THE DEVELOPMENT AND MARKETING OF NEW MATERIAL FROM BIOTECHNOLOGY IN THE COMMERCIAL SECTOR

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Introduction

The discussion today is going to cover several aspects of plant biotechnology. I'd like to start by talking about the rationale for plant biotechnology, what it is, and why are people interested in using this type of science. Given that rationale, how much are they spending on it? What is the magnitude of the total world investment? And again why are people spending that sort of money in this area? To answer that question I think it's going to be important to look at the commercial market for seed and the impact that biotechnology is likely to have in this area.

Coming back to biotechnology itself, I want to look at the progress industry has made using this science, particularly with respect to new plant varieties and hybrids in both the Organisation for Economic Co-operation and Development (OECD) and in developing countries. Then I think it would be helpful to look in some detail at one example, and the example I know best is ICI Seeds so I will concentrate on that. Finally, I'd like to draw it all together in a conclusion: where are we now and where are we going?

Rationale for Plant Biotechnology

Recent work both in Europe and the United States has estimated that worldwide something close to US$600 million is spent a year on plant biotechnology research alone and that excludes microbes, fermentation, animal biotechnology--it's just on plant science. About half of that is public funding and half private companies. We will go into a bit more detail on the private company expenditure later. The majority of all expenditure is focused in and on markets in the OECD. That's an enormous amount of money to be spending on anything. So why do both public and private companies think it's worth spending US$600 million a year on plant biotechnology? I think there are two fundamental reasons.

The first is well-illustrated in figure 1. World population now stands at over 5 billion, mostly in developing countries. By the end of the next century conservative estimates predict that this figure will have doubled to well over 10 billion with most of the growth coming in the next 50 years. Figure 1 also amply illustrates the way that population growth rates are expected to be significantly higher in the developing countries than in the developed parts of the world. This population growth is obviously

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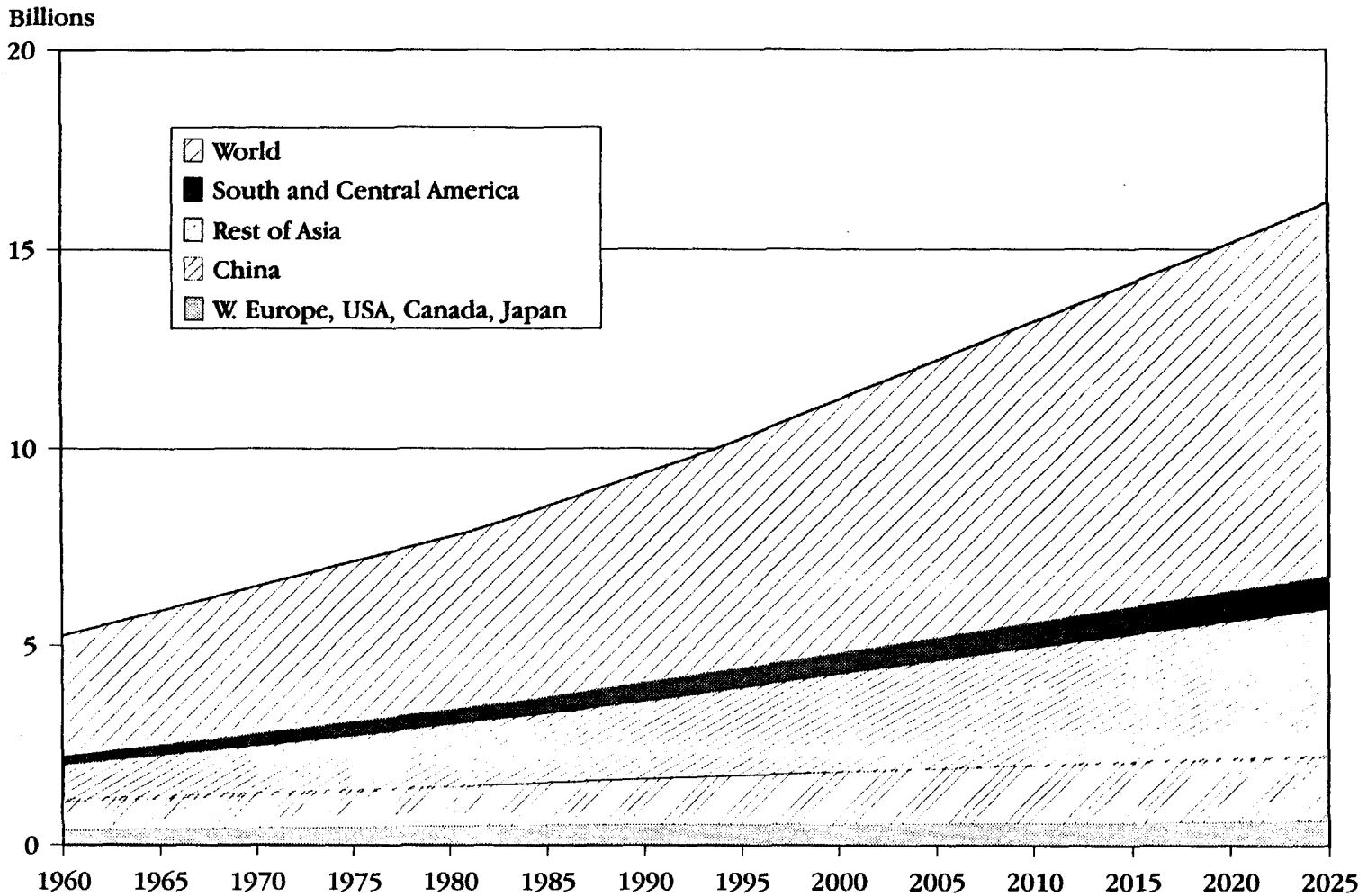
Figure 1. World Population



