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From Romance to Realism: Opportunities and Issues in Commercializing Biotechnology in the Food Industry

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Paper prepared for UNIDO Expert group meeting(EGM) on "Commercialization of Biotechnology"

October, 1991.

INTRODUCTION

Biotechnology is ushering in a new era in the history of mankind. Its impact is widely recognized to be far reaching. It is expected to radically change the way we do things -- be it in human health care, animal husbandry, agriculture, food processing or environmental management. Although the thrust of the first generation of modern biotechnology has understandably been in high value/low volume human therapeutics, the grass-roots impact of biotechnology is likely to be realized in a much broader and more significant way in agriculture and food processing. Biotechnology can influence every facet of food production and distribution -- from the farmer to the consumer.

"Modern" biotechnology owes its origins to the fundamental discoveries and inventions made in the mid-seventies which allow one to isolate, clone and express genes abundantly. Genes of interest can thus be transferred from one species to another. Success of this genetic engineering approach has been demonstrated in a wide variety of applications. Many of these developments have already been translated into commercial practice --- particularly in human healthcare products. A number of business issues have had to be dealt with and resolved before the successful reduction of the technology into commercial products. These include patent/ legal issues, government regulations such as those mandated by the U.S. Food and Drug Administration (FDA), consumer acceptance, and market development.

Commercializations in the agriculture/food area lag significantly behind those in the human therapeutics and diagnostics arenas since the potential barriers to enter the market place are even more challenging. For instance, many more federal agencies and regulations -- in addition to FDA --

are involved including the Environmental Protection Agency (EPA) and Department of Agriculture. [Although the U.S. agencies are cited here, similar organizations and regulations are operative in other countries.] Consumers' "fear of the unknown" presents an even more formidable problem when it comes to food products.

In this paper, I analyze selected examples of biotechnology- derived agriculture/ food products from the developed world which are already in the market place or are close to commercialization to provide insights into ....

- Factors contributing to successful commercialization .
- Related issues which must be addressed early on.
- Cost and benefits .
- Market positioning.
- Consumer perceptions
- Potential pitfalls.

Based on this analysis, I develop and recommend commercialization modalities suitable for developing countries.

BIOTECHNOLOGY DERIVED PRODUCTS IN FOOD AND AGRICULTURE

While a spectacular array of applications of biotechnology is being contemplated and worked on, they can be conventionally grouped into the following categories.

1. **Agronomic Improvement in the Field** These relate to the imparting of specific traits to field crops and include such applications as disease

resistance, herbicide resistance and the like. Also included here are improving field yield as well as tailoring the composition of the desired crop materials such as the alteration of protein to carbohydrate ratio in potato.

2. **Improving the Economics of Agricultural Inputs** The most noteworthy example in this category is the provision of adjuncts to nitrogen fixation and ultimately tailoring major crops to fix atmospheric nitrogen so that external introduction of conventional nitrogenous fertilizers can be obviated.

3. **Improvements in Animal Husbandry** Preventive vaccines for such diseases as foot and mouth disease in cattle, improving yield through the chronic administration of growth hormones, (for instance bovine somatotropin and fish growth hormones) are examples of this category. Use of embryo transfer technology to breed elite animal varieties also falls under this category.

4. **Food Processing Aids** Development of the next generation of food processing enzymes through the employment of genetic engineering is a major endeavor in this area. These include both novel enzymes as well as significant cost reductions in existing enzyme applications. Rapid detection of food borne pathogens such as Salmonella through DNA probe technology is another commercial objective.

5. **Food Ingredients** Cost reductions in ingredients already in use and development of novel functional ingredients are both targets in this category. Substantial reduction in the cost of sweeteners such as aspartame through

genetic engineering is already in the commercial arena. Development of novel polysaccharides and food gums is being actively worked on. A new generation of food flavors, ingredients and natural colors through improvements in tissue culture technology is also being pursued. That the latter represent "natural alternatives " to a chemically synthesized counterparts may present a unique market positioning opportunity in the developed world. The use of novel protein hydrolysates to achieve important functionalities such as fat mimetics represent yet another emerging commercial opportunity.

The basic technology in many agriculture applications is genetic engineering which has been particularly successful in conferring single gene traits such as s disease resistance into crop plants. Cell fusion and cell selection technologies including somoclona! variations and related ones have been successfully employed as adjuncts for this purpose. Where a desired trait is a multigenic one, the underlying problem is far more complex. The exact biochemical pathway leading to the culmination in the desired trait such as increased solids level in a tomato fruit is yet to be achieved since the exact genes involved in the pathway are not clearly delineated in such cases. Attempts have been made to resort to the identification and cloning of the likely genes responsible through brute force methodology such as restriction fragment length polymorphism (RFLP) technology. However, this has produced very limited success.

