excludes organisms that are made by conventional methods.

DR. FRANCIS ROLLESTON: That is true but I do not think it is binding upon this organization

R. V.N. IYER: Than the organization has to retain DNA.

AN UNIDENTIFIED VOICE: If I can clarify, what I say is that you can genetically -- inaudible -- and in this way you have complete control over the way you do it. You may get better resistance which is not present at that level and done in a way that you re more sure that you are not altering some of their - inaudible -- bacerias.

DR. BERNARD GLICK: Let's move for the momentto No. 14, microbial pesticides. I wonder, in eliciting some comments if we could get a couple of people from companies that have some interest in this area, although I won't single you out. If we could get

some comments on what they see as applications in this area and estimates of the time frame they see. There is at least a couple of people here who can tell us that.

DR. EARL NESTMANN: The Entomological Society of Canada recently published a booklet which should be useful in respect to this question. It is entitled "Microbial Insecticides in Canada: Their Registration and Use in Agriculture, Forestry and Public and Animal Health". There are quite a few of those microbial insecticides used in Canada and each and every one of them likely is going to be subject to more genetic manipulation and improvement by various people who have these products now.

DR. BERNARD GLICK: What do you think is the time frame? It is suggested it is current but as far as improvements, let's say, using the technologies we are talking about?

DR. FRANCIS ROLLESTON: I would guess we will see them when they arrive. There is the cost, the economic spheres. They are competing and are going to be pushing. I think we have to regard that as actually in a very short time period. It's merely a matter of modification of existing technologies.

AN UNIDENTIFIED VOICE: Let's face it, Bernie, any company in B.t has looked at genetics and it is the total economy that is going to rule, if you

want, with the social issues which will go with it, whether it's ever released.

DR. BERNARD GLICK: Do you have an extra copy of that booklet?

DR. EARL NESTMANN: This isn't my copy. I borrowed it from the office but I will pass it around and you can all take a look at it.

MS. IRENE COURAGE: You are dealing with these problems with pest control products and pesticides. Do you find that the application of these two pieces of legislation is working properly or do you feel you are hindered by it or are there gaps in the administration of it? Am I going too far into the policy side?

THE CHAIRMAN: I wonder if we might be able to hold on that, Irene? Have we arrived at the point of turning the lights back on? I think, Bernie, you wanted a comment from industry. You got it from one side of the room and you want it from the other side, is that what you want?

DR. BERNARD GLICK: Well, I think we had some comments. Is there anything else that remains to be said about microbial pesticides? I think we are all aware of applications for approval for field testing of microbial pesticides in the States, so I don't know whether we need to ...

DR. VERN SELIGY: There was one point that was brought up earlier. It seems to me there is a bit of distinction which should be made, especially on the regulatory side. The virus classification depends upon an organism to be able to generate either the episodic or propagate itself where the micro-organism is capable on its own to propagate itself. I think that's an important distinction and may provide later some avenues of control.

DR. BERNARD GLICK: You are suggesting that by definition ---

DR. VERN SELIGY: I just think earlier on the record one may have gotten the impression, because there wasn't enough time to have a discussion about it, but really I would think that I would be more concerned with the relation of a microbe that is capable of fully replicating itself rather than a virus.

DR. BERNARD GLICK: Which is dependent on its host ---

DR. VERN SELIGY: Because you engineer those very, very tightly to whatever.

DR. BERNARD GLICK: Does anyone want to comment on that? I think it is an important point.

DR. VERN SELIGY: What I'm getting at is when you are talking about recombinant DNA, you can engineer that, so there appears a much more tighter

restriction.

DR. BERNARD GLICK: Do we know that much about host specificity, David?

DR. SHINDLER: I would be very interested to try to engineer a virus which only had one host, that specific. I mean, it may be forty years down the road. I don't think it is possible now.

DR. VERN SELIGY: The one thing that is clear is that it is true we don't know much about the host strain, in fact what determines it. If anything, the trend might be to go the other way, to try to broaden the trend. I agree with that. But what I am trying to point out is in terms of recombinant DNA technology, you can make something very, very specific in the long term, not in the short term, but I think that is part of what the intention is, is to define very precisely what the specie is and that, of course, is appealing to patents as well.

THE CHAIRMAN: No. 15.

AN UNIDENTIFIED VOICE: Perhaps we should remove No. 15 from the list because we are talking about recombinant DNA and then covering it in No. 16. And I believe registering plant species after hibernization is already something that is fairly well established.

DR. BERNARD GLICK: No. 15 may not be an issue of environmental concern.

AN UNIDENTIFIED VOICE: I don't think we should discuss that here. I think it has already been eliminated by our previous discussion.

DR. BERNARD GLICK: Good. Let's jump to No. 16, and let me throw that back to you, Neil.

DR. NEIL GRAY: Well, they are already doing things in the States and certainly trying things elsewhere. So, yes, people are going to, in the very near future, be making efforts in that direction.

MR. DAVID SHINDLER: Just following our previous discussion, the question is that it has environmental impact but not of the same unknown order of magnitude that we are looking at with viruses and microbial species. I think there is a difference is. If we are using the stock from conventional farm plants, as we discussed earlier, I would ask the group if they want to include it as an issue of concern or an issue to look at?

AN UNIDENTIFIED VOICE: I think it should be excluded from our discussion.

DR. BERNARD GLICK: Let me raise the question to Neil, for example. What about engineering plants that are pesticide resistant and then the possibility or the potential of transferring that pesticide resistance to weeds, for example?

DR. NEIL GRAY: That depends on how the

plants are hibernized to other species. I don't believe that -- this is a point we make earlier. Trying to get the plants to grow is the real problem. There are a few plants which will probably out-cross such as brassicas and, I believe, it is more of an agricultural problem than an environmental problem. So I would really think that --

DR. BERNARD GLICK: Are we selecting also for, in this case, for situations where we use excessive amounts of pesticide because we select for pesticide resistant plants - or herbicides, I'm sorry.

AN UNIDENTIFIED VOICE: That is a different kind of problem from what we are discussing around this table, I think. That is an agriculture intensity problem. That is not a problem, I think, we are discussing today.

DR. BERNARD GLICK: All right.

AN UNIDENTIFIED VOICE: It is really nice to remove that one and concentrate primarily on microbes and viruses where control is perhaps a more difficult thing once it is in the environment. As I say, registering plant species and new varieties is already a process that is in order.

THE CHAIRMAN: But your reason for removing it is a regulatory one, not a science one, if I understand you?

DR. NEIL GRAY: You know, we are

in a situation here that scientists -- at a seminar where a bunch of scientists ad hoc are sitting down and trying to decide a future direction, what is going to be included and what is not going to be included. I think a few months after the seminar, where everybody walks away with a headache saying: "What the hell did we do there?" I think some committees of experts who have a little bit of time to study the situation really provide far better direction. It has happened with the MRC prototype that we might consider coming out of this committee and perhaps Francis will talk about how the subcommittee is defined, pathogeny and organisms that people could sound alarms to. Sure, people are going to genetically engineer plants but it is a definitely different, different, different situation than putting pesticide resistance into a bacteria that is going to have at the roots of the plant.

DR. FRANCIS ROLLESTON: I both agree and disagree with Neil. I agree with him in the context, obviously, of the simplicity of control, as we use the word, a chain saw or a side or something -- inaudible. However, we are dealing also in a public reception, political reception problem, and I have a feeling that the same comment that I took up with you, Bob Watson, I am also concerned with respect to industries that want

to start trying to revise plant species for economic benefits. I think that as regulators and also as people interested in the economy of the country, on both sides, we have to address this issue. So I would feel that despite the apparent regulatory simplicity, in terms of public reception, and so on, some of the other issues about outgrowth and so on, I think we need to keep this one under consideration.

MR. GOFF JENKINS: I think we have to have consideration on a slightly different viewpoint and that's because I disagree with the concept that it is easy to control a genetically engineered plant which suddenly gets out of control in the environment. If anyone has had to deal with aquatic plant species, once they become a nuisance and has tried to deal with the fact that there is no means of controlling the spread of these aquatic plants through the water systems in North America, and if you ever proceed to the situation where aquatic plants or weeds species became resistant to one of the only two herbicides we are allowed to use in the natural environments today, we would have a hell of a mess on our hands and there would be no way of harvesting or any approach like that to control that plant once it is out there. I think we still have to realize there may be a concern with these engineered plants encroaching on the environment they are actually set up in.

DR. BERNARD GLICK: All right. Let's move down to No. 17 which we can see, microbial waste treatment. I think this is likely to be a fairly big area of application. I wonder would anyone like to comment on this? Just a variety of possible applications that I can think of here.

DR. MICHAEL SALAMONE: Last year we were confronted with proposals on microbial waste treatment, in fact, of PCBs and PAHs and other anti-progenic chemicals, so I am sure that we are going to see a lot of this in the near future, particularly on organic chemicals which are produced by man.

DR. BERNARD GLICK: Any other comments?

AN UNIDENTIFIED VOICE: To a lesser extent in the food industry, of course, in protein production, certainly in Europe, and also in terms of the meat industry, too, but I don't know how far that would go in terms of engineering. But I would imagine, certainly, they are doing that in some cases -- inaudible. But I wouldn't rate that very high.

AN UNIDENTIFIED VOICE: I think right now one of the most immediate problems the Ministry of the Environment faces is the situation with microbial waste treatment. We are receiving applications now from all different aspects of industry, from the pulp and paper mill industry, which is very active in this field

of looking at microbial treatment, waste from the food industry, from all aspects, and I think this is certainly one of the most immediate things which is impacting on us, how to deal with this specific situation.

AN UNIDENTIFIED VOICE: Are these engineered organisms?

AN UNIDENTIFIED VOICE: Yes, they are engineered organisms rather than mutated organisms, and we know there is a lot of research currently being carried out which has not been reported to us for actual application of the research because of the fact the companies are simply not sure exactly what the regulations coming out are and they are waiting for that research and development going on at the moment.

MR. TERRY McINTYRE: In addition to that, Environment Canada, in co-operation with the National Research Council, under the National Wildlife Development Strategy, has established a network which is looking exclusively at the application of biotechnology, pollution control and waste treatment -- inaudible.

THE CHAIRMAN: So in a sense it says this one is fairly high on the list in terms of immediacy in terms of the need for attention.