Source: United Nations World Population Prospects 1988.

going to result in an increasing need for a sustainable supply of food and, of course, other agricultural materials from limited land and other resources. Biotechnology is trying to help meet this need, to help maximize self-sufficiency potential in some of these countries for food in particular, but also to maximize production for export or trade potential.

The second need applies perhaps more obviously to the developed world where there is an increasing demand for quality and choice in food, other materials, and land use. And again the tools of biotechnology can help to achieve these consumer and social needs.

Investment in Biotechnology

Having explored the need for biotechnology and the purposes to which it is being put, perhaps we could look in a little more detail at private company spending on biotechnology. Twelve companies account for about one-quarter of the total US$600 million bioscience investment. Obviously these companies believe there is a need for the technology to the extent that many are spending as much or more on bioscience as they are on plant breeding. Now clearly there is a debate as to whether some techniques actually fall within the plant breeding investment or the bioscience investment, but I don't think it really matters. There is little doubt that the investment is highly significant.

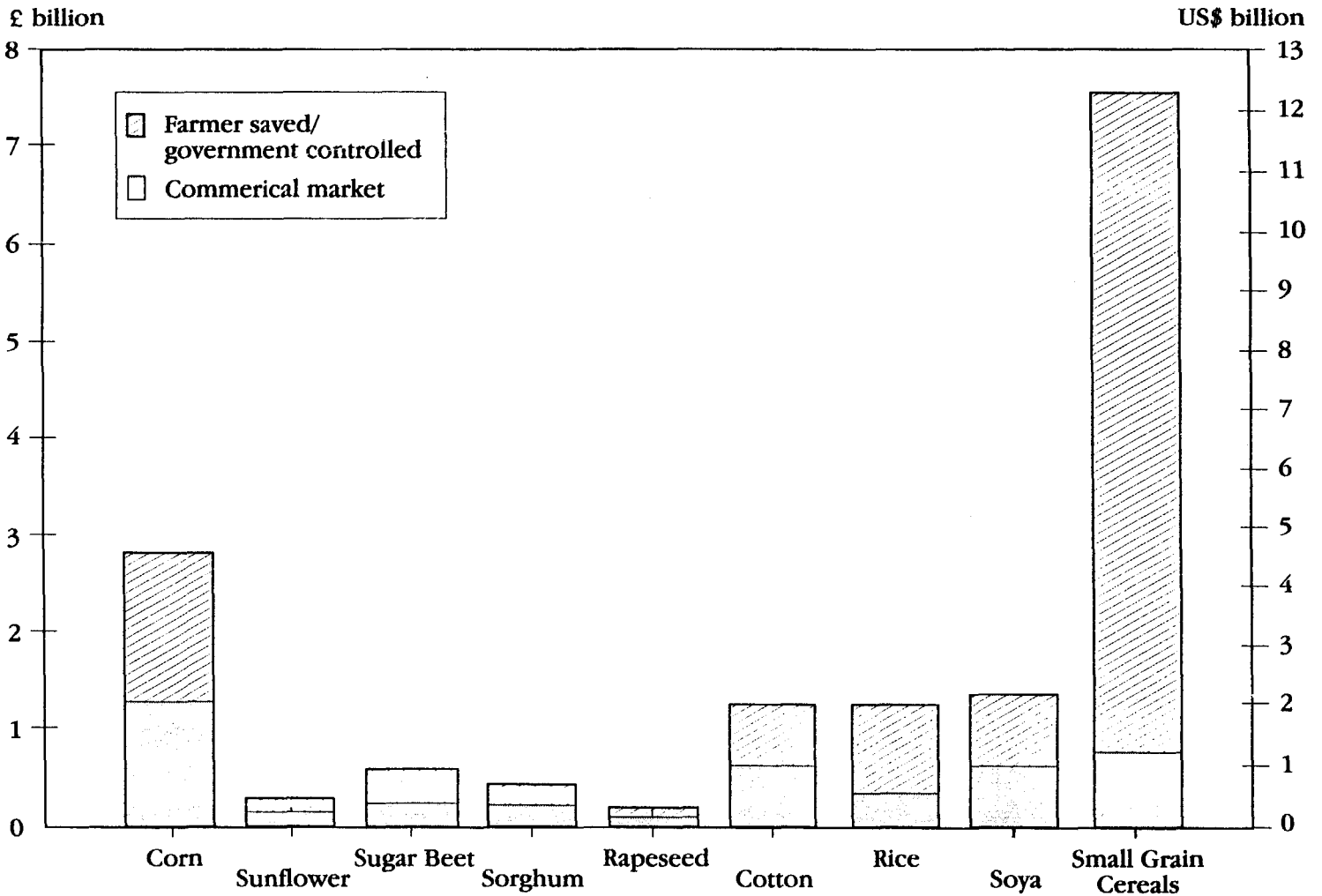
Some companies have significant investment in both areas of research: breeding and bioscience. Others, such as Dupont or Monsanto, concentrate entirely on bioscience. They have a different strategy. We believe that they are not aiming to take the products of their science to the market directly but rather to licence that technology to other companies who will then develop and market products to the farmer.

As you would expect, the top spenders on bioscience are also the top world seed companies in terms of seed sales. These companies spend between 6 and 16 percent of their total sales on research and between 13 and 50 percent of their total research on plant bioscience. Obviously these companies believe both in the future of the industry and the importance of plant biotechnology to that future.

As previously discussed, most of those companies are focusing their effort on hybrid seed markets in OECD countries and the reason for that is amply evidenced by a look at the current world seed market. Figure 2 shows the relative importance of different crops by total value of possible seed sales; both the current commercial seed market, and the additional seed, which is either farmer saved or government