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An Industry Perspective on the Benefits of and Regulation of Genetically Engineered Plants

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The seed industry has routinely incorporated new technology into its research and development programs. Plant genetic engineering is the most recent technology to be utilized for seed product development efforts. New sources of herbicide, insect, and disease resistance are being incorporated into crop plants using cellular and molecular biology techniques.

New regulatory guidelines have been developed which require regulatory approval before genetically engineered plants can be tested in the field and ultimately marketed. The impact of these regulations on product development is unclear. Hopefully a dialogue will develop among industry, government agencies, and the public such that reasonable and appropriate regulatory procedures evolve. Those procedures need to facilitate the development of beneficial plant products while assuring the public that safety and environmental risks are acceptable.

INDEX DESCRIPTORS: Plant genetic engineering, seeds, regulations.

Future seed product development will draw upon the techniques of plant genetic engineering to add useful new traits to our crop plants. Plants with improved resistance to herbicides and with resistance to lepidopteran insect pests are now in the early stages of product development. Crop production will benefit increasingly from biological controls of disease and insect pests as a result of recent laboratory advances in cellular and molecular biology.

Industry's objective in investing in research, including genetic engineering technologies, is to develop useful new products to sell. The prospects for plant genetic engineering have drawn increasing attention from the USDA, EPA, and FDA despite the historically minimal regulatory oversight in seed product development. Regulatory requirements can greatly impact the development of seed products that have been improved through genetic engineering. Increasing dialogue among industry, government, and the public is needed to ensure that reasonable regulatory procedures develop. American industry and American agriculture must remain competitive in a world economy. Regulation of seed product development must balance the economic and environmental benefits and the risks associated with genetically engineered plants.

The objectives for this paper include describing seed product development, providing examples of traits likely to be added to our crop plants using genetic engineering technologies, and discussing concerns I have about regulatory oversight. Regulatory policies must recognize the public's interest for environmental safety while not unreasonably constraining the commercialization of molecular genetic technology that will benefit agricultural producers and consumers.

PRODUCT TESTING AS A PART OF PRODUCT DEVELOPMENT

Testing new products to identify those suitable for market introduction and commercial use is an essential component of any well-managed product development effort. The same is true for products developed through molecular biology or genetic engineering as it is for products developed through existing or conventional technologies. Successful companies are those who effectively utilize available technology to develop new and useful products for their customers. Research-based companies also invest in technology *development* as well as technology *application* with the assumption that the added cost and risk of technology development will be rewarded when new technology is effectively delivered to the market. Hewlett-Packard, 3M, and Xerox are companies that have successfully delivered technology to the market and they have been rewarded for that. The domestic steel and auto industries are examples of industries that failed to stay on the leading edge of technology development.

DEVELOPMENT OF HERBICIDE RESISTANT CORN HYBRIDS

I will give you some examples of new technologies that are being developed to enhance performance of future seed products. Pioneer is currently developing herbicide-resistant corn. The trait was developed for American Cyanamid by Molecular Genetics Incorporated using tissue culture selection. Since genetic engineering was not used, our product development has not been restricted by the regulatory framework. Nevertheless, genetically engineered herbicide resistance will be one of the first commercial developments from biotechnology. Critics have stated herbicide-resistant crops are undesirable because they will increase usage of herbicides and thereby exacerbate ground water contamination problems. Are such criticisms valid? I think not. More than 95% of the corn acreage is now treated with herbicide. Herbicide-resistant corn will not likely change the percentage of treated acres. Furthermore, the herbicide resistance is to a new family of herbicides that requires very low use rates compared to herbicides currently used on corn. Two to four oz/A (140-240 g/ha) of these new imidazolinone herbicides will provide weed control similar to that achieved by 2 to 6 lbs/A (2.2 to 6.7 kg/ha) of existing corn herbicides. The 16-fold decrease in chemical applied to the soil offers a sound environmental advantage where ground water contamination issues are real concerns. The new herbicides have a performance advantage on problem weeds such as shattercane and wild proso millet. Furthermore, the chemicals possess very low mammalian toxicities compared to many existing chemicals. I believe that the benefits of this new technology clearly outweigh the risks. The commercial acceptance of this technology will depend, however, on the economic return achieved by the farmer if he chooses to use this new technology instead of his existing technology.

