PITA Project: Policy Influences on Technology for Agriculture: Chemicals, Biotechnology and Seeds

Novartis Agribusiness monograph

Annex C12

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Introduction to the PITA Project

Technological innovation in the agrochemical, biotechnology and seeds industries and in associated public sector research establishments (PSREs) has the potential to deliver more socially and environmentally sustainable farming systems and to improve the quality of life of citizens in Europe. This is particularly true of farms on the most fertile land. However, although policies developed in different areas may all aim to improve the quality of life, in practice, in their influence on company and PSRE strategies, they frequently counteract one another and so attenuate the desired effect.

Market-related factors also influence decision making in industry and PSREs, the most important for this project being the policies of food processors and distributors and also public attitudes and opinion, which often set more demanding standards than those of national governments and the EU.

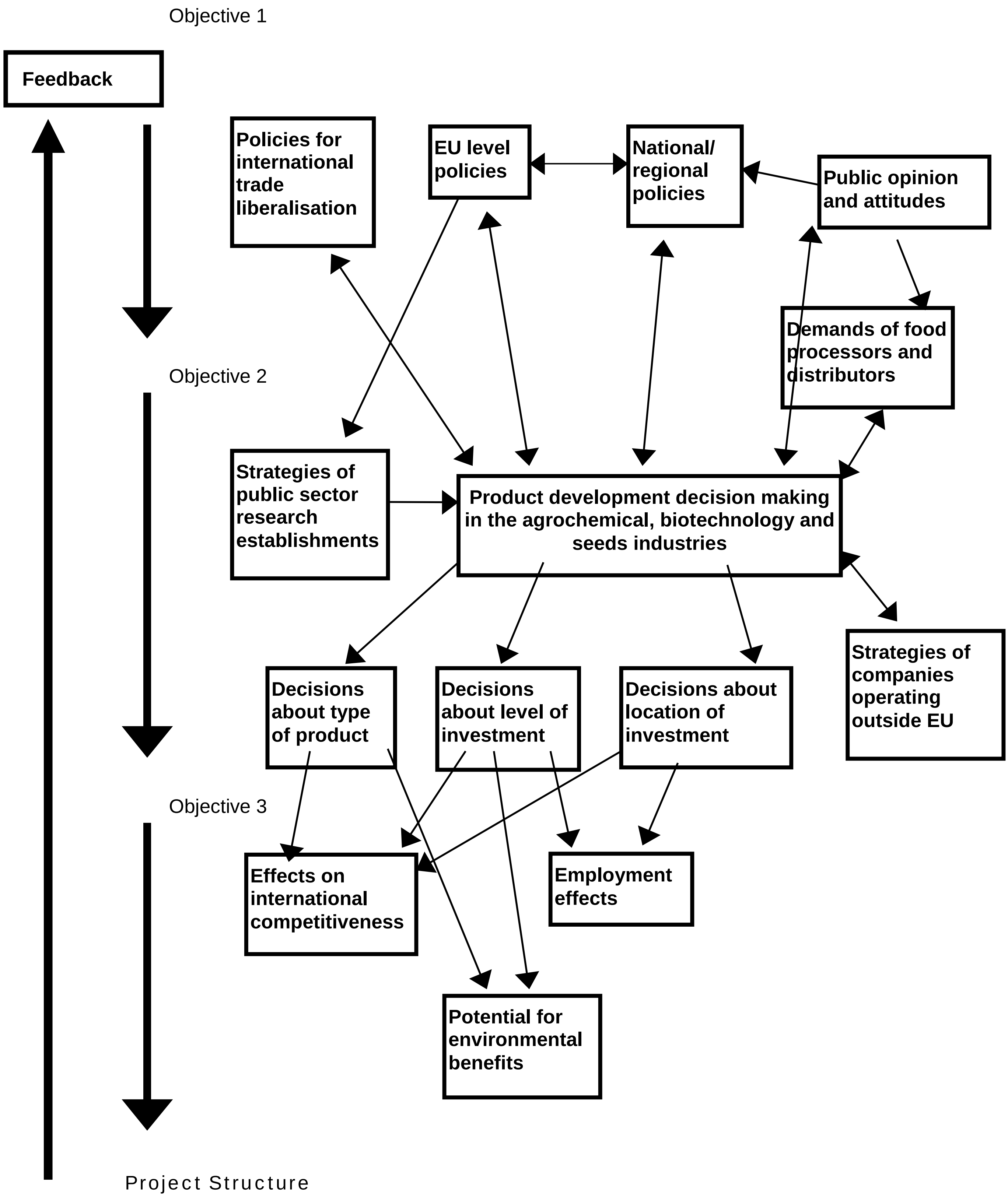
The PITA project (see Project Structure) is developing an integrated analysis of policies and market-related factors relevant to the agrochemical, biotechnology and seeds sectors. The core of the project is an investigation of the impact of these factors on the strategies and decision making of companies and PSREs and the downstream implications of these decisions on employment, international competitiveness and environmental benefits. The final outcome will be feedback of our conclusions to policy makers and company managers.

