Novartis Australia Pty Ltd
140 Bungaree Road
Pendle Hill NSW 2145
Australia

Tel +61 2 9688 0444
Fax +61 2 9631 3451

Internet: www.novartis.com
E-mail:
margaret.stuart@cp.novartis.com

Inquiry into Primary Producer Access to Gene Technology

House of Representatives Standing Committee on Primary Industries and Regional Services

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Novartis welcomes the opportunity to respond to the House of Representatives Standing Committee on Primary Industries and Regional Services' invitation for submissions to the Inquiry into Primary Producer Access to Gene Technology.

1. Introduction

Novartis Australasia is part of the international Novartis group.

Our core businesses in Australia are in healthcare (pharmaceuticals and vision care), agribusiness (crop protection, seeds and animal health) and consumer health (medical nutrition, over the counter pharmaceuticals and consumer nutrition).

Novartis employs around 550 people in Australia, with major offices in Sydney and Melbourne, branch offices in all states, a world-leading animal health research facility in western Sydney and development and sales staff throughout rural areas. Our activities in Australia encompass basic research, product development, production, sales and marketing.

The Novartis group spends more than CHF 3.7 billion annually on research and development. Headquartered in Basel, Switzerland, Novartis employs about 82 000 people and operates in over 100 countries around the world.

Novartis and genetically modified crops

Novartis has been involved in research and development of genetically modified seeds for a number of crops for over ten years. We sell genetically modified seeds in a number of international markets.

Novartis seeds include:

- BT corn and sweetcorn
  Genetically modified to resist insect pests

- Sugarbeet (jointly with Monsanto)
  Genetically modified to resist the herbicide glyphosate

- Soybeans
  Genetically modified to resist the herbicide glyphosate

Novartis also sells conventionally bred hybrid varieties.

Novartis and genetically modified crops in Australia

Novartis currently does not sell genetically modified seeds in Australia but is evaluating what products could be suitable for introduction into the Australian market. Should we bring these products to Australia, we will consult widely with relevant stakeholders as part of the process of introducing them.

2. The future value and importance of genetically modified varieties

The progress in recent years in the fields of molecular biology, plant physiology and genetics is of tremendous significance for the future of agriculture. The guiding principle of our agricultural research and development is to fully explore these new approaches for the benefit of our customers, the public and the environment and to harness progress for the benefits of society as a whole.

Novartis, and other biotechnology companies, recognised as far back as twenty years ago that agricultural processes and practices of that time could not be sustained and would not be able to meet long term increasing global demands. We therefore focused research on finding alternative approaches to ensuring sustainable agriculture.

This research led to the development of genetically modified crops as one potential alternative. Genetically

modified crops have been shown to play a vital role in agriculture and are expected to contribute greatly to ensuring more sustainable agriculture in the future.

Genetically modified crops are just one of many manifestations of the follow-through of the expansion in our knowledge of the living world into economic reality. They are a crucial tool through which we are trying to reduce the reliance of agriculture on non-sustainable resources (such as the inefficient use of pesticides and fertilisers, and the potentially degrading effects of mechanical weeding) and replace them with biological knowledge, packaged in the seed.

Genetically modified crops can also make a significant contribution to world markets to help increase the world's production capacity of food and fibre.

Seeds with these traits are valued so as to ensure that the farmer gets a net economic benefit relative to conventional varieties, when the cost of seeds, other inputs and increased production are taken into account. Thus, genetically modified varieties also offer farmers an increased financial return.

Future importance

Projections for future plantings of genetically modified crops vary, but all show massive increases around the world. Factors expected to influence this include farmer acceptance of the technology, consumer acceptance of genetically modified produce and development of further genetically modified seeds and plants.

The importance of this technology is also expected to increase as future developments will change the benefits and contributions of this technology over time.

Genetically modified varieties currently on the market focus on input traits – that is, traits that benefit the farmer and the process of agricultural production. These include traits such as resistance to an insect or a herbicide. The primary importance of these varieties is to increase output by reducing threats to production (pests, spoilage).