POTENTIAL FOR INSECT RESISTANCE USING BIOTECHNOLOGY

Biological control of pests whether insect or disease remains an elusive, but desirable, commercial business. Plant breeders have likely been the most effective developers of commercially viable biological control. Crop plants with resistance to one or more diseases are common. Insect resistance has been more difficult to accomplish, but there are some notable successes. Those include Hessian Fly resistance in wheat, greenbug tolerance in sorghum, and pea and blue aphid tolerance in alfalfa. Biological control in general has an efficacy

ranging from zero to perhaps 70 or 85%, depending on the pest pressure and the weather. Biological insecticides such as Dipel or Thuricide have such efficacies. These insecticides utilize a bacteria, *Bacillus thuringiensis*. The bacteria produces a protein crystal, i.e., the Bt toxin, that is toxic to certain insects when ingested. The products are widely used in home gardens to control cabbage loopers and tomato hornworms. The biologic insecticides are also used in stored grain for Indian meal moth control. The *Bacillus* insecticide has very short residual activity when exposed to ultraviolet light, and thus repeated applications at perhaps 3-day intervals are required for sustained insect control. The products have not been very successful for European corn borer control in corn because of this short efficacy period and the expense of repeated applications. Molecular biologists have cloned the gene for Bt toxin from *Bacillus thuringiensis* and have inserted the bacterial toxin gene into plants. The Bt protein is produced in plant leaves at levels sufficient to make the plants insect resistant. Bt toxin is not toxic to mammals, including humans. Insects have an alkaline gut that breaks the Bt protein into a component toxic to the insect. The Bt protein is simply digested without harmful effect in mammals which have an acid gut. Genetic engineering may make biological control commercially viable where it has had limited success to date.

Making biological control competitive with chemical control seems a worthy goal to pursue. The American consumer has demanded consistent insect control in our fruit and vegetable products. Only chemical insecticides have provided the necessary level of insect control. If genetic engineering improves plant insect resistance, for example by producing Bt toxin that is stable when exposed to sunlight, biological control may displace some chemical controls. That could enhance profitability to producers and offer desirable environmental benefits as well.

NECESSITY OF GENETIC ENGINEERING IN REMAINING COMPETITIVE

Pioneer Hi-Bred International is a research-based company, and we plan to use available technology to develop useful, new seed products for our customers. That includes using genetic engineering technology to introduce new, desirable genes or traits into plants. We must use genetic engineering technology as aggressively as we have used the computer or other technologies to enhance our product development if we are to remain competitive in the genetic supply business. To ignore technology due to regulatory uncertainty, due to a poorly informed public's concern over safety of the technology, or due to our unwillingness to risk the research investment is to renege on our commitment to deliver superior seed products to our customers. We must compete in the international arena of seed product development if we are to survive as a company and if we are to deliver seed products to our customers that will maximize their profitabililty. It is from this perspective that Pioneer views testing and marketing genetically engineered plants. This perspective is likely shared by most agricultural companies developing genetically engineered microorganisms and animal products. I think it should be a perspective shared by farmers who realize how critical being the low-cost producer of agricultural commodities is to their survival in today's world economy. It is a perspective our steel and auto producers failed to maintain, and they are struggling to regain their competitiveness and profitability.