The range of policies and other influences studied includes:

- policies to stimulate innovation in the agrochemical, biotechnology and seeds industries;
- purchasing policies of food processors and distributors;
- policies for international trade liberalisation;
- policies for the regulation of industry and farming (for environmental protection and public health and safety, particularly for pesticides and biotechnology);
- agricultural and farming support policies, particularly for crop production;
- policies to promote environmental sustainability and wildlife biodiversity in arable farming areas;
- public opinion and attitudes.

The overall aim of the project is to contribute to the development of sustainable industrial and farming systems and an improved quality of life by encouraging the development and uptake of ‘cleaner’ technology for intensive agriculture. Its objectives are:

- to develop an integrated analysis of policies and market-related factors relevant to technological innovation in the agrochemical, biotechnology and seeds sectors, to study their interactions and to develop hypotheses about their impact on strategic decision making in industry and PSREs.
- to study the influence of policies and market-related factors on innovation strategies in the agrochemical, biotechnology and seeds industries and PSREs, and their impact on decisions about product development, levels of investment and location of investment.
- to study the outcomes of the industry decisions investigated under objective 2, in their effects on employment, on international competitiveness and on their potential to deliver environmental benefits.



Project Structure

Contents

1. Introduction

This monograph reports on *Novartis Agribusiness*, including the *Crop Protection, Seeds* and *Nutrition* Divisions. The research was conducted at the time of the announcement of the planned merger between the agrochemicals and plant biotechnology divisions of AstraZeneca and Novartis to form Syngenta.

Section 2 of this report gives relevant background information on Novartis, based on publicly available information from press articles and company dossiers.

Section 3 is an introduction to the sections describing interviews carried out with Novartis managers. It lists the managers interviewed and outlines the cognitive mapping procedure used to analyse some of the data from these interviews. The cognitive maps referred to in Sections 4-6 are presented in Appendix 1.

Section 4 describes Novartis' innovation strategies, in general and in the contexts of agrochemicals and biotechnology innovation, and also 'life science'-related issues of synergy between chemicals and biotechnology strategies, as seen by Novartis managers.

Section 5 covers managers' comments on the policies which are the subject of the PITA project, including trade-related policies, farm support policy reforms, policies to stimulate innovation, direct regulation of pesticides and GM crops, public opinion and purchasing policies of food processors and distributors.

Sections 4 and 5 are based mainly on information provided by senior company managers in interviews, with direct quotes from these interviews printed in italics.

Section 6 gives our overall conclusions.

2. Background data on Novartis and the Agribusiness Sector

Material in this section is based on publicly available information, as indicated in footnotes.

2.1 Novartis Overview

The name 'Novartis' comes from the Latin, *novae artes* (new skills), denoting the use of research and development " … to bring innovative products to the communities we serve". Novartis AG was formed in 1996 from a merger of Sandoz and Ciba creating what were at that time the world's largest agrochemical company and second largest seed company. (These positions have been altered by subsequent mergers and acquisitions among the multinational companies active in these areas.) The merger decision involved rationalising and integrating the Group's Global Operations[1], including the disposal of a substantial portion of the former Sandoz US and Canada Agribusiness activities and the demerger of the Specialty Chemicals Division of Ciba and Construction Chemicals of Sandoz.