A particularly exciting technology, useful in reducing and /or eliminating undesirable functions is antisense technology. It has been used, for instance, to eliminate undesirable food processing enzymatic activities such as poiygalactoranase in tomato.

SELECTED COMMERCIAL EXAMPLES

1. Genetically Engineered Heat Stable Starch Liquefaction Enzyme

Enzymatic depolymerisation of native starch suspensions with α–amylase enzyme is the starting point for the multibillion dollar corn wet milling industry in the U.S . It has been used in this industry for many decades. It is a relatively simple enzyme which is produced as an extracellular protein by different organisms. The liquefaction reaction has to be carried out at temperatures above 105°C and the half life of the enzyme is limited at these temperatures. A more stable enzyme preparation could catalyze the same reaction with a lesser dosage and thus result in reduced enzyme cost. This objective has been achieved by introducing a thermostable α- amylase gene from a thermophilic bacterium to a Bacillus species.

Originally developed by CPC international, a major player in the U.S. corn wet -milling industry, this development has already been commercialized. Although CPC could have retained this as a proprietary development for its exclusive internal use, the competitive advantage to be gained from reducing the enzyme cost is somewhat limited. In other words, it accounts for less than 1% of the finished product value. Therefore, CPC licensed the technology to a separate entity, Enzyme Biosystems Corporation for producing and supplying it to all the companies in the corn wet milling industry - - thus generating a higher revenue for the product which would benefit the entire industry.

The choice of Bacillus as the host organism greatly simplified the regulatory approval process since the same genus has had extensive use as source of non engineered α– amylase for along time. In addition, the U.S.

FDA classifies Bacillus as a GRAS (Generally Recognized as Safe) organism and as such does not require extensive studies to establish its safety.

This is an example of a relatively modest cost reduction-driven genetic engineering success. Even though the unit cost reduction is relatively small, it still amounts to a meaningful level of total savings enabling it to be commercially viable. Very little consumer issues were involved here since the enzyme itself is used in extremely small quantities in processing corn starch and it is totally denatured in subsequent processing steps i.e.,the enzyme itself is not the final product nor does it appear in its active form in the final product.

2. **Bovine Growth Hormone** Bovine somatotropin (BST) is an endogenous growth hormone in cattle. By boosting its level through exogenous introduction, it is possible to improve the growth and performance of such animals, particularly dairy cattle. Essentially it results in increased milk yield in dairy cows by as much as 15% on a sustained basis. It is also possible to alter the body mass of such animals wherein the ratio of fat to protein is decreased. With the ever increasing demand for reduction of saturated fats in the western diet, such leaner animals would have a market appeal.

The BST gene has been successfully cloned and expressed in large quantities in bacteria. Extensive field trails have established increased milk yields and independent safety studies have indicated no adverse effect from the consumption of milk product. Nevertheless, BST commercialization is bogged down in a quagmire due to a number of external factors.

The principal challenge to commercial acceptance is the very genesis for the development of the project in the first place i. e. is there a market need? The western world is awash in a deluge of excess milk and dairy products. Therefore, the value of producing an even greater excess is being debated. Although the size of the dairy herd would eventually be reduced to maintain the appropriate market equilibrium (fewer cows producing the total milk demand) this issue has a become an emotive one among many dairy farmers. Several leading dairy states in the U.S. have banned the use of BST in spite of its endorsement by the federal FDA. Leading food processors such as major ice cream manufacturers have also independently and unilaterally decided not to use milk from BST-infused cattle. This is clearly a case of not satisfactorily managing consumer perception issues. Furthermore, the cost of BST is significant -- amounting to about 50 c per animal per day.

Monsanto is the leading developer of BST and the company has already expended millions of dollars in trying to bring it to the U.S. market place. The other players in this and other growth hormones are American Cyanamid and IMC(International Minerals and Chemicals). Whether this product will ever see the sun shine of the market place is still open to debate. It appears to have a questionable need, equivocal economics, strong political opposition and almost belligerent consumer non-acceptance. However, BST could be a boon to both Eastern Europe and many developing countries.