It is expected that in the second half of the next decade, technologies of genetic modification will focus on output traits. These are characteristics that offer a direct benefit to the consumer. This could include features such as enhanced nutritional benefit and medicinal properties.

Novartis believes that in time, genetically modified crops will come to be regarded as a normal and necessary tool of modern agriculture, in the same way that other farm inputs are currently viewed.

3. The ability for producers to compete using traditionally available varieties

Producers' ability to compete must be considered on two levels:

Internationally

In international agricultural commodity markets, where production cost is a key element in farm profitability, present generation input trait genetically modified crops provide tangible benefits and a competitive edge.

The most important reason for their rapid uptake by the farmers in countries like the USA, Argentina and Canada is that they have a direct effect on their bottom line. They offer value to the farmer - otherwise they would not be willing to pay price premiums for the seed.

In the future, the advent of output trait varieties is going to add to this advantage, because in addition to lower production cost, we will see farmers receiving premium prices for crop varieties with improved specific properties such as nutritional composition.

Given the acceptance of these technologies in major food producing countries such as the USA, producers using conventional hybrids, without the production cost benefit offered by genetically modified crops, will not be able to be as competitive.

Over time, there is likely to be a growing productivity spread between producers growing transgenic varieties and those growing conventional varieties, particularly as seed

producers put more effort into development of genetically modified varieties.

Countries that restrict access to these new technologies will fall further behind countries where there is widespread uptake and be less able to compete on world markets.

As Australia relies heavily on exporting rural commodities for income, if global markets move to new technology, particularly in quality output traits, the competitive position of Australian producers could be severely affected if we are not positioned in similar technology.

Domestically

Within the Australian market, the competitiveness of producers using traditional varieties will largely depend on consumer choice and demand for traditional varieties.

It is too early to see how Australian consumers will take up food grown from genetically modified crops. It may be that a large proportion of consumers may prefer to eat only food derived from "conventional varieties" and therefore a supply chain will grow to provide them.

Another factor that may influence producers' ability to compete is resistance management strategies that limit the area that can be planted with a particular crop, such as the cap on Bt cotton plantings in Australia.

4. The commercialisation and marketing of agricultural and livestock production varieties

Developing genetically modified varieties

It is generally more expensive to develop genetically modified varieties and bring them to market than conventional varieties, because of the additional research and development work and additional regulatory requirements.

There is a common misunderstanding that genetic engineering reduces development time. This misunderstanding is based on the assumption that the seed developer has achieved the goal as soon as they know the gene and can deliver it into the plant, where as conventional breeding can take

generations to achieve a goal because of the need to eliminate undesirable traits.

However, after fifteen years of research and development experience, it has become apparent that genetic modification can increase development time. The necessary laboratory work is complementary to – not a substitute for – field breeding work.

The actual plant breeding work in genetically modified varieties is the same as for conventional varieties, but before this breeding work can start, there is the need for extensive molecular development.

The advantage of genetically modified crops lies not in abbreviated time to market, but in the added value created by the new traits in the crops.

Regulatory systems

Regulatory matters can expedite or slow the commercialisation of genetically modified varieties.

Like all crops, genetically modified crops go through trials to assess their suitability in field conditions. However, field trials for genetically modified crops require special approvals before they can be conducted. As well, these crops must undergo rigorous risk assessments and must be assessed for the purposes of approval as food and feed before they can be brought to market.

The future regulatory system and operations of the Office of Gene Technology Regulation in Australia are not yet finalised, but if not designed well this too has the capacity to make the commercialisation of genetically modified varieties both more expensive and more drawn out. These costs will ultimately be passed on to producers. It is important that the Office of Gene Technology is established quickly to avoid disadvantaging Australian producers.

Novartis would welcome any opportunity to provide input as to how the Office of Gene Technology Regulation should operate.