The merger was thus "a conscious attempt to eliminate activities which ... do not produce any added value and which therefore stand in the way of sustainable efficiency improvements". It was seen as a strategic focus on life sciences and was intended to reduce operating costs by CHF 2Bn, 60% of which was achieved by the end of 1997. The total workforce was reduced by 9100 but the agribusiness workforce was slightly increased[2].

Ciba and Sandoz both had their origins as producers of industrial chemicals. Ciba-Geigy and its precursors began pesticide production in 1935 and bought seed companies in the 1970s and 80s (including Funk Seeds International, a US company). It established a special biotechnology unit in 1980 and was the first company to market genetically engineered hybrid corn seed in 1995. Sandoz began pesticide production in 1939 and also bought seed companies in the 1970s and 80s. It began to invest heavily in plant biotechnology in 1990.

Novartis is organised on a worldwide basis in three main divisions, Healthcare, Agribusiness and Nutrition (see Figure 2.1, components covered by this study highlighted in bold print):

- the Healthcare Division includes the Pharmaceuticals Sector (75% of sales), the CIBA Vision Sector (contact lenses, lens care products, pharmaceuticals and ophthalmic surgical products, 8% of sales), the Generics Sector (off-patent pharmaceutical products, 8% of sales), and the Consumer Health Sector (health and medical nutrition products and 'over the counter' medicines, 9% of sales);
- the Agribusiness Division includes the Crop Protection, Seeds and Animal Health Sectors;
- the Nutrition Division includes the Infant and Baby Nutrition Sector (40% of sales), the Health Nutrition Sector (32% of sales), and the Medical Nutrition and Distribution Sector (24% of sales).

In its first year of existence, Novartis as a whole achieved an increase in sales of 19% on a comparable basis. The business portfolio was successfully streamlined and focused on Life Sciences. Table 2.1 gives financial information for the Novartis Group as a whole. The streamlining process has included significant reductions in the number of employees (see Table 2.2). Distribution of personnel numbers and costs by region and by function in 1999 is shown in Table 2.3.

Novartis describes 1999 as the year in which it has taken further steps to focus its business portfolio, 'moving from a Life Sciences company to a pure Healthcare company'[3]. In

[1] Novartis Financial Review 1997, p11.

[2] Novartis Operational Review, 1997

[3] Novartis Operational Review, 2000

December the Boards of Novartis and AstraZeneca agreed to spin off and merge Novartis' Agribusiness Division (Crop Protection and Seeds Sectors) with Zeneca Agrochemicals to create the world's first dedicated agribusiness company (Syngenta) with pro forma combined sales of approximately $US 7.9 billion (1998 figures).

Table 2.1 Novartis Group Financial Information (in CHF Millions)

	1999	1998	1997	1996	1995
Sales	32 465	31 702	31 180	36 233	35 943
Cost of goods sold	-9 822	-10 052			
Gross profit	22 643	21 650			
Marketing and distribution	-9 561	-8 790			
Research and development	-4 246	-3 906			
Administration-overheads	-1 493	-2 034			
Operating income	7 343	6 920	6 888	5 781	5 714

Table 2.2 Novartis Group Employees

Year	Europe	Americas	Asia, Africa, Australia	Total
1999	38 125	20 007	14 652	81 854
1998	40 105	27 832	14 512	82 449

Table 2.3 Global distribution of total Novartis Group personnel by numbers (full time equivalents) and by cost (CHF millions) (data for 1999).

Region	Research and Development		Production and Supply		Marketing and Distribution		General and Administration	
	Number	*Cost*	*Number*	*Cost*	*Number*	*Cost*	*Number*	*Cost*
Europe	7 881	826	13 234	1 078	11 782	1 050	7 397	807
The Americas	4 230	548	10 170	669	10 422	1 101	3 232	414
Asia, Africa, Australia	1 086	88	4 157	80	7 371	422	1 515	101
Total	**13 197**	**1 462**	**27 561**	**1 827**	**29 575**	**2 573**	**12 126**	**1 322**

2.2 Agribusiness Sector

The Agribusiness Division (see figure 2.1) includes the Crop Protection, Seeds and Animal Health Sectors. Only the first two are considered in detail here.