3 . **Asparatme Intermediate** Aspartame is a major non-caloric sweetener extensively used in the western world. It is a methyl ester of a dipeptide derived from L-aspartic acid and L-phenylalanine. It is nearly 200 times sweeter than sucrose. Since its introduction in 1982, worldwide sales of aspartame has grown to be over 800 million dollars per year. It has replaced sugar in a wide variety of food products -- most notably in diet soft drinks.

Aspartame is an expensive sweetener costing between $50 and $80/lb depending upon a number of factors. Nearly 40% of the cost of production is attributable to L-phenylalanine cost which is primarily produced through classical fermentation. By applying r-DNA technology, the efficiency of the fermentation process has been improved dramatically. A commercial collaboration between a small biotechnology company (Biotechnica International) and a major food processor H.J. Heinz Company developed this improved process. The entire aromatic amino acid pathway was manipulated and the concerted expression of all the genes in the pathway was optimized. This results in a substantial increase in product yields, conversion efficiencies and reduced fermentation cycle time. The genetically engineered *E. coli* represents an interesting application of biotechnology in that the manipulated genes are all native to *E. coli* and no foreign genes from other species are involved. The improved process results in a cost reduction of over 50%. It is a relatively simple process, easy to scale up and employs a clean well defined medium. The process is entering final stages of commercialization.

This is a good example of a cost driven process development. L-phenylalanine produced by recombinant *E. coli* is indistinguishable from L-phenylalanine from any other source; the fact that only *E. coli* genes are involved and that the recombinant organism is completely destroyed at the end of the fermentation cycle significantly facilitate the regulatory status of this process. Traditional scale up methodologies could be employed to translate the process to commercialization levels easily.

A similar process has been developed and implemented for the production of L-aspartic acid. Although the cost reduction is not as great as in the case of L-phenylalanine it is still meaningful.

4. Insect Resistance in Cotton Plants Insect attack of cotton plants is perhaps the principal reason for reduced yields of cotton around the world. A number of lepidopteran insects are involved and the particular species varies depending upon the location and climate. Multiple sprays of chemical insecticides (upto ten sprays per season) are used broadly to control these insects. In some developing countries such as India, nearly 50% of all insecticides are dedicated to insect control in cotton. Such extensive and repeated use of chemical insecticides has led to the evolution of resistant mutants against which the chemical insecticide are proving to be no longer effective. The environmental burden caused by these chemical agents is also heavy.

An alternate approach to the use of chemical insecticides has been made possible through the application of genetic engineering technology. In essence, it confers an insect resistance trait to the cotton plant. It is well known that the protein toxin produced by naturally occurring *Bacillus thuringiensis* (BT) is an effective bioinsecticide. When sprayed, it is known to control certain types of insects on plants. By isolating and introducing the BT protein gene into the cotton plant, it can be made to resist attack by a number of insects including lepidopteran. The protein can be expressed throughout the plant; upon ingestion of any part of the cotton plant, the attacking insect is killed off. This is a superior approach to indiscriminate spraying of insecticides in that the resistance is contained within the plant itself.

A number of U.S and Western European companies have been working on insect resistant plants via the BT toxin technology . A major U.S. company has successfully demonstrated the technical feasibility and commercial utility of this approach. An important factor contributing to this accomplishment is the ability to amplify the gene expression level several orders of magnitude so that adequate protein levels are present throughout the plant. A close collaboration between the company and a major U.S. university facilitated this accomplishment. BT toxin itself has been extensively studied and it is devoid of mammalian toxicity. Extensive field trials have been conducted in multiple locations over at least two growing seasons to demonstrate the field effectiveness. Appropriate town meetings to win the confidence and concurrence of the local populace have been conducted. There were a number of informed discussions and deliberations among opinion leaders as well as the public at large concerning the approach being taken. This was in addition to obtaining the necessary approvals for field tests from the U.S. Department of Agriculture. Environmental activists lobbyist who generally tend to block the introduction of new technology or product into the environment have become a surprising support community as they view the *in situ* insect resistance trait to be environmentally more benign compared to the use of recalcitrant chemical insecticides.

In addition to proving the effectiveness of this approach in actual field performance tests, extensive studies are under way to insure the safety of cotton seed oil for human consumption and cotton seed as an animal feed.

The insect resistant cotton plant is projected to be far more cost effective than the use of chemical insecticides -- as much as 40 to 50% cost reduction is possible. A long term question that remains is whether new resistant mutant insects would arise and if so what would be the efficacy of this approach. One partial answer might reside in the use of different types of BT protein genes isolated from other species. In fact, a second generation BT gene with a different mode of action is already being developed.