DR. BERNARD GLICK: All right. It is getting harder and harder to see. No. 18 is microbial ore leaching and, certainly, as I indicated before, at

least I am aware that both copper and uranium mining involves both, I believe in the United States and in Canada, involve the use of micro-organisms. I am not aware that genetically manipulated organisms have been used in this way. Does anyone want to comment on that? Do we see an immediacy in terms of the use of genetically manipulated organisms in this regard? I am not aware -- most of this is, I think, Thiobacillus, and I am not aware that this is an organism which has been manipulated very much from a genetic point of view.

DR. VERN SELIGY: Certainly, in the industries I am aware of, the staff we have had contact with are very well educated on the subject. In the United States there are some fairly close to home who we are in contact with, General Electric, for example, but in Canada I was really quite impressed with how progressive their attitude is on that subject. No one has really discussed exactly what they are doing but I think it is in good hands.

DR. BERNARD GLICK: What do you say the prospects are for genetically manipulating these organisms?

DR. VERN SELIGY: Very good. The key thing, really, at this stage, is in ingenuity aspects, looking for new gadgets, so to speak, competitive edges. The main thing about it is that there is an

education already there which quite often is not in other sectors of the industry.

DR. BERNARD GLICK: Well, I guess my question from the scientific point of view is are there vectors, are there transformation systems, are there markers to do these kinds of things?

DR. VERN SELIGY: There are vectors.

DR. BERNARD GLICK: For Thiobacillus?

AN UNIDENTIFIED VOICE: Yes.

DR. CLARE FRANKLIN: The OTA document predicted there would not be much activity in this area for about ten years, mainly, because of the depressed price of base metals, so I think you are not looking at the short term. There may be a lot of interest in perhaps research but it is not a reality in the near future, according to the OTA.

DR. VERN SELIGY: But it is not being done in the United States as much as it is outside the country. It's one of those basic -- classic basic research type areas. It is very clearly being done to a very serious extent. It may come onstream a lot faster because of -- inaudible -- General Electric, what they have done is taken an organism which is parallel to biotic source and has focused on that to work out some of the details for transformation.

I would not say it is ten years. I

would say it is a heck of a lot closer. I would say it is within the five year parameter.

AN UNIDENTIFIED VOICE: Just to make a general comment, I think around the table we have heard one thing and that is feasibility in terms of research is here, but the actual application or when it will come onstream into society is questionable. I think the sense is that even in organisms that are difficult to manipulate, in the relatively short period of time you could expect that could be done, not necessarily will be done, but could be done. But that is different from saying it is going to be released into the environment in two years. I would just like some clarification from the Chair on that point. Are we talking about what is going to be applied or what we could apply?

THE CHAIRMAN: To the extent we are able, we would like to get a feeling from the group of what is going to be applied as opposed to what could be applied.

AN UNIDENTIFIED VOICE: Thank you.

MS. IRENE COURAGE: Just for clarification, if you are talking about researching these organisms, are you also talking about performing tests in the environment, outdoors tests, or are you just talking about thinking of models and having tests within the laboratory?

DR. VERN SELIGY: Well, for that parti-

cular area, it has to involve outside activities.

MS. IRENE COURAGE: And is outside activity currently taking place without any regulation?

DR. BERNARD GLICK: Not for genetically manipulated organisms.

AN UNIDENTIFIED VOICE: Do we know that?

DR. BERNARD GLICK: Do we know that? Well, I am not that cynical. I think, you know, just in answer to that comment, I think it is to the advantage of most large companies to stay within the guidelines and I think it would only be a small company which would breach the guidelines, and a large company has much more to lose.

I wonder if we could move to the last item on the list, No. 19, which is microbial oil recovery.

DR. VERN SELIGY: May I add something?

DR. BERNARD GLICK: Yes.

DR. VERN SELIGY: There is a biomet that is -- Claude says it is "canmet", but I think that -- "biominet", that is it. In other words, as soon as you can identify there is a network in the country on it, and you can pretty well be sure there is now orientation towards the application, so ---

AN UNIDENTIFIED VOICE: Can I just provide some comments on that, if I could, Mr. Chairman?

That network is to assess the feasibility of doing some of these things. As far as I can see, there are no reports that I know of about distinct genetic engineering work being done within that network. They are looking at the feasibility of doing it not actually doing it. Whether or not individual companies are actually doing it in-house, I could not say, but that is the state it is in at this particular time.

AN UNIDENTIFIED VOICE: I don't think you are going to see many reports from these companies.

AN UNIDENTIFIED VOICE: I think that's one of the things that might be slowing things up right now in the actual forging of activities in this area is the fact that there would obviously be concern on any company's part -- inaudible -- that is small field trials to assess their own research and then suddenly be forced into admitting that and being forced to face the consequences of that. That is why we don't have a really good handle on what is going on.

DR. VERN SELIGY: We have one staff member in our section that is specifically targeted to interface in that area. He has been active for the last two years. So all I can see is that it is going to be very big and very interesting.

DR. BERNARD GLICK: All right. If we can just have a quick look at comments, really, on the

last item, No. 19, microbial oil recovery. I am not aware of very much activity, certainly, in Canada, in this area, but I do not know much about this area. Does anyone have any comments?

DR. FRANCIS ROLLESTON: Well, oil is obviously in short supply right now.

DR. BERNARD GLICK: This is very true and perhaps your comment is that activity in a large number of areas is dictated very much not just by the science but by the economics.

DR. R.C. WYNDHAM: I was going to say in that area that it's mostly microbial products which are the cutting edge of oil recovery now rather than using micro-organisms.

DR. BERNARD GLICK: Are the Polyceterites necessarily separated from the organisms or are they used as killed organisms?

DR. R.C. WYNDHAM: I think the tendancy is to avoid putting organisms into the ground.

AN UNIDENTIFIED VOICE: Precipitated protein is not very good on a cracked oil well.

DR. BERNARD GLICK: I wonder if people feel there are things which should be on this list we have not included?

DR. V.N. IYER: Bernie, where does the ice bacteria come in?

DR. BERNARD GLICK: I would think of it as a microbial pesticide. The ice-minus. Ice-plus is the natural one. Ice-plus bacteria, I gather, is under consideration for use in conjunction with ice-making machines in resorts.

AN UNIDENTIFIED VOICE: That is natural plus.

DR. BERNARD GLICK: Perhaps we need a category, No. 20, which we call "miscellaneous".

DR. JACK TREVORS: What about organisms used in the food industry such as Thiobacillus or some of the strep strains? David and I were at a conference recently in the States at Miles Laboratories. Genetically engineering strains are useful to the food industry.

AN UNIDENTIFIED VOICE: They are actually using them, too. I don't know how.

AN UNIDENTIFIED VOICE: But it might be a category, since there is a possibility of -- inaudible.

DR. BERNARD GLICK: What sort of applications do you envisage there, let's say, in the near future, for example?

AN UNIDENTIFIED VOICE: Well, fog resistance is one they are going for.

DR. BERNARD GLICK: So replacing traditional strains which have been traditionally used in

the food industry with strains which are resistant to bacteria, for example.

AN UNIDENTIFIED VOICE: European countries are involved in this, too.

DR. BERNARD GLICK: Anything else? These are pretty immediate, again.

AN UNIDENTIFIED VOICE: Very much so. I would be interested in seeing how they get through the legislation here in Canada under the Food and Drug Act. Not what you term "environmental".

DR. BERNARD GLICK: That is a very good point.

DR. CECIL FORSBERG: The other aspect that you have passed over is bio mass utilization. Depending upon what level you are looking at, for example -- inaudible.

THE CHAIRMAN: Could you speak up a little, please.

DR. CECIL FORSBERG: You can think of things in composting through ruminant digestion. Certainly a lot of activity is going on as far as manipulation of organisms going into the systems and that is an area of release of -- inaudible -- the full range of things as well which is coming onstream at some point.

THE CHAIRMAN: It is ten past twelve. We are coming up to time for lunch. I think this has

been very useful. What we have done in the morning is decide what we are going to talk about in the afternoon. Bernie will give us the list and then we can -- I will give us the list as I, in my untutored manner, understand what we are going to be talking about. As I see it, in the afternoon we will be talking about a general conceptual approach, then the particular applications we are going to be talking about are vaccines and primarily in terms of rabies, Rhizobia in terms of nitrogen fixation, pesticides, and I guess the two there would be B.t and the ice-minus. Engineered plants, we kind of were a little "iffy" on but we kept it on until we get it knocked off, microbial waste treatment. And that was pretty well my sense of the list. Oh, there is the food industry organisms which have been added by Bernie. And we have just added bio mass utilization. So unless there is strong disagreement, it is those applications which will form the basis of discussion for environmental effects.

DR. VERN SELIGY: Under the pesticide one, I think it would be good also to include the counter to the B.t which is nBt which is -- inaudible -- insect viruses would still have that potential because they are actually being developed as well. If you look at that little booklet that Earl was passing around, it is quite well qualified.

Just at the end we had some discussion about food additives or cattle feeds which include live organisms for ruminant feed, for instance, the idea of adding some organisms or yogurt starters. Maybe that does come in the list somewhere. I don't know if it caught very well in the other categories.

DR. BERNARD GLICK: Yes, we did add that.

DR. VERN SELIGY: Okay. What is it called?

THE CHAIRMAN: Food industry. Before we break, are there any other comments, suggestions or thoughts? In that case, thank you very much, we will break and reconvene at 1:30. I am not quite sure how lunch works, but I think there are sandwiches around somewhere and we are basically just going to wander around buffet style with sandwiches and coffee.

--- Luncheon adjournment.

--- Upon resuming at 1:15 p.m.

THE CHAIRMAN: The agenda for this afternoon's discussions are more or less as set out in the printed page that you have before you. We were quite successful this morning in reaching agreement on the major applications which should be the subject of the attention of regulators in this country. What we would like to do now is to spend a certain amount of

time -- and we will keep this flexible and see how the discussion unfolds -- on the conceptual approach to regulation and, for these purposes, Bernie has put up one of his slides and we will be running through that and talking about the different elements and their use in the regulatory -- or an approach to understanding environmental protection and environmental effects.

As you can see from the agenda we are hoping to talk about effects associated with particular applications and to the extent possible, I am hoping we can go through the applications we have agreed are, through a combination of both science and economics, the ones which are most likely to be coming onstream earliest and see what agreement we can reach as to the potential environmental effects associated with each, which regulation we will have to address, to the extent possible dealing in fact rather than speculation. Then we will close with a brief discussion of what all this means for the policy process in Canada.

