
Ecological Aspects of Genetically Modified Crops

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ABSTRACT

It is evident from many recent analyses that the world's population will increase significantly in the near future. As a result, the demand for healthy, affordable food will also grow. Given that the area of available arable land required to produce food will not expand, new and environmentally sound technologies allowing farmers to produce more on the same amount of land must be developed. The development of genetically modified crops through biotechnology is one of several technologies now available to help address the world's increasing future demand for food. The first products from genetic engineering have been introduced recently into the market. Genetically modified plants tolerant to herbicides with superior environmental properties, along with crops that are protected from insect predation while posing negligible risks to beneficial insects, are now commercial realities. Unlike their traditionally bred counterparts, genetically modified crops have been studied in great detail to assure their food, feed and environmental safety. For the genetically modified crops currently on the market, the risk has been assessed in relationship to the benefits. An overview of ecological risk assessment is presented below along with an example of the environmental impact of Roundup Ready® Canola where attention was given to the potential for and impact of outcrossing.

THE NEED FOR NEW TECHNOLOGY IN FOOD PRODUCTION

One of the most important questions confronting society today is how will we produce food in a sustainable manner for a growing world population? Certain facts must be considered in the context of this discussion. Firstly, the world population will significantly increase to some level over the next 30 years. Global population estimates range from around eight billion people to much

higher values. The exact value is almost irrelevant if we simply accept the fact that population increases will be greatest among the poorest people in the world. Secondly, the world's landmass is essentially fixed and only a small portion of this land is suitable for producing food. Almost all of the world's food is produced in an area about the size of North America. Were the population to double, given current agricultural productivity, the land used to produce the food for these people would have to increase substantially. The simple fact is that this "extra" land does not exist. Furthermore, the world's most significant ecological and environmental problems are being created by the conversion of forest and desert areas temporarily suitable for food production. Shortsighted strategies to address the economic, social and environmental problems of a growing population will not be sustainable. Several technologies and new strategies are being developed and implemented to address the need for sustainable food production. A short list of these approaches is given in Table 1.

TABLE 1. TECHNOLOGIES AND STRATEGIES TO ADDRESS THE NEED FOR SUSTAINABLE FOOD PRODUCTION

- Genomics
- Marker Assisted Breeding
- Agrochemical Discovery
- Biocontrol
- New Farm Management Practices
- Biotechnology

Advances in genomics (mapping genes and genetic combinations) are an exciting new area that will enhance the ability to develop new and more productive crops. Plant breeders are also using marker-assisted breeding to facilitate the development of new varieties and reduce the time required to bring these varieties to market. Agrochemical discovery remains an area of important research. Environmentally superior crop protection agents are needed immediately to control pests and promote the growth of crops. In addition to chemical agents, biocontrol offers the opportunity for enhancing safe and efficient agricultural productivity. Important improvements in farming practices such as precision farming, conservation tillage and water management will enable farmers to be better stewards of their land. These technologies combined with advances in biotechnology like genetic engineering of plants are the foundation upon which the important improvements in food production are currently based.

Monsanto scientists are committed to using the techniques of genetic engineering of plants to develop products for the sustainable production of abundant food. As such these products must enable farmers to produce food in a cost effective, socially acceptable, and environmentally sound manner. In other words, to be sustainable, an agricultural product must meet the economic and environmental needs of the increasing world population. The increasing concern and demand for sustainable agricultural products, particularly those derived through the techniques of modern biotechnology, has resulted in significantly more detailed assessments of the safety of new products. This paper discusses some of the potential ecological and environmental impacts of genetically modified crops with particular emphasis on the impact of outcrossing. The discussion begins with an overview of the principles and methods for conducting environmental risk assessment, and concludes with a specific example from a product that has a significant potential to outcross, Roundup Ready® Canola.

GENERAL PRINCIPLES OF RISK ASSESSMENT

We have completed detailed environmental risk assessments on our Roundup Ready® and Insect Protected products according to scientific principles developed and accepted internationally (Kjellsson, 1997; OECD, 1992). The basic concepts of risk assessment applied to genetically modified crops are similar to those used for chemical pesticides where the risk is equal to the product of the exposure and the hazard.

Risk = Exposure x Hazard

In this model, exposure is the probability that something could happen that might potentially be harmful, while the hazard is the degree to which the occurrence is harmful. As a purely mathematical formulation, no exposure or no hazard (exposure = 0, or hazard =0) equate to no risk. However, in science and society there is no situation of zero risk since the potential for exposure and hazard can always be estimated to be greater than zero. This leads us to the concept of acceptable risk that is much more complicated, defies scientific definition and is culturally grounded.