Widespread commercial use of insect resistant cotton plants in the U.S. is waiting appropriate regulatory approvals. It is not expected for another three to four years despite the fact that there is an overwhelming acceptance of this approach by several cotton farmers.

Recognizing the value of this approach to many developing countries, the major U.S. company in question is actively embarking on a program to license the use of this technology to some of these countries. Several commercial issues need to be addressed before the technology transfer could be made: a) Although protected by major patents in the U.S. and Western Europe, the technology protection is far less in the developing world. Some of the countries are not signatories to the International Patent Convention. Considering that the BT toxin gene is ubiquitously present throughout the plant, the gene is potentially accessible to any interested parties. b) Hundreds of millions of dollars have been invested by the company in bringing the technology to the point of commercialization. Reasonable returns on this investment must be realized. c) Insect resistance trait must be transferred to individual varieties of interest in the particular country. d) Despite the successful demonstration of the technology there is some reluctance on the part of individual countries to make an up front payment. e) Potential application of this technology to other crops and the value associated with them.

Not withstanding these issues, a commercial license is being discussed between the company and a major developing country. The creative approach being followed here -- while not yet finalized -- involves the licensing of the BT gene and the associated technology for the country in question for an affordable sum of money spread over many years and triggered by meeting specific commercial milestones. The arrangement also calls for the training of selected scientist from the country in question in the U.S. to enable them to assimilate all the details and intricacies of the technology in a "hands- on" fashion so that this knowledge can be translated into tailoring the indigenous cotton plant varieties to incorporate insect resistance. This approach can be a model for transferring advanced genetic engineering applications to address pressing problems in the developing world in an efficacious and cost effective fashion.

5. **Bioinsecticides** Another approach to utilize BT toxin technology is to employ the toxin directly as a spray, i.e. instead of chemical insecticides. In fact, BT-based bioinsecticides have been used in certain insect control applications for many decades. However, its effectiveness is often limited. By amplifying the amount of the toxin protein through genetic engineering, it can be enhanced. This is the basis of development being pursued by a number of companies .

Among the new U.S. companies following this route are Mycogen, Ecogen, Crop Genetics and Calgene. Mycogen's version of BT insecticide is now commercialized. Perhaps the single most potential impediment to the commercialization of the BT insecticide spray was the approvals required to conduct the necessary field trails. The idea of releasing a genetically engineered organism into the environment deliberately was challenged by environmental and consumer activist groups at every turn. This became a highly charged political issue and it required major efforts to satisfy these groups before field trials could be conducted.

Mycogen took an interesting tactic to allay the fears of the environmental release issue. Its BT toxin is contained within the bacterial cell where it is fixed following the completion of fermentation when the cells are killed. Thus, only non-living cells are released into the field in the form of a spray (although the toxins's effectiveness remains unaltered). As the

" green" movement gathers momentum, this type of BT insecticide has won consumer/ environmental activists endorsement.

The successful commercialization of BT insecticides was thus facilitated by an improved product form, careful addressing of environmental issues (and in fact, turning them to BT's advantage) and providing better economics through improved performance of the product achieved via genetic engineering.

6. **Microbial Rennin** Rennin is a protease used in cheese manufacture. The traditional source of this enzyme is animal tissue (isolated typically form calf's stomach). Its supply fluctuates widely and consequently the price. A recombinant version of rennin has been successfully developed and commercialized. Pfizer and Genencor (in collaboration with Hanson in Scandinavia) are the leading Western developers. Pfizer's product has already been approved by FDA and is commercial. The latter's version is awaiting approval in the U.S. , although it has reached the market place in certain European countries.

The major economic benefit of this product is price stabilization since the genetically engineered rennin is not subject to the vagaries of the animal-based commodity market. It is slightly less expensive than animal - derived rennin.

This is yet another example of a cost and supply -driven product being brought to marketplace successfully. Rennin is considered a processing aid and as such the FDA regulations are a bit simpler. However, it has to go through the entire gamut of toxicity and safety testing.

7. Microbial Proteases This class of enzymes have broad application as industrial enzyme both in food and non -food areas. The principal thrust of genetically engineered proteases is to improve the properties of these proteases to increase the pH and temperature stability. Non- food applications have already been implemented in such areas as detergents and foods application are awaiting FDA approval.