David Shindler will spend a minute or so telling us what the Ministry of State for Science and Technology and its sister agencies at the federal level are doing, the process they are engaged in and where that is going to be going.

I will again speak for just a minute about our program and where we will be doing. I think

we will just have a general sort of discussion on any thoughts you people have on the development of regulatory regime. And what would interest me particularly is hearing from the viewpoint of a scientist who has to provide the information which is the foundation for policy and regulation, any thoughts that people have as to how that can best be done.

So with that in mind, my suggestion is that we start. I thought we would leave the lights on for this discussion. I will turn things over to Bernie who is going to lead us through the discussion of the conceptual approach.

DR. BERNARD GLICK: Perhaps before we get into discussing probabilities, the question was raised earlier, and I think it is worth raising again, that is to what extent a genetically engineered organism is different. Let me start off by saying that I don't think they are very different. Having said that, let me throw it open. Is there a comment here?

MR. BOB WATSON: I would say they are different in a way that we have had modified --

THE CHAIRMAN: Bob, could we ask you to speak up for the benefit of the reporter?

MR. BOB WATSON: We have had modified organisms being used for a hundred years, anyway, or more, and we know pretty well what we are up against and

we are not really concerned with them here now. I think, though, that we can define a difference in that any bacteria that is genetically engineered at some point, you have to do particular manipulations. The end result may be the same as the older techniques in some cases, but if you purify the DNA from an organism, modify it and put it back, then by definition it is genetically modified by recombinant DNA techniques. I think then you can draw that distinction quite clearly.

DR. V.N. IYER: I think what we are concerned with over here is not -- it is quite easy to establish a definition as Bob Watson has just pointed out, the issue is does an organism constructed the way Bob has just talked about, pose any risk that is greater or less than an organism that is coming from nature?

For instance, the issue seems to be that if you have a group of organisms or micro-organisms in an ecologically contained environment, and if you introduce a new organism, regardless of how that organism is constructed, does it change the existing environment or the existing population balance so drastically as to cause some foreseen or unforeseen harm? That is the issue. And from that point of view, I don't think that recombinant DNA new organisms -- there is any evidence to suggest they are going to pose a different environmental risk. Possibly a given

DR. BERNARD GLICK: It is not a unique threat. It is the same as any other micro-organism.

DR. V.N. IYER: Let me take an example, you used -- in the morning you used Rhizobium Cheponicom, as an example. Rhizobium Cheponicom, as far as I know, was not native to North American soils. It was introduced here along with soybean. No one, as far as I know, has really even studied the question as to whether the introduction of Rhizobium Cheponicom to North America has changed the micro-biological balance. The question has not been examined because presumably there was no need to examine it.

So I am not trying to argue from that one example that the introduction of any new organism is/not going to pose a threat. The question is really, you know, whether simply by virtue of constructing an organism by neutral methods you are increasing the level of risk. That is the question that I raise.

DR. BERNARD GLICK: The point about Rhizobium Cheponicom is a very good one. Are there any other comments?

DR. VERN SELIGY: I think there is one that is fairly interesting which should be brought up. That is that the simple transfer of, say, even a defined piece of DNA, whether or not that organism will change in response to it, and last year in Science a group of

people from collaborative research published a paper indicating fairly clearly that either by selecting naturally or by applying some pressure by mutagenizing that transformant, after the particular DNA was transferred over, they could get not only an increased performance but some other production of the protein coming from the gene that they transferred, and also some other properties of the organism,which sort of implies, and I think this is worth - coming from the genetic side, that we all realize that there can be improvements but we don't really know all the rules yet, the improvements, or the other way around, how it will turn.

But what does appear is that almost every construct that has ever been made so far is probably much more debot (sp?) when you test it against the salauge (sp?) or the wild type against - inaudible. So while we might be enhancing its performance in one defined environment, it does not necessarily mean that that applies to all the environments that that thing might seedif you released it. That probability is that it will perform less and survive.

DR. BERNARD GLICK: Maybe we should just run through some of these probabilities. I guess the first ---

AN UNIDENTIFIED VOICE: We can't pass up the point Bob, I think, has made very clearly, which is that

it is often the assumption, as a matter of fact, almost always the assumption, that a genetically engineered organism is dangerous, and put against what nature produces, I don't believe there is a different probability of danger.

DR. BERNARD GLICK: I don't think Bob has suggested that.

AN UNIDENTIFIED VOICE: He has suggested that.

DR. BERNARD GLICK: No.

AN UNIDENTIFIED VOICE: He has suggested that to some extent. He said is there a difference -- did you not say is there a real difference in constructing something using recombinant DNA? Is it more dangerous than what is produced in nature?

DR. BERNARD GLICK: I understood his comment to suggest that there is not a difference, in fact.

AN UNIDENTIFIED VOICE: That is what I said. I am agreeing with him.

AN UNIDENTIFIED VOICE: Then Vern made a point which I am not quite sure whether it was in disagreement or agreement.

DR. VERN SELIGY: Actually, in a way, what it is doing is reinforcing to some extent, but that

brings in another point which is that this is a catarologist transfer that we are dealing with.

AN UNIDENTIFIED VOICE: Which often occurs in nature.

DR. VERN SELIGY: It does not.

--- More than one person speaking at the same time. (Inaudible)

AN UNIDENTIFIED VOICE: Ground negatives don't go across the species.

DR. VERN SELIGY: Pardon?

AN UNIDENTIFIED VOICE: Ground negative bacteria do not go across the species.

DR. VERN SELIGY: What I am really including at the same time -- inaudible.

DR. V.N. IYER: I understood what Vern said to imply that the techniques of recombinant DNA actually pose a lesser risk not a greater risk than natural recombinant.

DR. VERN SELIGY: Yes, but at the same time there is another element one can add to that, that people, without much knowledge about the subject, look at it and say: "We can cite an example where this organism is actually doing this job and it seems to be producing a deadly product", and whatever have you, but the actual environment is quite narrow and if you took that organism outside that environment, its performance would be much less.

AN UNIDENTIFIED VOICE: So you are supporting Bob, as I am also supporting him, and I would like to underline that.

DR. CECIL FORESBURG: I would like to support the position put forward as well.

AN UNIDENTIFIED VOICE: It seems what Bob said this morning talking about the fertilizing organisms, that the Department of Agriculture wouldn't touch it - I am using my words -- if it was a genetically engineered organism, so obviously there is some perception that a genetically engineered organism is fundamentally different than the kind of organism developed through selection and mutation and possibly there is a perception, and I think it is a very important phenomenon, that if it does exist, there is ever going to be any regulation of recombinant DNA organisms that has to come to grips with.

MR. BOB WATSON: If I could comment on that, I think the government won't touch it because it would not know - inaudible.

AN UNIDENTIFIED VOICE: I think that is the key point. Why would they think it would be different from any other organism?

MR. BOB WATSON: Well, I think many people see it as dangerous and I would like to say I agree with the three others who have said that if you

make an organism by recombinant DNA techniques, genetic engineering techniques, it does not have to be dangerous by any stretch of the imagination. I would say it can be dangerous. I think there are situations that can arise where we should not release an organism into the environment because it would pose new risks we have never seen before. So the trouble is to decide where any difference in things lie.

THE CHAIRMAN: The problem, of course, to pick up on your point of why government would treat it differently is because government is operating in the political arena dealing with public perception. Public perception inevitably is influenced by the fact that some time ago there were statements coming forth that, yes, there are dangers associated with this. There has since, as I understand it, been quite a change in view, but very understandably public perception is the dominant element that the politician, representing the public, has to work around.

AN UNIDENTIFIED VOICE: I guess I would ask the question in a slightly different way; if a martyr existed in a Rhizobium, independent of genetically engineered, in other words, some enzyme that came up in a strain, a special marker, could that be passed through the existing regulations of the Department of Agriculture or Agriculture Canada?

AN UNIDENTIFIED VOICE: Well, I'm not in that regulation side of it.

AN UNIDENTIFIED VOICE: It was more of a rhetorical question.

AN UNIDENTIFIED VOICE: I would say no, as soon as they heard it was made by a recombinant DNA ---

AN UNIDENTIFIED VOICE: No, let's say it wasn't made by a recombinant DNA but it would be the exact same type of strain you wanted to achieve by recombinant DNA?

AN UNIDENTIFIED VOICE: -- Inaudible.

AN UNIDENTIFIED VOICE: The second point is the methodology of creating that.

MR. BOB WATSON: Yes, that would be the class of changes that one could get -- inaudible.

THE CHAIRMAN: Bob, you are going to have to speak up.

MR. BOB WATSON: The power of the technique is in the things we cannot do by the classical means. Those are really what we have to deal with. Certainly, there are many changes which can be made which would be benign and very similar to changes that could be made by the old techniques.

DR. BERNARD GLICK: Like the ice-minus bacteria, for example.

DR. VERN SELIGY: You know, the

experiment I brought up which was published says, which more or less reinforces what Bob is saying is that by additional mutation after you do the transformation, you create this piece, which is not any more different, same host but transferring over that gene, at that stage one can apply other techniques to it to adapt the gene or to adapt that organism into an environment so it would perform in a superior way. Most of the time they do not perform in a superior way, only maybe the gene. So there is a lot of capacity there. I think Bob has touched on the magic word, there is a lot of capacity which has not really been borne out.

THE CHAIRMAN: There are a group of people over here. Maybe we will just go down the row; Francis, Claire and Terry.

DR. FRANCIS ROLLESTON: I have sympathy with what Bob Watson just said about the -- inaudible -- make assessment around this technology. In a sense, what the MRC got into this, was a form of evaluation process whereas Agriculture Canada -- and I sympathize with them for wanting to stay out of that function, but this is a different kind of function sometimes, whereas I think the point we're talking about now, and what bothers me, is that we really have to be talking about a product of a situation. Perhaps one of the issues we have to distinguish is this issue

of process versus product.

DR. CLAIRE FRANKLIN: I just wanted to comment on the seeming statement that the government perhaps feels that genetically engineered organisms are in fact more dangerous. I think one has to be very careful in anticipating or realizing that there are different departments, different products and there are really -- perhaps that statement is supportable in some instances and not in others, and I think that history has shown in the drugs area that I don't think it is being construed they are simply because they are more dangerous than genetically engineered. I think they are being handled as a product.