CONCERNS ABOUT REGULATORY COSTS FOR PRODUCT DEVELOPMENT USING GENETIC ENGINEERING

That pragmatic view of the utility of genetic engineering might suggest that Pioneer or perhaps industry in general should pursue this new technology without regard for public safety or the environment. Clearly that cannot and will not be done. But what risk does genetic engineering technology pose? Newspaper accounts, often reporting scientists' claims or testimony before congressional committees, convey the message that genetic engineering technology is both powerful and useful. Others, including critics of the technology, point out risks they perceive from genetic engineering. The regulatory framework published in the June 26, 1986, *Federal Register* demonstrates the concern of the regulatory agencies who are charged with protecting the public health and welfare. I am not here to tell you that there are no risks associated with genetic engineering technology. There are risks associated with any new technology. There are also benefits. Pioneer is anxious to exploit the benefits of genetic engineering technology. We want to do so prudently such that benefits clearly outweigh risks. I feel the industry, the general public, and the government must work together to consider the risks and the benefits of applying genetic engineering to improve the efficiency of our agriculture, to diversify our agricultural production, to improve human health, to improve animal health, and to improve biological processing. Regulatory oversight is needed as we develop the technology. Yet that oversight must be consistent with the risks that are likely to be encountered, and quite frankly, consistent with the profit potential of a given product. If expenses to gain regulatory approval exceed the profit potential of the finished product, there will be no new product developed by the private sector.

I am concerned that the regulatory requirements currently being implemented may prove to be overly restrictive. How the various agencies will interpret and implement the regulations are not fully known. Pioneer and other companies have provided input to governmental agencies as the rules were developed. The industry has recognized the need for reasonable regulations. We have also recommended that provisions be made to relax the regulatory requirements as experience suggests such relaxation is warranted. The current regulations may be sufficiently burdensome to severely limit the development of the technology for the good of American agriculture, the good of American business, and yes, the good of the American public. We get mixed signals from the regulatory agencies, and that will likely continue until the coordinated framework is fully implemented. This regulatory uncertainty poses some significant risks for industry. An example may help make the point that products can be regulated out of the market. Let's assume that genetic engineering of soybeans and wheat is possible, and we have a gene that will control cyst nematode of soybean and one that will control Russian wheat aphid in wheat. Let's also assume each variety with the new trait will be treated as a new pesticide under the regulatory framework. Expense to meet USDA/EPA requirements for field testing will be several thousand dollars unless long-term animal toxicology studies are required. That will be an agency decision. The costs would then escalate to $1 to 2 million. Alternatively, if FDA feels a gene that enhances lysine content of cereal proteins must be considered a food additive, FDA food additive approvals can cost over $10 million. If regulatory costs approach $1 million or more for a single seed variety, it is unlikely that a seedsman can afford to deliver that product to the market. Pioneer has had few if any soybean or wheat varieties generate $1-2 million in profit before being replaced by a new variety. In fact, total net contribution over the past 5 years for Pioneer's entire soybean product line has been $7.5 million, and Pioneer's wheat product line has lost $4.4 million for the same 5-year period. Those contributions are before indirect costs and tax payments are removed. How much regulatory expense can these self-pollinated crops afford? Do we want more effective biological control of insects and disease pest in self-pollinated crops?

BALANCING REGULATORY COSTS AND PRODUCT BENEFITS

How can we keep regulatory costs low while providing for public safety? We must find an answer to that question if companies are to deliver genetic engineering technology to the market and if we are to rely more heavily on biological control in crop production. This will require industry, government, and the general public to work together to assess the risks and the benefits of the technology, and to implement regulations that support the development of the technology while not threatening public welfare. It is urgent that we begin developing the experience we need to identify the real versus perceived risks of the technology. It is also urgent for us to examine our experiences in field testing conventional products as those experiences may predict risks associated with products developed using these newer technologies. Small-scale field tests of genetically engineered plants in an isolated location where the plants are not allowed to set seed will not provide much valuable experience, yet that is all that is being allowed today. Furthermore, it is not clear how to get from this initial field test to a commercial product which can be sold to a farmer. Clearly more work has to be done. The work can only be done if we avoid being adversaries and instead decide we must answer the questions together. We need to lay all the problems on the table and decide which are real and which are perceived. We need to share relevant data and experiences that are pertinent to risk assessment. Relevant data do exist. Then we can work to solve the real problems, ensuring that benefits to society are weighed along with risks. Mistakes may be made, but under reasonable guidelines potential harm will be minimized and the information gained more valuable than if no experience were gained. The mistake I fear most is that we will be so cautious that beneficial products are denied society. Of course we cannot put a price on what could have been unless a competitor, either domestic or foreign, succeeds at our expense.