Several principles have been developed to provide general direction to assessing the safety of products derived from modern biotechnology. These principles have been applied to assessing the food, feed, and environmental safety of modified crop plants. Firstly, products developed through genetic engineering using plant transformation technology require a complete risk assessment that is reviewed by regulatory authorities. Secondly, the risk assessment will be conducted on a case-by-case basis. Broad conclusions such as all “genetically modified crops are environmentally safe” can not be made, and the long and short-term effects of each unique product must be examined. Thirdly, the information requested in a risk assessment must be science-based.

Experiments have to be designed to give clearly interpretable results concerning the environmental and ecological risks presented by the release of a genetically engineered plant. The safety factors imposed on modified plants will be modified based on increased information and experience (NRC, 1989). Taken as a whole, these principles establish a rational and cautious approach to assessing the safety of a product.

ENVIRONMENTAL RISK ASSESSMENT PROCEDURE

The first step in conducting an environmental risk assessment is that one must start with the most obvious potential environmental hazard posed by any product, its potential toxic effect. Genetically modified plants often, but not always, express novel proteins responsible for the improved phenotype and selection of transformed plants. If, as has been the case with Roundup Ready®, the potential toxicity of these proteins has been shown to be negligible, the risk assessment focuses on the properties of the modified plant. In the case of products modified to express a protein such as the *Bacillus thuringiensis* (Bt) protein, an assessment of potential effects on nontarget organisms is conducted in addition to an evaluation of the modified plant. The focus of this paper is on the risk assessment of the modified plant. A separate safety assessment of the Bt protein is conducted and will not be discussed further.

Procedurally, risk assessment is an iterative four-phase process including:

- Problem Formulation
- Risk Analysis
- Risk Characterization
- Risk Management

In the first phase, the risk manager assesses the problem using available information about the plant, the trait, and experimental endpoints. The risk analysis phase can also be termed the data collection phase where all the planning during problem formulation is reduced to data gathering. Thirdly is risk characterization, or data analysis. Based on the information gathered, the risk is characterized and the likelihood of an effect assessed. Lastly is risk management where the acceptability or unacceptability of the risk is determined. Very importantly in the risk management phase decisions are made as to future steps and conditions, if any, that must be imposed. The process is repeated until the risk manager is satisfied that all the relevant factors have been considered. In the process of gaining regulatory approval for a modified plant, the conclusions of the risk manager will be reviewed and questioned by scientists in the regulatory or reviewing bodies. It is also important to note that the risk assessment process does not stop after a product has gained regulatory approval or commercial acceptance.

PROBLEM FORMULATION

Much information is available in the literature about the biology, use and agronomic characteristics of plants that have been genetically modified. To date over 25,000 field releases have occurred. The experience and information gained from these releases as well as other data from the literature serve as the basis for determining the important measurements to be taken and the accepted range of experimental results. In formulating the appropriate questions for Roundup Ready® and Insect Protected products, we thoroughly reviewed the literature of the host crop (the traditional unmodified counterpart) looking closely at the agronomic, ecological and environmental properties of the plant. In addition, key academics were requested to provide expert input concerning the biology of the crop plant. Perhaps one of the greatest challenges in the problem formulation was assessing the acceptable variability present in the risk assessment experiments. This variation occurs from genetic and environmental sources, and is present due to the natural complexity of biological systems. Choice of the appropriate control and reference samples is key to developing a valid risk analysis. Information concerning interactions with other organisms, especially beneficial organisms, is often reviewed. The weediness potential and invasiveness properties, as well as the potential for gene flow through volunteers or to wild relatives (outcrossing) are also essential components. Since some crops like canola and sugarbeet have high potential for outcrossing, the necessary management strategies had to be formulated prior to release of the modified plant.

Other important factors related to the potential routes of exposure and hazard were considered in the risk assessments we have conducted on our Roundup Ready® and Insect Protected products. Special attention was given to end use and dissemination. A detailed understanding of how the modified crop would be produced, handled and transported was completed for each product. Since the Roundup Ready® and Insect Protected traits effect an agronomic advantage, it was assumed that their use would not change the production uses of the modified crop. Careful analysis was also given to the nature of the trait, its potential to confer a selective advantage and to produce harmful effect to a species other than the target. The potential for enhanced toxicity of the modified plant was determined by measuring levels of known toxicants (e.g., glucosinolates in canola and gossypol in cotton). Also, as stated earlier, all gene products, as well as the marker proteins used to produce Roundup Ready® and Insect Protected crops, were thoroughly evaluated and shown to be safe.

Because unintended effects are remotely possible, consideration is given to the potential impact of our products on biodiversity. In addition, the experimental strategy takes into account secondary genetic effects such as gene instability and pleiotropic effects. Genetic instability would be clearly evident in a loss or sudden change in the plant phenotype. Lastly, based on the factors

considered during the problem formulation phase, experimental design and endpoints are determined. The process is repeated when new information and knowledge gained from experimental results obtained during risk analysis.