In the pesticide area they will be handled on the product-by-product basis. They will not be identified as being different simply because they meet different requirements. I think what we should be trying to do today is define what sort of tests we need to be able to provide a sufficient data base so that a risk assessment can be made. There may be different decisions made for different uses depending on what you feel the benefits are or what you really feel the exposures are in doing this kind of thing.

I think we cannot just lump it altogether. I think we have to be very cautious that we don't do that.

MR. TERRY McINTYRE: I would just like to add that as far as the regulatory aspect, I can say that the department probably has different ways of looking at the regulatory aspects of biotechnology precipitated largely on the fact that most of the environmental studies -- inaudible -- in fact were based largely in terms of association with the nuclear industry and on that basis alone -- inaudible -- with regulation not being pejorative, in a pejorative sense, we need to assess how adequately the existing legislation may be in terms of -- inaudible.

THE CHAIRMAN: Terry, maybe I didn't hear, but I didn't understand your final point.

MR. TERRY McINTYRE: Okay. I am saying that we are interested in assessing the adequacy of the existing legislation for those reasons not because there is a fear -- well, I guess you could say possibly there is a fear that some of the novel aspects associated with genetically engineered organisms may be disrupted on the environmental prospective and "may" prove, the inoperative phrase.

DR. COLIN MAYFIELD: One point on topic and one off topic. The first question is there any difference. Perhaps I can turn that around, if there is not any difference between mutation and genetic engineering, what we are saying basically is do we

develop everything by mutation, given enough time, so the only claim to fame of genetic engineering is it is quicker.

Second, do you think mutation can develop humaningela (sp?) (inaudible) I don't think so. Therefore, there has to be a difference if you argue from the other side.

We do already have a model for regulation of these things. That is the Environmental Contaminant Act, all kinds of things, pesticide registration, where you look at the risks of exposure to your different population of different pesticides, how many people would be exposed, at what dose level, then you go into routine testing based on the likely exposure, et cetera. Surely, you will agree that the time for discussing whether or not the things are different is past. The fact is the public and the government perceives them as different. Therefore, you treat them as different. To do something about it, you have to get a procedure and a set of protocols for testing. We can't go on going around arguing anymore about whether they are different. It simply doesn't matter. It is an irrelevant argument. We have been told by the legislators, therefore, the next thing is how do we deal with this.

The obvious thing for me is to set up

a series of test situations, what do you need to do under certain situations, the situations, I think, could be modelled on the Pesticide Registration Act in Canada. It is very clear, a very well-established procedure involving at least seven arms of government, so they should be able to co-operate in some areas, Health and Welfare, Fisheries, Agriculture Canada -- inaudible. It is not the people who are proposing to introduce a pesticide. You have to develop a data base. It is then submitted to Agriculture Canada and they come back and say, well, that's not quite good enough and you have to go away and do X. This seems to be a very reasonable model on a case-by-case basis to deal with our present problem. That is all I have to say about that.

DR. BERNARD GLICK: Francis, did you want to respond?

DR. FRANCIS ROLLESTON: No, but I think there are going to have to be made subsequent comments. -- Inaudible --

DR. BERNARD GLICK: I think Colin's point is well taken. It may be the discussion of are recombinant organisms different should move along.

DR. FRANCIS ROLLESTON: But where do we land in terms of our decision this afternoon? Do we agree with Bob or do we agree with Colin?

THE CHAIRMAN: You can agree with both. You can agree there is an objective reality and a political reality.

DR. COLIN MAYFIELD: I agree with Bob.

DR. FRANCIS ROLLESTON: That's a good sign. Now if Bob will agree with Colin.

AN UNIDENTIFIED VOICE: I think from the point of view of the government looking at the genetically engineered versus the natural organisms, they may have a procedure and protocols in place right now to look at microbial pesticides in assessing them. When you have a genetically engineered organism, I think the approach that would be taken will be approximately the same as for any other biological organism. If you look at the chart on the slide right now, look at all those probabilities, I think that is basically a good straightforward approach as to how any government mechanism would look at a genetically engineered or a biological organism that was going to be released into the environment.

The big problem with the genetically engineered organism is that when you get down to P-6, the probability of harm, whereas with the natural organism you have a data base to base your judgment on. You have experience as to what its natural environment is and what ecological issue it might have impact upon.

When you have a genetically engineered organism, you do not have a data base anymore, and the problem of assigning risk benefit factors to the probability of harm is still not a clear one with regular biological organisms. But you have this added uncertainty factor of having no data base to fall back upon whenever you have a new genetically engineered organism and that leaves P-6 totally up in the air. I think that is where the main problem is, not from the fact they are different, but the fact is that we do not have a data base on these genetically engineered organisms to fall back on at all. That is why there is so much uncertainty in the first place.

DR. BERNARD GLICK: All right. That leads us into, really, two questions. First, without going through the probabilities individually, the first question is how do we assess these probabilities. The second question is what do the numbers mean? If we say that there is a 10 per cent chance of survival or a 1 per cent chance, what does that mean? What is an acceptable level?

AN UNIDENTIFIED VOICE: I don't think we accept your basic premise. May I just put forward one thing on that before we get started into it? That is that this is based on Martin Alexander's thing in the first place. When Martin Alexander was asked what

those numbers meant, and how to go about deciding the numbers, he said, "I don't have a clue". He said, "Nobody knows how to assign the probabilities and nobody knows the significance of an assigned probability". Until somebody develops a reasonable risk benefit procedure for P-6, we are not going to get anywhere with this approach. He thought that one of the key things was to get more research money into developing a risk benefit procedure which meant something, and that is what we do not have. No matter what you do with this equation, until you have risk benefit analysis in P-6 which means something, you can go around in circles assigning any values you want for P-1 to P-5.

DR. BERNARD GLICK: Well, in fact, this is deliberately formulated so it is not an equation, in fact.

AN UNIDENTIFIED VOICE: Oh, I agree. He didn't actually say -- (Inaudible) -- the factors, the approach that must be considered.

DR. BERNARD GLICK: He saw them as multiplied by one another but I thought that was a little bit too much.

DR. FRANCIS ROLLESTON: Mr. Chairman, is there a need for research funds? Is that the reason I was invited?

DR. BERNARD GLICK: What has been said

is clearly true, because if P-6 is viable, the rest doesn't matter.

AN UNIDENTIFIED VOICE: I'm not sure we need to get even involved in this because most legislation now usually indicates if it is harmful or poisonous or deemed to be harmful or poisonous, then it is considered not acceptable. It is up to the manufacturer or producer to show that it is not harmful or poisonous. I don't think we should get into the business of quality control where you say anything over 90 per cent is acceptable, you know, consumer acceptance or producer acceptance.

DR. BERNARD GLICK: How do you prove with a genetically engineered micro-organism that it is not harmful?

AN UNIDENTIFIED VOICE: The same way as you work with salmonella, staphorious, amoebactum. Given the right condition, even those known organisms, as was pointed out, we don't know, so I would hardly want to spend my time this afternoon trying to devise a probability of harm from a genetically engineered organism.

It is certainly very important but legislation for hundreds of years, or a hundred years, anyway, in Canada, simply defines it as that which is poisonous or harmful.

DR. BERNARD GLICK: All right. If I understand the comments correctly, or some of them, the suggestion is while this is one assessment framework, it is not necessarily an adequate one or a complete one. Maybe this is not the right format for suggesting others but are there other models which one could apply? Are there other ways of going about this process?

AN UNIDENTIFIED VOICE: I'm not sure what the issue is but I think obviously what people want to know, if you are releasing an organism, what is its survival condition, or chance of survival, what is its chance of replicating or the chance of dispersing into another niche, and what are its chances of possibly transferring DNA, although that obviously is available. But the bottom line, just to reiterate, is by knowing those things and also doing other tests which I assume are in place.

I don't know if there is required unique tests to determine these criteria or, at least, these characteristics.

DR. BERNARD GLICK: Are those tests in fact in place?

DR. FRANCIS ROLLESTON: It is no different from getting sort of like a food additive -- inaudible. If those tests are in place, and specified certain tests, and if they pass those tests, they allow

the thing to be sold. If they don't, they won't allow them to be sold. I guess the question is what test do you choose. Again I quote the Act, the Food and Drug Act, which I am most familiar with in terms of trying to get things through the federal government, there are specific procedures set out and they are as vague as hell, but never mind.

DR. VERN SELIGY: Well, I think, just going back to this definition which has already been applied earlier to EK-2 vectors, way, way back, and there are values assigned, you know, experimental values actually assigned to some of this. The bottom one, P-6 is really, I guess -- the most concern is whether or not there is, first of all, any probability of harm, to begin with, and you know a little bit about the host itself, and just addressing an earlier statement that we don't know very much about these organisms, what worries me is that in most cases we may think that we are dealing with a large number of organisms in industry and yet in reality we are not. In fact, there is a push to contain the number of organisms, the recombinant products and the ones which are defined and have already gone through some earlier legislation and screening. I think that is one of the strategies, and it is a very good one. Certainly, in Europe that is what's being used and I am sure it is

being used in the United States.

Now, in some cases you cannot avoid a new host but then there is another aspect of the guidelines that comes in, that is cloning back into the original host from whence something came -- inaudible -- and you define the vector and everything else so you are building on the information you have.

I really think that the last one, the probability -- starting backward on this -- what we are basically doing is again risking anxiety, like was brought up at the beginning, because some of us have been at earlier meetings where we have seen similar scenarios going on but a lot of this data is in place for whatever value it is worth and you can only be challenged on a case-by-case basis.

MR. SHINDLER: If a commercial operation would like to introduce one of these things for environmental use, I am sure they would try to pick a system that is well-defined, and safe as it can possibly be, because in making any of the applications they are going to be under pressure to answer the questions about the organism. So if one is going to be introduced tomorrow, you can bet it is not going to be very far in the evolutionary sense, from the existing organism that is used, if there is any prayer of getting it into society whether the U.S., Canada or

Europe.

I think this is a phenomena we, around this table, should take close note of, the evolution towards using the well-defined systems with small steps, small changes to each one, and I think ice-minus is the first example of an extremely small change that was put in and it is going to be -- inaudible -- it is taking a long time but I think this is an example of what is likely to happen, a very slow evolution towards more sophisticated changes in organisms.

Therefore, our predictability, based on these small changes, is much greater than we give ourselves credit for right now. So we don't need to put the scenario on the whole "new life form" which I heard around the table and I hope we don't hear it again because I don't think that is relevant. We just need the scenario of the small change in an existing product that does something very useful and has a lot of benefit to agriculture, to forestry or to food production in our society. That is really what we are looking at. So if we look at it that way, we can have a little bit more confidence in our ability to regulate these things.