This opportunity is based on the ability to understand the structure - function aspects of these enzymes and modifying the catalytic activity to secure additional advantages. The genetically engineered versions are all cheaper than their non-engineered counterparts.

8. Engineered Tomato As mentioned earlier, antisense technology has been successfully employed to substantially reduce undesirable enzyme activities in the tomato fruit. Calgene and ICI are two key companies involved in attempting to commercialize these developments. The advantages are better ripening control, improved field handling and transportation characteristics and enhanced yield in processing. This development is yet to win FDA approval. Key questions surrounding the approval process are safety of finished products and effective testing protocol to assure the same. Appropriate market positioning would also be necessary to assure the consuming public about the safety of the products. Ultimate economic parameters are also yet to firmly established.

This is an exciting application of anti-sense technology which is a precursor to a number of similar applications in other fruits and vegetables. The factors mentioned above have to be worked out to ensure in each case commercial viability.

A related example is the application of tissue culture and related technologies (non genetically engineered) to improve the organoleptic and textural properties of selected vegetables. Spearheaded by DNA plant technology corporation such vegetables are being test marketed in a joint venture with DuPont company under the brand name "Vegisnacks". These products do not require FDA approval as no gene transfer is involved. The purported advantages are improved taste and color parameters. Whether the consumer is willing to pay a premium for this remains to be seen. Clearly this development is market-driven. While an interesting a concept, it is perhaps of little interest to the developing world.

FACTORS CRITICAL TO SUCCESSFUL COMMERCIALIZATION

The foregoing examples illustrate the unique application of modern biotechnology techniques to commercial targets. There are a number of commonalties among the issues that have to be dealt with. In my opinion these would be equally important as these technologies are translated to appropriate applications in the third world. Discussed below are the specific aspects of some of these key factors.

1. **Market need** It is imperative that the market need for a specific application is understood and established *a priori*. This could manifest itself in the form of a cost reduced product, improvements to an existing product such as a chemical insecticide, unique new products and applications, price stabilization, etc. The size of the potential market and barriers to entry would dictate the extent of affordable research and development cost. Market positioning and dealing with consumers issues -- real and perceived -- is of paramount importance. As exemplified by the BST case , it is easy to underestimate opposition from different constituencies.

2. **Development Cycle Time** The genetic engineering industry is fraught with certain degree of herd mentality. A number of companies pick and work on similar targets. Therefore, the ones who could leverage not only their internal resources but also external relationships with the academia and potential strategic alliances with market oriented companies stand to gain substantially. In fact, the latter are becoming more of a norm i.e a developer of an advantageous trait such as insect resistance working with a seed production and distribution company to ensure early and ongoing market knowledge and access to an established distribution system. To develop and

implement a true vertically integrated chain is becoming less attractive – particularly since getting to the market place first is a powerful competitive advantage.

3. **Patent/Legal issues** There is an enormous back lag in the biotechnology patent applications. It takes considerable time and expense to work one's way through the system. Unlike pharmaceutical products, agricultural/food applications tend to have a less comprehensive patent protection. This is further exacerbated by the fact that the patented entities are often present in plants in the open field and as such are readily accessible as illustrated in the case of BT resistant cotton plant. A number of approaches are being pursued to ensure such intellectual property is protected including the imprinting of a genetic signature and the use of hybrid seeds. While these are of some value, their ultimate utility is yet to be tested in real life cases.

4. **Field testing** It is meretriciously appealing to project optimistic commercialization timetables based on limited green house and field tests. But these tests always take longer in real life. Not withstanding the time and effort required to obtain necessary approvals for field trials it is imperative to conduct extensive and thorough multi - generation field evaluations. Teaming with and /or employing first rate plant breeders is a pre-requiste to ensure successful completion of this phase. In addition, to proving the efficacy of the improved trait, there must be no significant changes, in all the other agronomic traits such as s filed yield i.e. the engineered trait should be a valuable addition to the existing commercial traits. Even when approved for commercial use, market penetration takes time and tends to proceed in successively increasing segments and certainly it is seldom an overnight conversion. Appropriate field sales force must be deployed to convince and

win the confidence of the farmers. An exciting technology alone does not represent a winning ticket.

5. **Cost benefits** While intuitively obvious, the economic benefits must be real and convincing. In the case of agricultural applications improved traits should ensure adequate economic incentives to the farmer. For instance, if a herbicide resistant tomato variety saves about $100 per acre net in reduced weed control cost, the grower expects to capture at least 50% of the net savings. This in turn should enter the overall economic equation of a given product to keep potential returns in a realistic perspective.