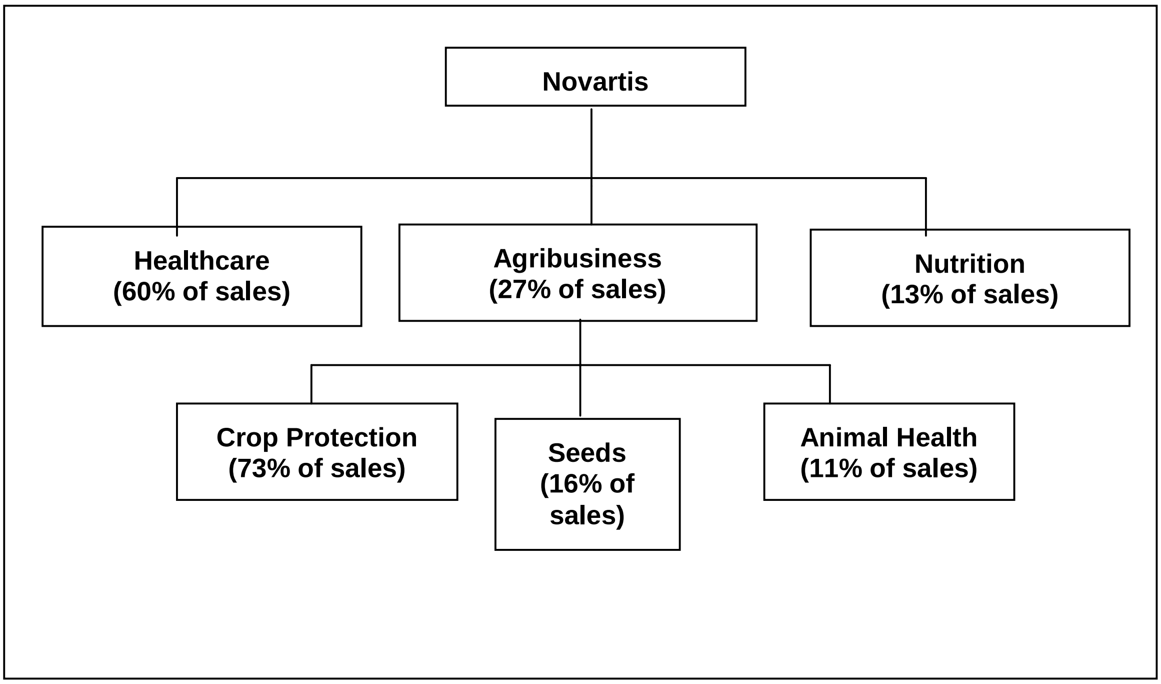


Figure 2.1 Novartis Structure[4]

The following facilities have been developed or expanded to support R&D efforts in the Agribusiness Division.

- Novartis Agribusiness Biotechnology Research, Inc. (NABRI), based in Research Triangle Park, North Carolina, was established in 1983 as the Ciba Geigy Agricultural Biotechnology Research Unit to develop and use biotechnology in support of the Crop Protection and Seeds Businesses. In 1998 a $28 million expansion project was undertaken leading to the employment of 320 professionals. It is involved in the development of new agronomic products (seeds and chemicals). More than 20 chemical and genetics projects were in progress in 1999[5].
- The Novartis Agricultural Discovery Institute Inc. (NADII) in San Diego, California was founded in 1998 with a team of over 180 researchers and planned investment of US$ 600 million over 10 years. It is described as the largest ever effort in plant genomics research[6]. It will spearhead Novartis' strategic focus on biotechnology research and maximise cross sector co-operation between Crop Protection and Seeds. It will also work with NABRI and other Novartis research stations worldwide. At the time of the announcement in 1998, NADI was also expected to optimise cross-business synergies in genomics research in both agribusiness and pharmaceuticals by working with the nearby Novartis Institute for Functional Genomics[7].
- The Biology Research Centre in Stein (BioStein), completed in 1999, employs 100 people. It contains the high throughput screening facilities to profile agrochemical compounds with the aim of discovering novel crop protection products and also chemical regulators for input and

[4] Based on information in Heinz Imhof, 1998, 'Challenges for Sustainability in the Crop Protection and Seeds Industry'. Rabobank International's Global Conference, 28-29 May, 1998, Zeist, NL.

[5] Novartis Operational Review, 1999, p25.