Second, on following that exactly, in establishing the data base, a lot of energy has to be put into the building of the data base, even for the

small changes, a lot more, perhaps -- if I can go off the record for a minute -- a lot more than has been done, and I think that is where it should be aimed at, working with those things that come through the line. We have lots of examples from the States and from Europe with products which are likely to be coming right here to our regulators and we can do our homework now. We don't have to wait to do that homework, and we are starting to do it, and -- inaudible.

I think we should talk about how that homework should be done and how we can help our regulatory authorities, hopefully, whether it's a public perception problem -- it may not really be a technological or scientific problem of such great magnitude.

THE CHAIRMAN: Bernie has turned things over to me, for better or worse. My understanding of where we are at is the group does not feel that there is another whole conceptual approach other than that which should be put forth, and that there is general agreement that there isn't a major difference between the potential ills associated with genetically engineered organisms and those derived by more traditional means but that there is a political difference and there is a public perception factor which has to be taken into account, and that reality is that this is going to be regulated on a separate -- in

a separate manner, presumably in this sort of incremental approach that Dave was talking about and probably by a case-by-case basis.

AN UNIDENTIFIED VOICE: I think you have gone a little too far, Mr. Chairman, on the second part of that.

THE CHAIRMAN: I will stop and back up a couple of words. Probably on an incremental basis. I think, unless anyone else has some comments they would like to advance on the broad subject of the conceptual approach to understanding the environmental effects ---

AN UNIDENTIFIED VOICE: I just have a question. When you say there is a political difference, if you could elaborate where that is and when you say that there is a perception that it will be manipulated differently, what you are basing that on?

THE CHAIRMAN: All right. I am basing it on my ongoing reading -- and again I am speaking in terms of environmental protection as opposed to, say, food and drug administration, and the impression I have is that is very different for whatever reason. And, again, looking at environmental as opposed to other things like occupational health. Having been involved with this for a couple of years, I have a very clear impression that what has to be dealt with to allow development of this industry, and to allow release into

the environment, is public perception and that the political arm in Canada is very aware of that.

I can give you one example which has illustrated that to me. Sometime in, I believe, early 1985 -- I can't remember when, but there were news releases of the application to the Ontario Ministry for the use of genetically engineered techniques to clean up PCBs in Pottersberg Creek. This is the thing that Goff was dealing with. We, as we generally do in these situations, sent a letter to the Minister saying we certainly hoped there would be a full environmental assessment with opportunities for public participation in this. We got back a very bland, meaningless answer saying, you know, we are cleaning up PCBs, and that was about it. Then the election was called and out of the blue we got another letter from the same Minister to my original letter -- I hadn't written them back. I hadn't replied to his first letter. It was Mr. Cailes (sp?) who was then Minister. He wrote me another letter expressing great concern over the potential use of genetically altered organisms and release to the environment.

The only thing that I could see that had changed -- I have never gotten two replies to a letter in my life. The only thing that changed is that an election had been called in between. That made me

think that he thought he had a potential political problem and he was trying to cover his bases by means of his second letter.

What gave him political problems eventually was rats on the highway in Kenora and everything, but that convinced me that that is the political perception.

AN UNIDENTIFIED VOICE: I guess the reason I'm raising the question is I think we have to be very clear as to anecdotes such as that which are very real at the point and time, and what may be an underlying political impression on this whole thing. It may be hard to sort out but I think that we should be very cautious before we make a statement that it is going in a certain direction because it may not actually be going in that particular direction. I think I would not like to see us back ourselves into a corner ---

THE CHAIRMAN: A self-fulfilling ---

AN UNIDENTIFIED VOICE: Yes. I truly think that that is a danger, the statement which you made that there was a political difference as well as a regulatory difference because I am not convinced there is at the level I deal with, at the federal level, that that is real. I think we try very hard to not crystalize a position until we have enough science to tell us which is the right direction to go in. I would think that

this group should be very cognizant of that kind of situation.

THE CHAIRMAN: I think your point is well taken and I think it is a very good introduction to where we are hoping to take this discussion now, this afternoon, which is to see what the thought is among this particular group of scientists as to the potential environmental effects which regulation must cope with. But before we do that, Francis?

DR. FRANCIS ROLLESTON: I think the comment that the drive for regulation comes from the public will, and the political process, is quite clear. The question I think we should look at is not just whether or not we as scientists should simply accept what the public demands when we do not feel there are regulations necessary. The approach then goes back to the public in some way in terms of information about the real situation rather than some of the fanciful cartoons that Bernie Glick reminded us about in his discussion.

I think there really is a role not only of a group that is here to evaluate the pressures for regulation but also to pronounce upon and, if necessary, educate the public, if we can, which is not easy, I know, about the reality of the situation because that influences us once again. So I think the

need for regulation is not something we have to take for granted.

THE CHAIRMAN: Are there any other general comments along those lines?

DR. DON HART: I don't know whether it was just suggested that regulatory agencies just decided to regulate biotechnology separately or not. I think there is going to be a need to take a closer look at these parameters and decide whether the mechanisms are in place to obtain appropriate information about any new product. What types of tests, for example, are we going to apply to get a handle on decimination or genetic transfer? What types of tests are industry going to do? What type of information the community requires to assess environmental risk on a case-by-case basis? I think that is where we need to focus our energy in defining those educational parameters and those tests.

AN UNIDENTIFIED VOICE: I can agree totally with my colleague except it is going to be hard to do that in the absence of some good examples, and this is partly why we have adopted to propose a case study approach which goes into some defined examples and, hopefully, with agreement of our provincial and federal colleagues, we can get together and analyze exactly where the legislative and legal gaps,

perception of gaps are, and the real data gaps, exactly where they are so we can put energy into solving the real problem. Rather than speculating that we have a gap, let's find out if there is really one with real problems or hypothetical ones which are close to going through the regulatory scheme.

And just jumping ahead to what I was going to say later, this substantive kind of homework is really what is needed. I think we have to get down to some real cases, try them out on the system, see how our existing framework, provincial and federal -- there is a lot of players in this. It is not an easy task -- provincial, federal legislators, our regulators, how it appears to them, how they would handle it, whether they can handle it or whether they will just say: "We just don't have the information".

There are lots of cases where we don't have information. Obviously we have to devote a real effort to information gathering, sharing of information with other countries, actual research effort to really delve into this and be prepared for when the product does come on line because they will come no matter what we do. The choice is only when we do our homework, whether we do it after the fact or before. I think the whole technological development of biotechnology indicates that we try to do our homework before with our

case studies and things like this. This is what has been going on as a result of biotech. So that kind of approach can be imminently sensible at this stage of development, and we are much closer to the products now than we were a few years back. We are far better able to look at the things objectively than we were a couple of years ago. I think we are really ready to do this now. I can't speak for my provincial colleagues but I think on the federal scene we are really ready.

Sure, there are differences in preparedness between the different departments but, still, as a rule we are ready to look at how we could handle real cases at this point and in doing so are prepared for the next ice-minus, whatever it may be, or the next one that comes along. That is really the guts of what we should be doing on the federal scene and if we get the approval, that is what we will be doing.

DR. VERN SELIGY: Can I mention something which might be useful, I am not sure? There has been two companies where I have had the privilege of getting very, very close to the end in terms of one was a cutative recombinant product and the other one was in hand. What impressed me in those two cases, and in a search by a company in the United States and Canada for a possible application of a patent, the thing that struck me when I dealt with regulatory agencies in

Canada is that there was already very good mechanisms in place. Conventional mechanisms, it seems to me, would be more than adequate to handle in terms of the rigorousness what we were dealing with. So in a way I feel actually fairly confident that, you know, there is a very stringent mechanism to start with but it is a very co-operative one. There was no question at this earlier meeting which I referred to, which I can't tell you too much about, but where we had European companies sitting down -- this is in the food industry -- sitting down and we were talking about new products and about using certain organisms preferred over others because those were already cleared. There was no question in that room there was a lot of co-operation and interest in making sure that the best way to deal with the question of would my product go through is on a confidential basis, one on one, just one at a time, and that is the way they were able to maintain confidentiality, even recommending beforehand -- in fact, what they always urge every time you approach them, and I don't know why I'm talking, there should be some other people here saying this instead of me, but what I was impressed with is they keep on saying: "Listen. You are a company. You are looking to perhaps have an application in this country. Contact us early. We will give you somebody that can bird dog you all along and help you

along the way to get this thing into place where it will be properly cleared". Where the problems come in everytime, and I say this in big letters, is when someone comes in and thinks it is going to be done just like that and it won't be done like that anywhere in the world, and that is where the problems lie.

But I don't see any difference between, say, a recombinant product and the other. Actually, I am stepping on thin ice right now but where I saw something that was very interesting is where -- this is now the provincial level, where a provincial agency would, in co-operation with a program, make special concessions for testing, but, in a way, that was the best way to have it because we were under complete control.

DR. V.N. IYER: I just wanted to ask David here if he could expand on one of those case studies.

DR. DAVID SHINDLER: Well, I can't, I haven't started yet. They are just starting very soon, assuming there is no freeze on the federal side at the financial stage, and assuming we get our budget for next year, but this is such an important area we are pretty confident we will get agreement, number one. Number two, we are very confident we will have good co-operation between the federal and

provincial governments in this field through the independent individual agencies and their contacts or through the biotech community which has set up a co-ordinating committee between the federal reps and the federal departmental community to get agreement to proceed on a case study. What we thought we might do is take five different case studies, modelled on a list very similar to what we were projecting this morning, we would take a microbial pesticide, either a virus or a bacterium, give it particular qualities and make a hypothetical genetic makeup with a definition of how it was made and challenge the agency to say how they would handle this, basically walk it through the system, the regulatory system, as if it were a real application, and ask everyone how they would handle this one, what information they would need, who would handle it, who has the legal responsibility for it, whether or not we can handle it at all, whether or not it's a provincial or federal responsibility, or how they would split it up between the two. All of these questions could be answered if we get the right co-operation from the agencies.

Since it is an educational process, so far the response from all of the regulatory agencies is that that's great because they can key in on our key problems, where we have to put our resources to

solve the real things coming down the road, not hypothetical problems. Number two, let's go away from fighting forest fires and trying to be public relations experts and let's just get down to trying to do the scientific side of the regulation. Leave the public relations problems to someone else while we do our homework and we have a mechanism which can handle that, other types of consultations. In fact, organizations such as this are going to assist us a tremendous amount with the public kind of consultations which have to go on. This is a public issue. It is an issue of public policy and meetings such as this are tremendously helpful and could be tremendously helpful in bringing the awareness up to the proper level of what the real situation is.