Inadequate intellectual property protection for the improved products of plant breeders and seed companies can prevent their introduction to a country. Intellectual property protection is important to ensure an appropriate return on investment for innovative companies because of the time and money developing new varieties of genetically modified plants. Issues relating to intellectual property are exhaustively treated in the new international system of Plant Variety Protection as part of WIPO. The community of breeders and seed companies continuously refines its proposals on this, in close collaboration between small and large companies and public breeding institutions such as the CSIRO.

5. The cost to producers of new varieties

The entire agricultural industry operates under a "price for performance" mindset.

That is, the industry expects that any agricultural input, such as chemicals, fertilisers, machines, feed, land and labour, will be priced in order to ensure that the economic benefit to farmers of purchasing them is greater than the cost of the input.

Based on overseas experience, transgenic seeds generally sell at a premium to conventional seeds. This price premium is justified by the high cost of the research required relative to conventional varieties.

Producers have paid the premium as they recognise that the seeds deliver a trait that gives them additional value.

Seeds are typically priced at a level that recognises the added benefits to the farmer, such as more efficient chemical usage, increased yield and reduced effort/time. Thus, while producers pay a premium for the seeds, this is more than offset by the reduced cost of the other inputs required to bring the crop to harvest. Thus producers can expect a higher profit from the crop.

The pricing premium can be passed on to farmers through two channels; either through an increased purchase price or through a licence fee. The licence fee is a clear way of

demonstrating the additional value per hectare of the genetically modified seed to the grower. Many genetically modified seeds are the result of work on the gene by one organisation, and plant breeding work by another, based on licensing agreements between the two organisations. For this reason, the licence fee may be paid by the grower to directly to the organisation which has done the genetic modification development work, rather than to the organisation which has done the plant breeding work and marketed the seed.

6. Other impediments to the utilisation of new varieties by small producers

While the underlying technology is new, there is nothing about genetically modified seeds to make their use different from other seeds. Given the normal course of events, it is not expected that there would be impediments to the utilisation of new varieties by small producers that go beyond those experienced with conventional seed varieties, or for that matter, any other agricultural inputs.

However community concern could lead to various barriers to the use of the technology, based on factors other than scientific assessment. These could include regulatory barriers, barriers to plantings (other than where required for resistance management purposes) and a domestic consumer backlash.

Some concern has been raised about “Terminator Technology”. In simple terms this is a hypothetical germination control process which involves the step-by-step expression of three introduced genes. While the expression of these genes leads to seed that develops normally into fertile plants, the seed harvested from those plants is not able to germinate, preventing producers from harvesting seed from their crop.

Novartis does not intend to use this control of gene expression to prevent seed germination in food crops at any time in the future.

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7. Opportunities to educate the community of the benefits of gene technology

A clear need for community education has been identified in a number of surveys.

Given the wide range of messages and differing needs of stakeholders, the role of community education needs to be shared by a number of parties. It is appropriate for both government and industry to be involved in this process.

Government needs to communicate the role and nature of its regulatory processes and act to ensure that they are viewed credibly by consumers. It is particularly critical that government is active in communicating the credibility of systems that assess the safety to the environment and human health of genetically modified crops. It is apparent that at present, the need for concerns about safety to be addressed far outstrips other issues.

It is also important that industry actively communicate the benefits of the technology. This is complex because modern farming practice is generally not well understood in urban communities, so changes gene technologies will bring to farmers are not appreciated by consumers. Companies involved in supplying genetically modified seeds clearly have a role in educating their own customer base about benefits and issues with the technology. To that end, Novartis is planning a communication program to reach our distribution network and their customers, that is, farmers.

There is a role for food manufacturers and retailers to communicate benefits to their customers. It has been Novartis' experience that communication to consumers closer to the point of sale, that is, through food manufacturers and retailers, may be more effective than communication from seed companies.

For further information please contact:

Peter Gerner, Managing Director, Novartis Seeds Pty Ltd
Tel: (03) 9706 3033

Margaret Stuart, Public Affairs Manager, Novartis Australia Pty Ltd

Tel: (02) 9688 0531

Representatives from Novartis are happy to appear before the Committee in relation to any matter regarding primary producer access to gene technology.