[6] NABRI, Novartis Agribusiness Biotechnology Research Inc., Published by Novartis.

[7] http://www.cp.novartis.com/e1e4_con.htm

output traits. It also conducts research on anti-resistance strategies for existing products. It brings together all crop protection biology units, previously scattered around Basel[8].

The Agribusiness sector is described by Novartis as providing products and services that support sustainable agriculture and enhance the production of safe, healthy and high quality foods, food ingredients, animal feed, plants and plant derivatives. It operates through 116 affiliates in 50 countries worldwide.

In 1997, sales were distributed 46% in the Americas, 38% in Europe, and 16% in Australasia and Africa[9]. Sales decreased by 7% (in local currencies) from 1998 – 99 (see Table 2.4), primarily due to difficult marketing conditions, including weak farm economies, price pressure, the introduction of a new class of fungicides by competitors and acreage reductions (set aside land). In seeds, corn was affected by price pressure and acreage reductions and soya beans by increased use of farm-saved seeds (due to low commodity prices). Sales, particularly of herbicides and fungicides, declined in the US, Europe, Brazil, Russia and Ukraine but increased in the Asia Pacific Region. Sales of insecticides remained stable.

Despite these difficulties, Agribusiness maintained the level of investment in Marketing & Distribution and in Research & Development needed to guarantee the launch of key products in 2000 and secure future platforms in biotechnology[10]. Investment in R&D is expected to continue at a high level in 2000.

In 2000, the declining market for products in this sector is expected to bottom out, leading to some profit recovery but no clear improvement before 2001. Important products with continuing market development in the agrochemicals area are expected to be Actara/Cruiser and Flint (see Section 2.2.2). In the Seeds sector continued sales growth is expected in vegetables and oilseeds but continuing uncertainties with GMOs are predicted for several key markets[11].

Table 2.4 Agribusiness Sector Data, 1997-99[12]

	1999	1998	1997
Sales (CHF m)	7 056	7 478	7 434
Operating income (CHF m)	737	1 098	1 462
Research and development (CHF m)	673	668	668
No. of employees	17 361	16 722	18 029

New Agribusiness Strategy – Project Focus[13]

Novartis describes the operating environment for the agribusiness industry in the following terms[14]:

> "The agribusiness industry is in a state of upheaval and rapid change. Low farm commodity prices and depressed farm income have impacted sales. Margins have eroded, putting pressure on financial results and the distribution channels.

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[8] http://www.cp.novartis.com/e1e13_con.htm

[9] Novartis Facts and Figures, 1998, p35.

[10] Novartis Operational Review, 1999, p23.

[11] Raymund Breu, CFO, Novartis, Financial Review

[12] Novartis Operational Review, 1999, p 4

[13] Novartis Crop Protection Media Release, 'Novartis Announces First Steps in New Agribusiness Strategy', Basel, 22 June 1999.

[14] http://www.seeds.novartis.com.news_article Backgrounder: New Agribusiness Strategy (Basel, 9/15/99)

> Restructuring in the agribusiness industry has created a more aggressive competitive environment. New technologies, including genetically modified crops and precision agriculture, are challenging traditional farming practices. Moreover, farmers and growers are increasingly influenced by other players in the food chain, from food and feed processors and food companies right down to supermarkets and consumers."

In June 1999, the Agribusiness Sector initiated the New Agribusiness Strategy (Project Focus), with the objectives of growth, fitness and sustainable leadership, to provide a framework for the future of the Seeds and Crop Protection sectors. The project will strengthen leadership and cost savings by implementing new product priorities, improving the product mix, optimising asset utilisation, reducing purchasing costs and also by eliminating approximately 1100 jobs world wide. The project is intended to provide flexibility in the face of new market dynamics characterised by lower agricultural subsidies and commodity prices. Research projects will be prioritised to focus on the most promising products and to reflect the growing importance of new technologies and output traits[15].

The new course charted by the Agribusiness Strategy focuses on:

- the food and feed chain and crop solutions
- integrating breakthrough technologies
- exploiting joint synergies between Crop Protection and Seeds

Global crop teams, operating jointly between Crop Protection and Seeds, have been formed to define overall strategies for *pillar crops* (corn, vegetables, cereals and rice) and *important crops* (oilseeds, sugar beet, cotton, fruits and grapes).