So between those two things, I think we could make pretty rapid progress. We are looking for about a year for these case studies. As a result of those, we are in a much stronger position federally and provincially to recommend what priorities and what mechanisms might be needed to regulate this thing we call "genetic engineering" or the release of organisms into the environment. That is the real objective, not to hypothesize about it but to put down on paper what we really must do, where we really must get information, where we really must develop criteria.

I think it is going to take quite a lot of imagination and quite a bit of effort to do this right but I think it is worth it. I really think it would be worth it. So far the response to this suggestion has been excellent. Everyone wants to co-operate because of the amount they can gain from that sort of process.

THE CHAIRMAN: David, I am wondering, perhaps you have covered everything you wanted to say, but I was wondering if we could switch things around. We were going to set aside a little time for getting an understanding of what David's Ministry is doing. Do you just want to take another few minutes and add anything else which would do that and perhaps we can then break for coffee.

DR. DAVID SHINDLER: First of all, I wanted to define more carefully what our Ministry's role is. As you know, the federal government has adopted a strategy to encourage the commercialization of biotechnology and retention of the social benefits of biotechnology for our society and we are responsible -- we have a lead policy role. The NRC and the other agencies have lead scientific roles in this policy. We are trying to pull together the requisite efforts to make sure we have an adequate regulatory system which has some credibility, which stands up to public

scrutiny as well as political scrutiny, and most important around this table, scientific scrutiny, that we have all the things we need in place to give us confidence that the new technology is not something that is going to streamroll us and overwhelm us as a society rather than being applied in a sensible and measured way to obtain those benefits we all want.

We formed a small co-ordinating committee, a small working group, made up of a few regulatory agencies to be a watchdog on this process. We will contract the case studies. We want to isolate the regulators from the public relations function, as I mentioned, for a very good reason; they will never get this done with our limited resources if they have to fight forest fires. So we want to help them, not to present them with an additional burden of problems or another layer of bureaucracy.

On the federal-provincial side, this will be presented at a special meeting of provincial representatives with federal representatives on December 3 and the action plan will be presented for consideration at that time.

I guess the key words are clarity, so we understand where we are, a map or a guide for people who wish to apply with new product processes some idea of the published criteria that will be used,

or where we are in each agency of publishing the necessary criteria and, last, a list of key contact people, perhaps, in each agency, federally and provincially, who could answer questions in this area that may be difficult if you have to go through the entire bureaucratic system and no one can answer you. So these are objectives, aside from the purely scientific aspects.

In the end, this sort of effort relies on the goodwill and co-operation of a lot of people from different points of view and I think around this table we can see it is there. The difficulty, I think, is in just identifying how we can contribute to such a process which is going to be good for Canada and for our society. The difficulty is how we can be mutually supportive and give an accurate definition and perception and analysis of where we are precisely because this field has been frought with so many rumours and hypothetical cases and hypothetical problems that we don't want to go down that road as has been done in other countries with gigantic confrontations. I think we are fortunate that we are coming in a little later and we can look at the process with a little bit more objectivity. This is basically the philosophy and this is what I think is the only thing we can do, the only right thing to do. The only really

sensible thing to do is put the facts on the table and see where we go from there.

THE CHAIRMAN: What is the timing on this?

MR. DAVID SHINDLER: We would like to begin the planning on the case studies almost immediately. The selection of which ones we take, and I invite this group to suggest particular ones they feel will be most important to take up as a case study, I think that can be very useful this afternoon, and perhaps this list is a good start. It's very similar to the list we have drawn up. I think it will take a year to do the cases.

THE CHAIRMAN: I guess my question is when is the federal government going to say something about how it intends to regulate?

MR. DAVID SHINDLER: The federal government is already saying things about how it intends to regulate. If you look at the releases from every department, you see, for instance, Agriculture Canada just recently sent out draft guidelines. These are ongoing efforts. We should not get the idea that some-day lightening will strike and we will know how to regulate all this stuff. This is a truly evolutionary process. The case studies are designed to add to this and speed it up a little bit. But we are not in a

vacuum now. I think two years ago, in your symposium on the regulation of biotechnology, you used the words "regulatory vacuum", which I really take exemption to. I don't think that is the situation.

We have a lot of good regulations, a lot of good regulators, and they are handling things. We have problems and we must define what they are and give them attention and that is really the objective in the next year or so, to find out what the problems are and to be precise about what attention we give to them.

THE CHAIRMAN: My understanding was that you were preparing a set of regulatory options which were going to be discussed with your provincial counterparts. Is that what is happening at the December 3 meeting?

MR. DAVID SHINDLER: Yes. I would say it would be an action plan for this regulatory work I have been talking about.

THE CHAIRMAN: But there is no one date contained within that document?

MR. DAVID SHINDLER: No, I don't think as a central agency we could be so presumptuous to be able to prescribe how this is going to be handled for every other agency in the country, given the breadth and depth of it. I think that would be too presumptuous.

But we can go in that direction together. As far as dates, that does not seem to be suitable for where we find ourselves now in this situation.

THE CHAIRMAN: Just one final question, Dave. When you say you are separating out the public relations or the public consultation part, could you give us just a few words on how that is going to work and the timing on that?

MR. DAVID SHINDLER: Well, being that there are Ministers involved, I can't talk about that at this point. All I can say is we have to give our regulators room to do their homework and not be involved too much on the public side because it could very well mushroom. The public consultation could take all their time and we would never get the homework done. That is the basic problem.

THE CHAIRMAN: Unless anyone has any other questions of David, what has been done by MSST, my suggestion is that we move into the afternoon coffee break and then come back. What I am hoping we can do when we come back is to have a discussion focusing as much as possible on the environmental effects which are associated with the different applications which were identified this morning.

The reason for this exactly as Claire and a number of other people have said, if this in

Canada is going to be dealt with in a productive manner and not get caught up in problems of misunderstanding or lack of information, we need to get information from the people that know, and this group is as representative as any as to what the potential environmental effects are that we should be dealing with, this incredible fear that the public perception is going to get out of hand. Every time I go to talk to anyone about what we are doing in biotechnology, the conversation starts by me being given a little speech about how we should not be stirring up the public. The way to make sure the public does not get stirred up is for people like the group in this room to be as clear as they can on what the potential problems are that we are trying to deal with. So I am very much hoping that after coffee we can simply go through the list of applications, go through the list of possible effects, and then I am hoping we can conclude with some general discussion on what all this means for the Canadian regulatory process.

We will convene again in about twenty minutes.

--- Short adjournment.

--- Upon resuming at 2:40 p.m.

THE CHAIRMAN: If I could take a moment at the start of this final part of the day's discussion to again clarify the purpose of today's seminar? I can

do that very quickly. I think the discussion has been extremely useful today, certainly for my purposes and given my non-scientific perspective I have found it very valuable, indeed. Just to again set out what it is we are trying to achieve today, this fits within the larger program which we, the Canadian Environmental Law Research Foundation, is doing on biotechnology policy which, in turn, we hope will complement the work being done by other agencies in Canada, mostly government, and, in particular, David, and the work he is doing with his provincial colleagues. This seminar is one part of the two parts of what we are doing to try to establish the foundation for the further work we hope to do. What we are trying to do is identify the potential environmental problems we are dealing with and what are the potential policy problems we have to deal with. By "problem" I mean what are the environmental effects, is probably the best word, and by "problem" on the policy side, what are the policy questions which have to be dealt with.

What I am hoping we will do over the course of the next hour is to reach as much agreement as is possible, or as much consensus as is possible, on the potential environmental effects which are associated with the applications which earlier in the day we agreed are the ones we are most likely going to

have to deal with first in Canada. So, Don, if that provides the clarification you were looking for, what I would like to do is turn things over to my very able colleague who is going to run us down the list and see where we are in terms of the environmental effects associated with these different applications. Bernie will be expanding on the discussion presented in his paper, which all of you have received a copy of.

DR. BERNARD GLICK: And you will be tested on it later. All right. Basically, what I am going to do, based on the discussions this morning, Doug has written down a couple of areas of application and I would just like to run through them. Some of this may be done fairly quickly. In fact, a lot of it may be done fairly quickly.

Just to get a sense, perhaps, of what some of the problems are in terms of these applications, and what issues, in terms of these applications, people feel need to be addressed, and what intrinsic hazards there are, if any. Let's just start at the beginning. The first thing on the list, of course, is the area of live vaccines. In particular, it was suggested that we could very well see within the next little while a live vaccine, and a vaccine that is released to the environment against rabies, having a gene or genes from rabies virus spliced into a vaccinia virus and that

vaccinia virus, in particular, would probably be introduced in bait, that is, food dropped from an airplane or spread out in the environment in some way. The target would be probably foxes, and obviously other animals would be attracted to this bait.

The question is what kinds of concerns do people have about this and, you know, are there problems with doing this. I think there was a comment here that there is -- I know the Ministry of Natural Resources of Ontario does have a very active rabies program. I also know in particular that rabies is a particular problem in Ontario. So if this kind of vaccine appears to be a useful way to approach it, and I know that in fact it is being tested in the laboratory right now in Ontario, and it has been tested in the lab outside of Ontario, so we are likely to see applications for permission to field test very, very soon. Are there any comments?

MR. DON LUSH: What I was going to say, one way to attack this would be to say if this group were charged with giving the approval for the use of this, what questions would they want to see answered before approving it.

DR. BERNARD GLICK: All right. What questions would you want to see answered?

MR. DON LUSH: I was going to say that

one of the obvious things is are there any target organisms which may take up this vaccine other than the foxes you are aiming it at, and is there any potential for interaction of this vaccine with those other organisms in a negative sense? How do you define "negative sense"? That is a general question in terms of non-target species.

DR. BERNARD GLICK: I am sure there will be lots of non-target species that will take it up. There is no question about that.

MR. DON LUSH: Is there any implication of that or is there any negative effect of that? There is a potential for negative effect.