controlled and hence is not immediately available to private seed companies. Obviously the private seed companies are interested in the commercial market only. They are also, as you would expect, interested in the margin available from seed rather than the sales themselves; that figure is much more difficult to identify but the one place where it might change the conclusions from figure 2 is opposite small grain cereals. Margins generally available from the sale of seed in small grain cereals are much lower than for the other crops. The reason for that is that they are not hybrids and hence it is relatively simple for a farmer to save seed. The value of purchased seed to the farmer, therefore, is relatively low and hence so is the margin to the seed company. For other crops the benefits in terms of yield and quality associated with the purchase of hybrid seed by a farmer easily justify the seed price and provide a return to farmer and the seed company.

Figure 2 shows that corn is the biggest commercial market, therefore, a significant amount of research in general and biotechnology in particular is focused on corn. Other important markets are sunflower, sugar beet, sorghum and maybe in the longer term cotton, rice, and soybean, particularly

Figure 2. The World Seed Market Field Crops, 1990



if these last three become generally hybrid. These crops are reflected in the focus of plant biotechnology research.

A similar situation exists geographically. As far as the commercial market is concerned, North America and West Europe dominate, and that would also be true for margins. However, South and Central America and Asia also have significant opportunities for private commercial seed sales. This then explains the primary focus of seed companies on OECD countries.

Impact of Biotechnology

The impact of biotechnology on those seed markets is amply illustrated in figure 3. To date the science of breeding has been the source of new products of research. If we include biotechnology in its broadest form, which includes breeding aids to speed conventional breeding programs, a combination of breeding plus biotechnology is going to take over from conventional breeding over the next 10 to 15 years in bringing new products onto the market. Other opportunities for biotechnology also exist, particularly in helping to improve opportunities downstream from the farmer. These opportunities are illustrated in the top of figure 3. Figure 3 reiterates why companies are willing to spend significant amounts of money on this new science. It is the science that will be supporting the agricultural market through and past the year 2000.