RISK ANALYSIS

We have used a tiered approach to the risk assessment of Roundup Ready® and Insect Protected crops based on the results of our problem formulation. The Tier I data is summarized in Table 2. We have assessed that these data are sufficient to thoroughly assess the risk associated with genetically modified crops. However, a second tier has been included for the situation where more data are needed.

TABLE 2. TIER I RISK ANALYSIS FOR ROUNDUP READY® AND INSECT PROTECTED CROPS

- germination / emergence
- growth assessments
- reproductive potential
- seedbank longevity
- volunteer potential
- susceptibility to pests and management
- field observations and monitoring

In Tier I, data related to the emergence and germination, plant growth, reproductive potential, weediness, and susceptibility to pests were collected. In addition, fields were monitored for effects on subsequent rotations and any evidence for gene flow / outcrossing. When detected, volunteers were assessed for their quantity and tolerance to management practices. Most importantly, all field data and observations were made using a control that was a nonmodified counterpart of the genetically modified plant. For the Roundup Ready® and Insect Protected crops, these data provide a detailed picture of the potential ecological impact present.

If the risk presented by a genetically modified crop were characterized to be significant after Tier I analysis, or if the Risk Manager concludes that more data are required, some or all Tier II analyses could be conducted. Some of the analyses listed in Table 3 are very detailed and may necessitate multiple years to complete.

The results of our risk analysis using Tier I data have been sufficient to conclude environmental safety for all Roundup Ready® and Insect Protected crops. Nevertheless, we have facilitated Tier II analyses of some of our products. For example we supported an outcrossing study with Roundup Ready® canola (Bing, 1991). We also purposely made hybrids between Roundup Ready® sugarbeet and wild beet to study the effect of the trait in the weed (unpub-

TABLE 3. TIER II RISK ANALYSIS

- Hybridization studies
- Outcrossing studies
- Tier I analysis of hybrids
- Allele persistence
- Morphological character analysis
- Multiple crossing experiments

lished). Monsanto will continue to conduct more than the minimum risk analysis as well as make improvements to our risk assessment procedures as a part of our commitment to product safety and overall stewardship.

It is interesting to highlight that outcrossing studies are not a component of Tier I experiments. This is due to the fact that much is usually known about outcrossing to wild relatives from breeding and the scientific literature. Furthermore, as will be discussed later, the inherent ecological risks associated with gene flow from modified crops are not related to the phenomenon of outcrossing (Jorgenson et al., 1997; Hancock et al., 1997).

RISK CHARACTERIZATION

In the third phase of the risk assessment process, all experimental data and observational information are submitted to risk characterization. For the Roundup Ready® and Insect Protected products, the basis for characterization of the modified plant is founded in the concept of substantial equivalence. Though originally developed for assessing the safety of foods and feeds derived from modified plants (OECD, 1990), the basic premise is also appropriate for assessing the ecological and environmental safety of modified crops. The null hypothesis for genetically modified crops with agronomic traits such as Roundup Ready® and Bt is that the modified plant is substantially equivalent to the traditional counterpart. In other words, the modified plant has not been changed in any substantive way in terms of its impact on the environment allowing for the presence of the novel trait. Furthermore, the trait is assessed separately for its potential ecological and environmental impact. Once the experimental data confirm that the plant is unchanged in its ecological and environmental properties (allowing for the presence of the novel trait which is assessed separately) it can be concluded that the modified plant is as safe as the traditional plant.

This method is widely accepted as scientifically valid because of the extensive experience with large-scale environmental releases of the traditional plant. Furthermore, as products with improved environmental properties are developed and introduced, the principle of substantial equivalence and use of appropriate controls will serve as the reference point for future improvements

and sustainable products. However, there is probably a need to differentiate substantial equivalence in the context of food and feed safety from ecological and environmental safety. As such we propose using a term like biological equivalence which defines that the modified plant is biologically (ecologically and agronomically) equivalent to the nonmodified plant in the absence of the target of the intended modification, i.e., the herbicide or insects.

In addition to the risk characterization of substantially (biologically) equivalent, it is possible to conclude that the plant is not substantially (biologically) equivalent. If this were the case, one would proceed appropriately in the risk management phase (*vide infra*).

As mentioned above, the risk of the introduced trait must be thoroughly characterized. For the Roundup Ready® and Insect Protected traits, the most significant potential impacts have been characterized as resistance management to glyphosate and Bt protein, respectively. These characterizations serve as the focus for the risk management phase of the risk assessment for these crops. Appropriate risk management procedures will define the overall impact of the release of a modified plant and the introduced trait.