The thermostable α- amylase example shows that in spite of improved functional properties and reduced enzyme usage it does not translate significantly to the bottom line since this enzyme accounts for less than 1.0% of the cost of the finished product.

6. **Managing the regulatory approval process** It is easy to underestimate the extent of field trials and other testing required to get through the regulatory hurdles. Although the regulatory process is progressively getting systemized and to some extent simplified, there are still areas where the regulation are not clearly defined. Early dialogue with the regulatory authorities and working with them closely and with their inputs is an essential ingredient for success.

7 **Consumer issues** Food products are conscientious choices made by consumers on a daily basis. As such it represents a complex set of realities and perceptions. Careful education of not only the consumers but also the key opinion leaders in a credible fashion is an absolute requirement for market place success. Clearly, there is no single way to do this. Each product and application must be approached on an individual basis. Involving representatives of the affected constituencies and proactively seeking their

counsel and incorporating their inputs into the overall development plan is a must. Continual follow up and timely responsiveness are also critical elements.

OPPORTUNITIES AND DEVELOPMENT STRATEGIES FOR THIRD WORLD COUNTRIES

Biotechnology-derived products and applications represent a dramatic opportunity for the developing countries-- particularly in the food/agriculture sector. Fruits of this technology can be managed to benefit the populace at the grass-roots level. Agriculture applications such as disease resistant crop plants can be introduced without major capital investment requirements. In addition to capturing the obvious benefits of the technology in terms of reduced costs of plant disease control, other benefits such as drastic reduction in pollution and foreign exchange savings are obtainable. Food processing developments can similarly be harnessed to produce and possibly export value-added food products.

While the governments of the developing world as well as international organizations such as UNIDO have definitely recognized the potential benefits of biotechnology and have clearly instituted many projects and programs, a concerted effort should be mounted to move the early fruits of this technology to the commercialization front. Agricultural developments of the type described here are excellent candidates to transfer to the developing world now. They can, in effect, provide "jump start" to push biotechnology to practical utility. Properly planned and executed, they can be complements to existing biotechnology programs in these countries.

In the short term, selected technologies and specific applications can be licensed in from the West, as a means of accelerating commercialization. Following are suggestions and recommendations to consider in this regard.

- License and internalize single gene trait genetic engineering applications such as disease resistance.
- Licensing agency can be a government body or a private entity or a consortium of private companies.
- If appropriate, form a joint venture with the appropriate Western company.
- Stage payments over a period of time tied to accomplishments of specific measurable and meaningful commercial milestones.
- Make arrangements to train local scientists/technicians to incorporate the technology to local entities.
- Leverage local strengths such as ability to conduct extensive less expensive field trials.
- Protect local germplasms and leverage them as part of technology licensing consideration.
- Local production and export of hybrid seed could also be part of such consideration.
- Review and modernize patent and trade secret laws and regulations.
- Where appropriate, simplify regulatory approval process without unduly sacrificing the necessary rigor.

To speed up commercialization of internally developed technologies and applications, a variety of traditional and novel mechanisms can be considered.

- A new breed of entreprenurialism should be encouraged.
- Provide start-up venture capital for initiating commercial project.
- Capitalize on outside management talent to support and encourage technology-based ventures.
- Encourage local private industry involvement in biotechnology projects early on; emphasize commercialization; promote university-industry collaborations.
- Form a variety of strategic alliances with Western companies and academic/research institutions; balance basic and applied research programs.
- Strive to implement and "show-case" one or two short term commercial success.
- Provide a forum for on-going dialogue between industry and academia.
- Harness developments in food processing technology via similar type collaborations/licensing/ joint venture routes.
- Invigorate and incentivize projects and programs to develop and commercialize value-added products.

Clearly, there is not one "correct" approach. A portfolio of approaches and initiatives are needed. Biotechnology is still in its infancy; some early commercial successes are needed to sustain the momentum of development and its propitious translation to practical value.

Acknowledgements

I express my deep appreciation to several people who generously spent time and shared their views with me over the last several years. These include several staff members from Biotechnica International, ICI Chemicals, Monsanto Company, DuPont Company, DNA plant technology Corporation, H.J. Heinz Company and Genencor. I am particularly indebted to Mr. Paul Kiefer of Monsanto and Dr. Ben George of Heinz and Dr. S. Ramachandran, Secretary to the Department of Biotechnology, Government of India.