CASE STUDY 5: Application for Commercial Release of Genetically Modified Herbicide-Tolerant Soya

1. Brief Description of the Genetically Modified Plant

The transformed soya varieties (*Glycine max*) are all suited to local production. They have been transformed with a *Gox* gene from the soil bacterium *Streptomyces*. This gene confers resistance to the herbicide, Roundup. Herbicide tolerance offers a significant benefit for farmers, consumers, and the environment. This technology allows the farmer to use fewer agrochemical applications, to plough less, to use less fuel, and to produce a product with lower chemical residues.

2. General Release

The seed will be marketed to farmers through existing channels. The bags and brochures will be clearly labeled "genetically modified," and information about the modification will be provided to all seed buyers. Information will also be provided on the revised growing strategies and how to make the very best use of the technology. Farmers will be encouraged to declare the harvest as genetically modified at oil seed depots. The first crop is expected in two years. The first year will be used to bulk up seed for sales in the second year. The second-year crop will make up about 10% of the total soya production. This is expected to increase to 80% over five years, with 20% kept GM-free to exploit European niche markets and their inflated prices.

3. Description of Any Product Derived from the Plant

Soya is used in about 1,600 processed food products as a filler and as a source of healthy, affordable protein. Processing and cooking denatures the foreign DNA and foreign gene product. In the absence of local labeling guidelines for GM foods, food processors have been asked to label all foods containing detectable foreign protein as "genetically modified." This will probably require the labeling of milled, unprocessed soya meal, but no other products in the processing line. Soya seed is exported to neighboring countries and will be declared "GM" before shipment.

4. Brief Summary of Field Trials Undertaken

Six years of field trials have been undertaken in this country. The trial data have shown that gene transfer to local flora does not occur and have supported the claim that the herbicide-tolerant soy leads to increased production, decreased herbicide usage, decreased plant damage, and decreased soil erosion through the associated conservation tillage techniques.

Table 1 shows results obtained in comparative trials with four GM soya varieties in three growing areas. In each area the suitable GM soya varieties were compared to the best available conventional variety for that area. These data are the average of results over two growing seasons.

Table 1: Data collect from comparative trials during two growing seasons

	PERCENTAGE DIFFERENCE COMPARED TO BEST CONVENTIONAL VARIETY FOR THE GROWING AREA				AVERAGE % FOR THREE
PARAMETER	VAR1	VAR2	VAR3	VAR4	GROWING AREAS
Herbicide used	–23	–34	–21	–19	–24.25
Soil erosion	–63	–57	–71	–58	–62.25
Plant damage	–9	–6	–11	–13	–9.75
Yield	12	9	11	9	+10.25

5. Pollen Spread

Pollination in soya occurs before the flower opens, and remaining pollen is largely infertile by the time the flower opens and is visited by bees and other insects. The pollen has proved nontoxic to seven local pollinating species known to visit soya fields. No cross-pollination was observed to related weed species, and no indigenous relatives of soya occur in this country.

6. Seed Dispersal

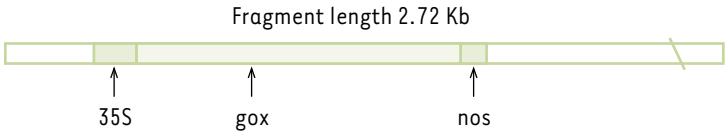
The marketed seed will be labeled as "genetically modified" and all growers will receive information on the technology and how to implement revised herbicide treatment and conservation tillage procedures. The plant is spread by seed dispersal and the seeds are viable. However, studies around soya fields show that there is little dispersal beyond the planted area and no evidence of roadside volunteers could be found. Soya is also controlled by three other registered herbicides in this country, enabling volunteers to be controlled chemically or by tillage. Should GM soya escape into natural areas (no evidence of this has been observed with unmodified crops), it will have no selective advantage, because herbicides are not used in these areas. No adverse affect on the environment is expected.

7. Vegetative Spread of the Genetically Modified Plants

Soya is not spread vegetatively.

8. Foreign Genes and Gene Products

The soya varieties all contain the same gene construct. The *Gox* gene is from *Streptomyces* and codes for a single protein that inactivates the active compound in glyphosate herbicides. The protein lies behind a CAMV 35S promoter that expresses the gene in all plant tissues at all growth stages. Foreign protein levels in seed are between 8 to 20 ng per g dry weight. This is very low and is undetectable under some growing conditions. The DNA and the protein from the *Gox* gene are quickly digested in animal digestive juices (10 to 15 seconds) and are rapidly degraded during the heat and shearing processing methods used to produce processed food additives (Table 2). The genes have been stable for 12 growing seasons.



Linear DNA fragment transformed into soya to give RR resistance

KEY

P35S = CaMV promoter
gox = herbicide-tolerant gene from *Streptomyces* sp.
nos = nopaline synthase terminator from *Agrobacterium* sp.
\ = a second insert (93bp) has been detected in RR soya, but has no coding region, produces no protein, and does not alter plant physiology in any detectable manner

Table 2: Quantitative PCR determinations of GM DNA as a percentage of soya food products

PRODUCT	NEGATIVE*	< 0.5%	0.5% < x < 2%	> 2%
Soya flour	0	0	17.9	82.1
Soya grist	0	8.75	74.0	17.25
Soya protein	0	10.0	87.5	2.5
Composed food	92.0	8.0	0	0

A comparative study by 16 Swiss analytical laboratories averaging the data for two primers: RR and 35S (Nat/Biotech 17:1137–1138, 1999)
* All negative controls were correctly detected by all laboratories.

10. Resistance

No resistance developed to the herbicide tolerance gene in the first 12 growing seasons. However, some recent reports suggest that 6 years of intensive use over large acreage may lead to the development of resistance in some weeds. Should this be the case (it is currently being investigated), the use of alternative herbicides at certain intervals will correct the problem.

11. Human and Animal Health

The *Gox* protein has been tested in human and animal health trials by three independent teams. No evidence of toxicity or allergenicity has been found. A nationwide French study in 1998, to investigate increasing reports of allergenicity to soya, found that the increase correlated with increased consumption of soya and improved allergenicity testing procedures, not with the advent of GM soya as had been hypothesized. The researchers reported that GM soya is the only soya that is tested for allergenicity.

12. Environmental Impact and Protection

Soya has been grown in this country for 15 years with no adverse impact on the environment. Soya is neither weedy nor invasive. The GM soya is not going to change this pattern. GM soya is no more likely to escape into the environment than conventional soya varieties. Any selective advantage conferred on GM soya by the Gox gene is only effective when the Roundup Ready herbicide is used. Thus, the selective advantage is confined to agricultural areas and can be quickly reversed by other herbicides and mechanical treatment. Roundup Ready soya has been shown to be safe for consumption and to have significant environmental benefits including a decrease in soil erosion, input costs, and herbicide usage.

13. Socio-Economic Impact

Soya is mainly grown by commercial farmers in this country. No adverse socio-economic impact is expected. On the contrary, the GM soya will enable commercial farmers to produce soya more competitively, with less environmental impact, and to produce better quality crops.

14. Waste Disposal

The plant waste associated with the harvest of soya will be used in animal fodder, as is that associated with unmodified soya.