RISK MANAGEMENT

The philosophical basis for risk management must be founded in product stewardship. Products developed under a strict philosophy of stewardship where the quality, integrity and benefits of the product are viewed against the risk they present will meet the requirements of the stakeholders (customers, consumers, and society in general). Roundup Ready® and Insect Protected products from Monsanto must afford environmental and economic benefit as mentioned earlier, and must enhance the ability to produce a crop in a sustainable manner. The safety of products derived through genetic engineering are assessed by independent regulatory agencies and determined to be at least as safe as existing agricultural technologies. This review is one assurance that appropriate stewardship policies and practices are being utilized. Other assurances are risk management and product support practices after commercialization.

Upon completion of risk characterization, the risk manager must weigh the risk presented by the product against the benefit gained. Clearly, such analyses assume that no action (or inaction) has zero risk. It is this balance between risk and benefit that form the concept of acceptable risk. When the benefits outweigh the risk, the risk is acceptable. All Roundup Ready® and Insect Protected products on the market today have exceeded these criteria. In addition and because our risk management is based on product stewardship principles, appropriate monitoring and resistant management procedures have been developed. These post market surveillance practices are continually being refined based on input from the leading experts in the fields of insect and weed resistance and knowledge gained after release of the modified plant.

Conversely, when the benefits are inadequate compared to the risk, the risk is unacceptable. In both situations, secondary steps must be taken as a part of appropriate risk management. The risk manager may wish to conduct additional tests (eg. Tier II) or propose post marketing management procedures that will manage the risk. In this situation, one additional option available is to consult regulatory, industry and academic experts regarding appropriate management strategies.

THE ENVIRONMENTAL IMPACT OF THE RELEASE OF ROUNDUP READY® CANOLA

Since the focus of this meeting is the impact of outcrossing from genetically modified crops, I will address this issue specifically. Risk assessment experts around the world have shown that introduced genes are inherited in the same manner as endogenous genes (Jorgenson et. al., 1997, Hancock et. al., 1997). Furthermore, outcrossing is not a new phenomenon created through genetic engineering. Plant breeders have been using these principles for years to modify and improve crops. Thus, the impact of outcrossing is not dependent on the phenomenon. Rather, it is related to the nature of the introduced trait. Since the environmental properties of the trait are thoroughly evaluated in the risk assessment, one can gain insight into the impact of outcrossing based on the selective advantage observed in field tests. If the trait confers a selective advantage to the modified plant, it is reasonable to conclude that any hybrids resulting from outcrossing of the trait will also possess the selective advantage.

A real life example of a highly outcrossing plant that also tends to volunteer that has shown no environmental impact is Roundup Ready® Canola (*Brassica napus* var. *oleifera*). This product contains the genes for two proteins, CP4 5-enolpyruylshikimate-3-phosphate synthase (CP4 EPSPS) and Glyphosate Oxidoreductase (GOX) which confer tolerance to glyphosate the active ingredient in Roundup® herbicide. The commercial line was first field tested in 1991 and ultimately received environmental regulatory approval in Canada in 1995. In their decision, Agriculture and Agrifood Canada looked very closely at the issue of outcrossing because *B. napus* is sexually compatible with two common weeds *B. rapa* and *B. juncea*. They concluded that outcrossing to weedy relatives is likely to occur at some low frequency, but that the presence of the herbicide tolerance trait in the weeds confers no greater fitness either in managed or unmanaged situations. They could state this because the plant had not undergone any fundamental changes in its biology, and currently accepted weed management measures were still applicable to control weedy relatives and volunteers. In 1998 the potential exists to plant approximately three million acres of Roundup Ready® Canola in Canada.

Based on farmer experience over the last 3 years, we can confidently conclude that the impact of outcrossing from Roundup Ready® Canola has been negligible. Furthermore, the issue of control of Roundup Ready® Canola volunteer plants has been manageable.

CONCLUSIONS

In conclusion, the ecological and environmental impact of genetically modified crops can be estimated through a rigorous science-based risk assessment. Furthermore, the impact of outcrossing will be assessed in the course of this experimental work. Based on our experience and information to date, the Roundup Ready® and Insect Protected products are at least as safe as their nonmodified counterparts. These new products offer benefits and fit better with sustainable agricultural practices. Most importantly however, risk assessment does not stop once a product receives regulatory approval and commercial acceptance. Superior risk management must be grounded in product stewardship which includes post market surveillance, resistance management, customer service and feedback and other appropriate monitoring practices. One of the critical challenges facing industry and academia today is to design appropriate post-commercialization monitoring activities that will ensure that these and future products contribute to sustainable agriculture.

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