MR. GOFF JENKINS: As an example, along that line, we had a perceived application of a planned testing program for a rabies vaccine that will be released in Ontario this fall. Apparently, it was done last year, too. There are no details provided to us at the moment on how they made the vaccine or what virus is actually used, but there is indication, of course, that the prime targeted species are the foxes. There are a number of supplementary results that are appended to the request for our comments as to whether the Ministry of the Environment has concerns. In those other results you can note things like they have done some testing of about seven or eight species of animals.

For instance, they showed that when the vaccine was fed to mice, they tested 100 mice and that 46 out of those 100 mice developed vaccine-induced rabies.

They have asked for permission to simply go ahead and use it anyway knowing that mice don't bite people very often. But when you study your slide with data that says there is vaccine-induced rabies in 46 per cent of the mice tested, and they are still going ahead and doing it and do we have any concerns, we are left with sort of an awkward question as to what concerns should we raise immediately on this, and our first approach is to try to get a lot more information quickly as to what virus is being used and how the vaccine was developed.

We don't know for sure whether it's the vaccinia virus which is the key virus here.

DR. BERNARD GLICK: Can I raise the question -- first, just let me respond to your last comment, then raise a question. The suggestion would be, first of all, that a vaccinia virus that has a rabies gene spliced into it certainly could not contribute to the development of rabies.

MR. GOFF JENKINS: Well, we would hope that would not be the case.

DR. FRANCIS ROLLESTON: But you just said it does.

MR. GOFF JENKINS: What we are saying is that the results supplied to us indicate that 46 per cent of the mice tested developed vaccine-induced rabies. However, it is believed non-transmissible.

DR. BERNARD GLICK: Well, the suggestion there obviously is that you are dealing with rabies virus and not vaccinia virus.

MR. GOFF JENKINS: It might be it is a modified rabies virus, in this case, rather than a vaccinia virus, but the same thing applies as to what your concerns are.

AN UNIDENTIFIED VOICE: In terms of testing resistance, where the mice were made resistant by the vaccinia and they weren't? Isn't that what ---

DR. BERNARD GLICK: No, no, he said ---

AN UNIDENTIFIED VOICE: That is not what you said, but I am just checking to make sure that ---

DR. FRANCIS ROLLESTON: You are trying to be rational and assume things.

AN UNIDENTIFIED VOICE: Well, Bernie was trying to be rational. I don't see why I shouldn't be.

DR. BERNARD GLICK: That is an important question and, really, there are two questions. First of all, how much disclosure is required? And given that may be a significant amount of disclosure is

required before environmental release, how do you guarantee confidentiality?

AN UNIDENTIFIED VOICE: It depends, I think, basically there has to be a system set up in certain departments of government that would ensure confidentiality. All of the information may not be supplied to other arms of government that may have to make a decision. For instance, we have been asked for our approval of this testing program that will be done in the environment. The actual raw data was all supplied to the Department of Veterinary Biologicals at the federal level. I assume they were able to get their hands on all the necessary data to judge this. Often enough this is a problem that provincial agencies are put under, is that they are not given the proprietory information because there is no established guarantee that it would be protected. As a result, certain federal departments have the final jurisdictional say to receive this and give their comments but we are left to make our comments without the basic information.

DR. BERNARD GLICK: So what you are saying is, first of all, confidentiality is not always assured and a question, again, that arises from this is who decides what information to pass on to whom?

AN UNIDENTIFIED VOICE: I don't know.

DR. BERNARD GLICK: That seems fairly critical

Some people will have some information and some others, and it is sort of difficult to make a decision with only part of the information.

DR. VERN SELIGY: Listen: This is not going anywhere. This is like a kangaroo court right now. I myself don't think I want to play anymore. I mean, it is not rational. We don't have a real honest-to-goodness example in front of us. We are talking hearsay and someone is recording it and somebody is going to pick it up later and look at it and say: "Look at these jerks, what the hell were they doing this afternoon".

As far as I'm concerned, it is not a good thing. This is not the process that is actually done at any particular time. I'm telling you, if people -- some people don't have experience with that. Certainly, even with a minor amount, I know that it's a lot more critical now. To answer the first question, that if we want to find out the information, we would get the experts, we would get the people, to actually seriously interview them and it wouldn't be done once, it would be done several times. So there would be quite a bit of information before there were any steps taken. There would certainly be a concern for being confidential.

THE CHAIRMAN: Maybe we could back up.

DR. VERN SELIGY: I would lose my damn job, frankly, if that was the case. Don't write that. You can write that part, but you don't have to put my name to it.

I have a question mark on line six. As far as any values you can put on the front of that, and the rest of the "P-s" this afternoon. I think we should really start worrying about what are the real serious mechanisms. I feel, frankly, that we have several experts in this room, not necessarily on the bench science side of it, but we have experts in this room that can tell us a couple of things. Maybe that's the best way of doing it. What is your reaction to all of this so far? And help us decide a little bit about what could be meaningfully salvaged this afternoon because very soon I am going to be going.

THE CHAIRMAN: Vern, if you want to go, don't let me stop you. What we are trying to do is to see if we can find an opinion from this group as to potential environmental effects connected with the applications. I quite understand if you don't want to talk about particular applications which have been submitted to the Ministry. Fine. Let's talk about the agenda we have. I don't think that the general tenor of your comments is going to help us get there.

DR. VERN SELIGY: But it is not going

to get there by asking us to deal with a problem that, first of all, the way it is is so unrealistic and what we are starting to touch upon are some issues that, I think, are very, very sensitive, you know, the question of confidentiality. I mean, you write that down and it sounds like the rest of us in government never pay attention to confidentiality and things like that. I take exception to it.

THE CHAIRMAN: I quite agree. The whole question of confidentiality is outside the parameters of today's discussion. What I would like to suggest is that we back up and take another run at the first thing we were going to talk about after the coffee break. Let's pretend we all just sat down and start again. We are busy looking for any thoughts which people have on potential environmental effects associated with this particular kind of release.

MR. DAVID SHINDLER: Doug, I just have to comment because we did the same thing at the OECD. We ran around the table with the same kinds of problems. We came up with a process-type answer. We cannot evaluate an individual case unless we have the case in front of us -- inaudible. The only answer is a process that brings us to the point where we want to be in the future, and that was, before the coffee break, what I was trying to suggest. A group like this could

comment on that sort of a process, which is a case study approach, with the kind of detail I was talking about. Is that going to get us where we want to be? Is this the only practical way to do it? Or do maybe some of the people want to comment on their experience, getting us to the place where we want to be by some other route that could help us, being the regulators, the federal and provincial people, get to where you and some other people think we ought to be if we are not there already. That is really what I came here to hear today, to try to learn and to help you as well assess this problem. But really it would be more useful to me, if I could be selfish, if I heard some comments on that kind of approach because it is obvious we cannot discuss cases around this table. It would be too difficult to do that. We tried that two years ago and it doesn't really get us to a satisfactory resolution.

THE CHAIRMAN: What is your suggestion then, David?

MR. DAVID SHINDLER: At the risk of my job, I put myself on the line. I put my Minister on the line. Off the record, please. That is the approach and perhaps some agency of the federal government could help get us where we want to be with more criteria, more scientific bases and a

problem-solving approach for the regulation of the introduction of genetic technology. That is what I said before the coffee break.

I would like comments around the table if anyone thinks that this is not the right approach to take, if there is an alternative approach to get the required information to where it matters, that is, to the regulatory agencies.

THE CHAIRMAN: Well, I guess we had better turn our minds to this. I am hearing from people that the way in which we suggested the conversation be structured is not going to work, for whatever reason. Is that the consensus?

DR. VERN SELIGY: I think some of the concern is what we just came through. We have the one issue, the real scientific issue, and then there is the public perception. I think many of us at the table do not want to see this meeting generate the wrong public perception such as the example we just went through which had a reaction from myself. I don't see this as being a productive meeting if we generate witches behind garbage cans that don't really exist. As scientists we have to deal with facts and we should not be in the business of generating fear based on speculation unless we know everything. That is what I think we want to avoid at this table by setting up a process such as

David talked about whereby these problems can be handled, that would have a useful and productive function. Going through examples such as one often gets at School Board meetings about my little boy is being mistreated, is just going to cause problems, and I would really like to avoid that and be constructive.

THE CHAIRMAN: I am sure we would all like to avoid that and would all like to be constructive. I guess maybe I am misunderstanding you. The impression I have is that your fear of misrepresenting the facts or of unduly -- of putting emphasis in the wrong manner, is the impression, I guess, precluding any possibility of discussion.

DR. VERN SELIGY: I think Francis summed it up when he said I was trying to be rational. I think the opposite of rational is irrational and I don't think we should be that way at this table. I think David has a very good suggestion as to what we could do after the coffee break, and that is to discuss a mechanism whereby these things can be dealt with instead of dealing with scenarios which may or may not be true.

AN UNIDENTIFIED VOICE: If you ask people around the table to speculate on the adverse impacts that you can perceive, you will come up with every scenario from destruction of the world to -- inaudible.

What you are asking for, you are going to get. I don't think that is what we mean to do here at all. I don't think it is possible to perceive. I think, you know, if I perceive of adverse consequences of anything, that you would look at it as something just like making a broad general statement like saying there may be adverse ecological impact. You cannot discuss the specifics. You cannot discuss really, any individual set situation here without the facts presented completely before you get into it. And you just speculate on the downside. We will speculate every downside that you want but that would not be a logical and rational discussion of what we are trying to do.

DR. VERN SELIGY: I think the most important thing is not to misinform you, and that is what it is all about, I think. You people arranged for this and brought us down here and you are expecting a professional opinion. I can't give you a professional opinion. That is what I said at the very beginning of this thing. What I feel what might be happening is we are assessing anxiety. We are assessing the risk of anxiety. That is what came out of a lot of meetings before. One constructive thing that might be done in future, if we look at a scenario, one of the most interesting ones might be the B.t's because already the Canadian Forestry Service has quite a bit of data on

== a mechanism for the dissemination of it. They have some longevity studies. They have some impact studies. And I was very fortunate to be privileged to see part of that last spring. It was very impressive and the take home message I had from them was that you really have to have people who are field experts on various aspects of this to help you in this manner so you can sort of get an idea of what kind of environmental impact. They have data for it. They have gathered quite a bit of it.

We already know that there are several articles that have been written in the United States, published in Biotechnology or in Nature's Biotechnology, commenting on it. Another one is the Pseudomonads Story and it is not all bad. It is not all good, but the point is that we have to have time to really -- what you could do is maybe send some people away -- in the future, send them away asking -- you can send me away anytime you want -- in the future, saying: "Listen. We would like to have a study session on this topic and here is the topic itself and these papers we want to address". Maybe Bernie or his colleagues could pick that out and then come back and ask for an opinion. By then I have the data and I know what ten minus six means. In this case, I don't know. I have a question mark because I don't know. We have no reference points.