An Agribusiness research plan will incorporate technology planning for research and development, including existing Agribusiness research initiatives such as NABRI and NADII. The traditional areas of input traits, discovery of crop protection chemicals and conventional plant breeding will remain very significant. However, projects will increasingly focus on areas such as crop output traits, chemical trait regulation, marker assisted breeding and genetics/genomics[16].

2.2.1 Acquisitions, subsidiaries and collaborations

In 1997 Novartis completed the 910 million $US acquisition of the crop protection business of Merck &Co. Inc. In the Agribusiness area, this strengthened its profile in the high value acaricide/insecticide and fungicide markets, including abamectin, thiabendazole and new high value, low dose insecticides in the production pipeline[17].

In the same year, Novartis announced the sale of its world wide spray-on *Bacillus thuringiensis* business to Thermo Trilogy Corp. in the USA. The press release emphasises Novartis' continued commitment to integrated pest management (IPM), based on the optimal combination of cultural, chemical and biological pest control measures, and refers to the active ingredients abamectin, emamectin and pymetrozine (the first two being part of the Merck acquisition), giving them a unique portfolio well suited to a sustainable agriculture (see Section 2.4).

Further Novartis investments in seed and agrochemical companies are summarised in Table 2.5.

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[15] http:/www.cp.novartis.com/e1e14_con.htm

[16] http://www.seeds.novartis.com.news_article Backgrounder: New Agribusiness Strategy (Basel, 9/15/99)

[17] http://www.cp.novartis.com/e1a_con.htm

Table 2.5 Recent Novartis Investments/Acquisitions in Crop Protection and Seeds

Company Name	Date of creation/ acquisition	Location of Sites	Product/ technology
CC Benoist	1998	France	cereal seeds
Maisadour	1999	France	maize seeds
Agritrading	1998	Italy	maize seeds
Sturdy Grow Hybrids	1998	USA	seeds
Trega Biosciences	1998	USA	
Oriental Chemical Industries	1998	South Korea	agrochemicals
American Sunmelon	1998	USA	seeds
Wilson Seeds (50% with Land O'Lakes)	1998	USA	hybrid corn (white and yellow); specialty grains
Seoul Seeds	1998	South Korea	seeds

Novartis' research units have made a number of agreements with other institutions, including the following.

- Chiron: in 1997 Novartis Crop Protection announced a three year agreement with Chiron Technologies based in Australia for the supply of new chemical compounds generated by combinatorial chemistry.
- Myriad: NADII signed a two-year $33m partnership in cereal genomics with Myriad Genetics Inc, Salt Lake City.
- Diversa and Novartis will apply their resources to discover and optimize novel enzymes for use in animal feed additives and formulations. Novartis will develop enhanced crops bearing genes identified by the joint venture. New options will enable farmers 'to produce value-added crops primarily for the feed chain in an environmentally and economically sustainable manner' (Novartis press release, 14.12.99).
- University of California Berkeley: in a five-year research agreement, NADII will have rights to negotiate licenses to the patentable discoveries from the university's labs. NADII may grant the university scientists access to its proprietary databases (Novartis press release, 22.03.99).
- Clemson University, US: mapping the genome of rice and its pathogens.

2.2.2 Novartis Crop Protection Sector

Novartis Crop Protection Sector ranked first in the world in 1996 with sales of 4527 million US $, well ahead of its nearest rival Monsanto, with 2997 million US $ (figures from AGROW World Crop Protection News).

The Novartis approach to insect and disease control is described as firmly based on chemistry, with links to the seeds business getting closer as new crop genomic leads are found[18]. Within Novartis Crop Protection, the Research and Development section supports all research departments, finding new innovative active ingredients, defining and performing safety studies for all products as required for registration, supporting global product

[18] 'Company Spotlight on Novartis', Crop Protection Monthly, 31 October 1998.

development, and coordinating development activities across departments and Group Companies as follows [19].

Crop Protection Biochemistry

The Biochemistry Group works with Chemistry and Biology on the discovery of novel crop protection agents and their mode of action. Their work spans the whole product development chain from initial identification of 'hits' to commercial introduction of new products. They co-operate closely with biochemists at NABRI.