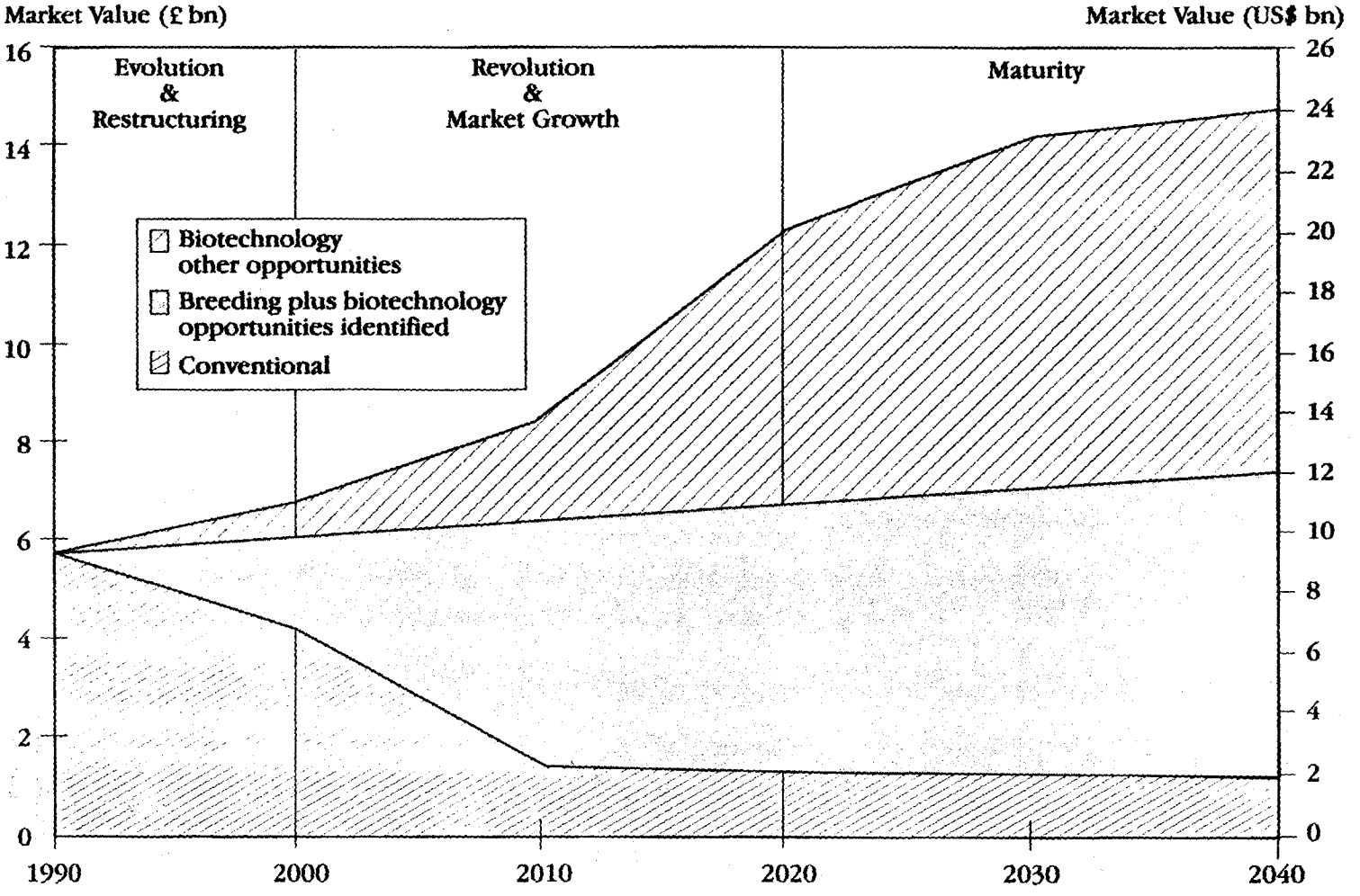
Figure 3 is fine as a sort of vision but how are we going to get there and how far have we come already? Let's look at the sort of techniques that are being used and the possible impact they might have on the seed business in the short, medium, and longer term.