THE CHAIRMAN: Just so I understand you, Vern, you are saying you would feel uncomfortable talking unless you had a particular fact situation in front of you and a particular case. Then you would be willing to talk, but in terms of general discussion ---

DR. VERN SELIGY: It would be totally irresponsible because that is not the mechanism -- that is the difference between the legal profession, which has to deal with society and, you know, I get this all the time because of the background I come from. But that is the difference between the legal area, the responsibility they have to take in interpreting what it is that is at fault or what is in question, and the scientific community. In the scientific community, if we don't have an answer, we formulate, we hope to try to find the mechanism, the funds for it, and everything else, and formulate a plan to get the information. Sometimes we don't get the information we are expecting, or what have you, but it all leads in that direction. But it is coherent and builds on existing things. That is the trouble with meetings like this, we can't really do that. I promise to shut up now.

THE CHAIRMAN: If this is the general consensus of opinion, I think we should simply abridge the agenda and move to the final item. If this is what

people feel.

DR. CLAUDE BISHOP: Just maybe, to put the final nail on this coffin, I would indicate that it is awfully difficult to really say anything about host/parasite relationships with any micro-organism within the Canadian population. Probably 5 per cent to 10 per cent of the population in this room is carrying nicerium (sp?) meningitis. No one is going to get it, probably, but there have been outbursts of meningitis epidemics in Brazil, Finland and Europe. No one knows the cause of it because no one knows enough about the relationship between these pathogenic organisms and their hosts.

So if you start applying that to an infinite number of species, I don't know where you are going to get to.

THE CHAIRMAN: My thought is that the most useful thing we could do at this point is to move to the final item on the agenda and then close a little earlier than we had planned. David has spent some time telling us what MSST is doing. The final thing we were going to talk about were general, sort of, implications which -- implications for the development of regulatory policy in Canada in very general terms. If anyone has any thoughts they would like to advance, we could go into that.

DR. CECIL FORSBERG: One aspect here, as far as recombinant DNA being separate from the release of regular organisms into the environment, and that has been the discussion moving back and forth, when we come back to the regulatory systems that are currently in place for the handling of applications of non-recombinant organisms, or the latest things, into the environment, and I just briefly considered this, in fact, there are well-established protocols for handling pharmaceuticals, for handling Bacillus Theringensus as it exists, and the one point which has been reiterated before, and I would just like to deal with again is that these systems are in place and for recombinant organisms all we are doing is just adding another variation to it so it is a matter of just a slight modification of additional things to the existing regulations without a whole new set of regulations.

This is the one aspect because if we move back to base zero and ask: "Do we handle recombinant organisms as a totally new separate set of organisms and systems?" That is the extreme point of view but we have systems in place. The problem we are running into is that a number of scientists are not totally aware of some type of comeback, trying to make a contribution by contributing science, and we are not fully informed of the existing regulations that

already are in place. So it is very difficult.

Just to preface this, and this has come up at previous meetings, because we ran into this specific problem. We don't know the regulations and, therefore, it's very difficult for us without the added information we need. This is what Vern was addressing a few moments ago.

AN UNIDENTIFIED VOICE: I just want to make a concluding comment. From my point of view, existing regulations are probably very good. I think we should become familiar with them and simply build on them.

DR. CLAIRE A. FRANKLIN: I would like to comment on some of them. I think we have to keep in mind when one uses such a global term as "biotechnology". That causes a great deal of problem. If you are looking for regulations in the classical sense, we can only regulate certain kinds of products. We have not necessarily regulated all products. So I think you have to be aware if you are going to use such a global term as "biotechnology" that there will be aspects of that which historically have not been regulated.

The issue is whether or not we choose to have those ones regulated. For the ones that are in categories that are similar to products that are currently regulated, there is no doubt in Canada, as well as

internationally, that the existing regulations are adequate. They will require fine tuning and modulation but we don't need a whole new system.

Chemicals, for example, that are sold as pesticides, the existing legislation is adequate to cover microbial pesticides and genetically engineered pesticides. That is not to say the exact same tests that are necessary to provide sufficient data on efficacy and safety are going to be the same. The system exists.

With drugs it is a very similar process. In most countries it is a case that you don't have to implement new legislation. You may have to modify some of the existing regulations to cover those aspects. The same with the food additives. You may have to incorporate or bring in a new regulation but that is a minor task when one sees what is required.

The areas where there are weaknesses, in fact, the Environmental Contaminants Act, the definition for chemicals, is very narrow. It is not as broad as the definition in the United States. So that we could not easily incorporate products of biotechnology, either the microbes or the sort of aspects or components of microbes. The Act is being considered for amendment. The amendments are such that the definition will be broad enough so that that aspect will be covered.

There are going to be groups of products that have not been covered because people had this "feeling" they were safe. Bacteria that are used for mining, they have been safe. I don't think there has been any attempt to regulate them, specifically. That is not to say they could not be because there is going to be an intentional release to the environment. My understanding is that it would be a major task to have a mechanism to do this.

So I think the spectrum of things are there. What we really need help in, and I say this as a regulator, we really need help to find the specific tests we might need for new categories or products. I think we can define a core of data that would be very basic, identification of the micro-organism, identification of what you've done, what you have added in or taken out, that sort of thing. I think we can come up with that. And then there is going to be surrounding that specific information that is very necessary for that specific product. Therefore, you have a case-by-case. We have that for chemicals. There is a core of data you need, but each one has to be looked at on its own.

So I think those are the kinds of things we have to look at as far as able. What are the tests? If I was given a product today, what I would be

faced with is, is the data provided adequate and what do I need in addition to that? That is where we need input from people that are actively doing research in these areas, and we need it quickly.

DR. FRANCIS ROLLESTON: I think this is where David Shindler's approach is -- inaudible -- because this is exactly what we have been going through right now. We tried to make a case study and then decided we should not do so because we didn't have the data, and it needs to be done by experts. I think a case study approach is going to define the holes in the regulatory process we have now. Our next question is going to be is it necessary for us to fill those holes. It is a value judgment. It depends on our aspects of safe and non-safe, et cetera. That is, I think, where, as a group, the scientific community and the public communities have to start talking about some element of reality and not conjecture on this issue.

Everyone has to have a focus to fill those holes. One of the things which worries me about the aspect of trying to work one's way through these things is the focus of activity, the agency which has the responsibility. It is quite clear that when a company comes through or some process comes through, it has to go to that agency because it's that kind of an approach as opposed to that agency -- inaudible. I

think there needs to be a series of post signs with both localized responsibility in the sense of ministerial responsibility but also localized responsibility as to how the industry interacts with government in the simplest and most effective means possible.

The thing that I am very interested in with this idea of a case study is not the question of how we identify the holes but also how it identifies overlapping jurisdictions with different folks asking the same kinds of things, different agencies and different interests.

So I say the case study approach that David talked about as one which really looks, perhaps, to make more complex, i.e., more complete, the existing structure, but also to simplify the existing structure, because I have a feeling that the public, in many cases, doesn't want it more complex than it needs to be to achieve the ends that we require. So my answer to this is the whole issue of case study is going to give us the credibility, the information, that we decided around this table that we were unable to provide, and rightly. It really is a function, in the end, and I have come back full circle, to the role of government, not only in making life safe for existence but also in making life profitable for its citizens as a whole, and the government has to face those issues.

DR. VERN SELIGY: Can I ask a question?

THE CHAIRMAN: Sure.

DR. VERN SELIGY: I said I wasn't going to talk anymore. What I like d very much in the last comment was the concept of one door for all which has come up many times in brief contacts. Last year we had a biotechnology meeting in Montreal and one of things that came up, almost throughout that meeting, in contact with industrial people, was that how the hell do you find the door in place for the regulations because, you know, it depended on what it was. It struck me that there is only one door, so to speak, for the thing, when it first hits. After that it gets directed with very little information passed out, it's directed off to a specific agency. That is an important part because it is quite often very difficult. It was put to me very clearly last year when I had people from CIDA call me personally to say: "Vern, we haven't been able to find the right contact", and I spent an afternoon getting to know a lot of people but I really didn't actually know who it was that would deal with it. So it is all there but for a lot of people who are naive about it, they don't know where it is.

AN UNIDENTIFIED VOICE: We could go on all afternoon on this but I think, if I may add to your case study, and I want to emphasize what has just been

said, if you are going to do a case study, you might look at this question of overlap. I think it can easily be done by setting up a case study which involves something with more than one Ministry. For example, one can bring up a scenario which the same micro-organism can do something in fish, poultry and some stabilized foods and some kind of pharmaceutical use, and submit the same submission. We tried this one with the most interesting results. I think that would be useful, certainly in terms of biotechnology.

My second question is -- and again I do not wish to cast aspersions on the regulatory agency, because I have already had my fill, but I would be interested to know just what they are doing in terms of education to regulators to raise their awareness of the developments in biotechnology and what its limitations are. Again, I am not trying to be facetious. I did meet with some colleagues of mine in Health and Welfare some time ago and they were actually quite amazed as to how far biotechnology had gone, particularly in the food industry. There must be some magnificent people in government for whom we certainly pay our taxes, but I think there should be some kind of training program. My final point is that you may have to go the same way as the radiation or irradiation went about 30 years ago. That is, in the 1950s, if you wanted to get a

submission through radiation you had to give the earth and walk on water at the same time. Now you can get a radiation submission through without any problems at all. It's all a question of historical data. Once the historical data is in place -- what I am saying is it is my impression that the regulators are going to have to wing it for the first ten years with respect to biotechnology and then once the historical base is built, they are going to make decisions. That is my best shot.

THE CHAIRMAN: Unless there are any other comments, I think we will close on that note. There are no other burning suggestions? I would like to thank all of you very much for taking the time to join us today for this discussion. I will be frank, I haven't got from the discussion what I had hoped to get, but I have learned something about how to go about structuring an agenda. I am not being facetious at all. I have learned something about the problems with the approach we had and how to go about structuring this kind of discussion.

As I mentioned, we will provide all of you with a copy of the final report which results from this project. Thank you.

--- Whereupon meeting adjourned.

Certified Correct to the best of my ability to hear the speakers.

Joan E. Henderson CSR

Joan E.Henderson.