In the short term techniques to help breeding programs--like Restriction Fragment Length Polymorphism (RFLP), somaclonal variation, embryo rescue, haploidy--are going to be widely used for many crops. That's going to have the effect of improving fundamentally the efficiency and effectiveness of the current style breeding programs. Following on from that we expect to see single gene effects, such as herbicide, insecticide, virus resistance and the increased regeneration of plants from single cells. This is the area that many people would really describe as biotechnology and may involve transformation and putting new genes into crops. The effect of this on the market is to produce new hybrids with a major benefit to the farmer because it often will be possible to manage high yields with lower inputs, for example of pesticides.

In the longer term more complicated effects are likely to be achieved through the use of biotechnology. Such effects are disease resistance or stress resistance. New crops tolerant to drought, aluminum, and other stresses are likely to result. We could also manipulate biomass or the quality and quantity of the output, for example oil versus protein in oil crops. Ultimately these techniques could result in the regulation of plant processes, for example senescence. The impact of that would be to produce for the farmer and for the end user of the products modified crop species to some form of 'blue print' bringing significant increase in value throughout the chain.

We have talked a little about methods of achieving the vision and the sort of targets that are likely to be achieved on various time scales, but what about the crops that are likely to be affected and on what time scales can we expect to see results in the market? The most immediate crops that are relatively easy to transform and hence add new genes to are those likely to be affected in the short to medium term. Cotton--I'm sure you've all heard about insect resistance; soybeans--where herbicide resistance seems to be taking the lead; and canola where novel hybridization methods are likely to be one of the first products on the market. Corn and rice have proved a little more difficult to transform

Figure 3. Commercial Impact of Biotechnology



and therefore they are likely to come along a little later. However, the interest in corn and the amount of work going on in that area means that products should be on the market in the medium term, say 1997-98. Finally, for two reasons, wheat is likely to take much longer. First of all it is difficult to identify a worthwhile return on this sort of biotechnology given the current market structure in wheat. Therefore companies are reluctant to invest significant amounts of money. Second, transformation of wheat is by no means easy technically and has yet to be fully demonstrated. Therefore, widespread use of the techniques associated with biotechnology in wheat is going to be a much longer-term prospect.

Nearly all that I have talked about so far applies primarily to the developed world. Work is concentrating in the OECD as I mentioned before. So what is the prospect for other countries outside the OECD and, in particular, in the developing world? I believe technology transfer will depend on four key elements. First if private companies are going to transfer technology to the developing world, then it is critical that there is a supportive commercial environment in the recipient country. For example, that there is reasonable property protection, that any private company is not going to lose its investment overnight. Second sensible regulatory processes and procedures should be in place. Third the only way that transfer can really take place is if there are appropriate local skills. Local skills to develop and build on techniques or traits that transfer from the developed world to produce products appropriate to the recipient country. It's going to be critical that there is some sort of reasonable commercial return to the private company undertaking the transfer. No company can afford to put money into areas where there will be no return on that money.

Finally perhaps one way that we can all facilitate that transfer is to think about setting up mutually beneficial collaborations between the public and local private sector research and private companies willing to transfer their technology. Where these conditions exist, transfer will be rapid because a great deal of the initial technology and work will have been paid for and developed for other markets. Therefore I believe that for products or traits developed by private sector companies, technology transfer is likely to be aimed first at newly industrialized countries and is likely to be first for hybrid crops also grown in OECD countries. That would suggest corn and sunflower are good crops on which to start. Again, collaborations probably offer a route to bring forward products for other crops.

ICI Seeds

Let me now be a little bit more specific and talk about the example - ICI Seeds. ICI Seeds is organized around three bioscience centers. One based in the United States, as the largest potential market particularly for corn. The second in the United Kingdom, because ICI is a U.K. company and has a very strong biological research base in the United Kingdom from which we hope to derive important synergies. And the third one in Continental Europe, also is a very large and significant market. Each of these centers works on world targets so that the laboratory in the United States will also be working on targets for Europe, South America, Thailand, and Australia. Similarly for the other two labs, with each lab having its own particular expertise. As you would expect in the United States we concentrate our work on corn and sorghum. In Belgium we concentrate our work on sugar beet, sunflower, and canola. The United Kingdom concentrates on what you might call fundamental research; gene hunting and cloning and bringing in new technologies that we want to evaluate or develop.

The reason we concentrate on only three centers, rather than diffusing the technology around the world immediately, is that the technology is still fairly difficult. It still requires highly trained scientists and we have found that having a critical mass of those scientists who can work together and develop ideas together leads to faster progress in the science.

I thought you might be interested to know a little bit more about the sort of targets we are working on. I can be a little more specific than I was earlier when talking about the industry. I have picked out a few of the targets we are looking at and identified their first launch dates, and where that first launch will probably be. But then also once we've made that first launch, what are the other countries we expect similar traits to be moved into?

Let's start with a product we have already launched in the United States--that is imazethapyr tolerant corn, a product you probably know better as "Pursuit" ("Pursuit is a trademark of American Cyanamid) tolerant corn. This product already has been launched in the United States and it is positioned for two purposes. The first is to offer the farmer an additional herbicide choice so he can manage his herbicide regime more effectively. And the second is in places where carry-over after a soybean crop is a problem. Other countries which have shown an interest are Brazil and Thailand and both of these opportunities are being actively followed up now so that launch should take place in 2 to 3 years. We are working on several corn diseases, primarily by using breeding aids at the moment. The first launch of these should be sometime in the mid-1990s. Again starting in the United States but also with an application in Europe.

As you probably know ICI is a leading player in the sunflower seed market. We are therefore working on several sunflower diseases using a variety of different techniques. There will be a range of launch dates ranging from the mid- to the late-1990s. One of the prime recipient countries for this technology will be Argentina where the sunflower market is large and we have a significant stake. Other countries to follow will probably be in Europe and the United States.

You may already have heard about our improved processing tomatoes which should be launched in the early- to mid-1990s starting in the United States but with potential for application in Chile, Europe, Japan, and Turkey.

I have just touched on a very few of the targets that we are working on but our problem is the same as yours. Although we spend a large proportion of our turnover on research, our resources are still limited and the ideas generated as to what we could do **vastly** outweigh the number of targets we can **effectively** pursue. If we believe a target is worth pursuing we should resource it to a level where it has a fair chance of success. So that leaves us with a problem. How do we decide what to pursue among all the ideas coming from the scientists and the commercial people, all of whom believe their idea is the one we should follow?

The process we use is fairly straightforward. It actually takes a significant amount of time because one of the things that's critical is that we take with us those scientists and commercial people--that there is some form of consensus on the targets we follow. We start by looking at both the technical and commercial implications of each target. First of all how technically feasible is each? Can the scientists say what we need to do to achieve the target or is it just a woolly idea? If it's a woolly idea, we're likely to be wasting money if we put significant money behind it at this stage. In parallel with that review, we look at the commercial value of each target. We are a commercial company, and we need to produce a return to our stakeholders, staff as well as shareholders. So we need to rank possible targets as to the sort of return they are likely to bring to ICI. What we then do is to take both those pieces of information and look at targets both by commercial value and technical viability. We then need to balance our portfolio. We need to make sure we have a fair spread of short-, medium-, and long-term targets, spread both by crop and by geographic area. Ranking these and discussing them within the commercial and technical groups gives us a short list of targets to pursue within the resources available.

So how do we pursue those targets? First of all we start out with a clear, critical path. A clear idea of where we are going on the science, what we expect the scientists to achieve and when. This also helps us to balance our resources over the next few years, both in the field, where significant support is required, and in the lab. The bioscience work in the laboratory is obviously the first step but then the work has to go out into the field, into a development program where bioscientists and breeders must work closely together. To ensure that this happens we have set up an organization around crop management groups where a small team consisting of a lead breeder, a lead bioscientist, and somebody from the strategic or commercial area work together to ensure there is a clear path to the market for any products on which we are working, and that that route to the market is the most cost-effective on a worldwide basis. Eventually the product is then launched commercially in the lead territories.

We are a fairly complicated organization. All aspects of the business must work together, must be pulling in the same direction, in order to make that commercial launch. It is necessary to pull together the basic science, as represented by the universities and our own laboratories, into field development and through to a commercial product. It is only by the whole group working together and understanding their expectations that we can make this happen on a reasonable time scale.

Conclusions

Finally I'd just like to say that ICI Seeds believes the potential market for bioscience is worldwide. We have to start somewhere, and that is where the major markets lie today, but the eventual aim is to reach markets around the globe. I believe that a great amount of effort is being expended in using biotechnology as a tool to pursue world targets to improve crops for the benefit of all countries around the world. Because of the market dynamics initial exploitation is likely to be in the OECD countries but technology transfer to other areas will be rapid if and where the right conditions exist and if we work together to make sure it happens.