Discovery Technologies and Natural Products (DTNP)

This unit provides the sector with novel research tools, methods, services and information systems, including natural products using microbiology and fermentation methods to isolate biologically active substances. DTNP also maintains High Throughput Screening Methods.

Human Safety

This unit develops scientific information for assessment of the human safety of Novartis Crop Protection products and produces all necessary scientific information to satisfy the needs of product registration.

Environmental Safety

This unit ensures that all products are safe for the applicator, the consumer and the environment, generating data on environmental fate and effects and making proposals for risk management in the context of product registration.

Special Projects

Special Projects units help to manage and lead major projects to improve Sector research facilities, evaluate the impact and importance of new crop protection technologies and help to establish policies and standards for human and environmental safety of products.

Development Support

This unit provides standards, processes, tools and services in support of global development and the maintenance of active ingredients and products.

Research and Development in Novartis Crop Protection has benefited from the introduction of target-based discovery and high-throughput screening (at BioStein), dramatically increasing its efficiency for discovering novel compounds. Target based assays in these high throughput screens boost the discovery of novel pesticides.

The synthesis and production of chemicals is carried out in:

- Monthey, Switzerland
- Schweitzerhelle, Switzerland
- Kaisten, Switzerland
- Muttenz, Switzerland
- Grimsby, UK
- St. Gabriel, USA

[19] http://www.cp.novartis.com/n1_cont.htm

Insecticides

Insecticides account for approximately 20% of Novartis' total pesticide sales and this percentage is expected to increase. Insecticide production priorities announced in 1998 focused on products with growth potential with the objective of making Novartis the market leader in pesticides offering the best possible technology. Concentration of resources on products with the highest levels of performance (see Table 2.6) is balanced by replacing products with decreasing market potential over time and on a country by country basis (including dichlorvos, disulfoton, formothion, isazophos, monocrotophos and phosphamidon). This plan also includes the divestment of some products; for example the global spray-on *Bacillus thuringiensis* business.

This rejuvenated portfolio will offer:

- technically superior solutions
- effective and efficient concepts in integrated pest management (IPM) and insecticide resistance management (IRM)
- innovation to develop products with new modes of action from the high throughput screening process and biotechnology research[20].

Table 2.6 Insecticide product priorities

Abamectin	High performance, low rate acaricide/insecticide, naturally derived, produced by fermentation. Registered and used world wide
Thiamethoxam	Low rate neonicotinoid product against sucking and certain chewing pests; launched in major markets in 1998; a good candidate to replace carbamates and organophosphates
Cryomazine	Leafminer specialist; IRM partner Abamectin
Diafenthiuron	Whitefly specialist for cotton, mainly in Near and Middle East, Africa and Asia
Emamectin benzoate	Low dose lepidoptera control, launched in Japan in 1998.
Fenoxycarb	Lepidoptera control in pome fruits and nuts
Lufenuron	Lepidoptera control in maize, vines, soybeans and some vegetables (mainly Latin America, Europe and Asia)
Methidathion	Foundation control of scale insects in fruits, nuts and citrus
Profenofos	Broad spectrum, foundation product for cotton and vegetables worldwide
Pymetrozine	Unique chemistry for control of aphids and other sucking pests; useful for IPM and IRM programmes
Tau-fluvalinate	Synthetic pyrethroid, safe to bees; strong in small grain cereals and fruit trees, mainly in Europe and Asia.

Innovative crop protection agents based on thiamethoxam will be marketed as the seed treatment *Cruiser* and the spray application *Acarta*.[21]

The top three crops for Novartis insecticides are cotton, citrus and other fruits and vegetables; the major markets are USA, Japan and southern Europe.

In addition to chemical insecticides, Novartis supplies beneficial insects and nematodes for crops in greenhouses or under plastic through the subsidiary Novartis BCM (Beneficials for Crop Management). Novartis also supplies compatible chemical solutions for use with these living organisms, including abamectin, thiamethoxam, pymetrozine, lufenuron and cryomazine.

[20] www.cp.novartis.com/ele1_con.htm

[21] Novartis Operational Review, 1999, p23-24

Crop Disease Diagnostics

Novartis Crop Protection is developing a series of diagnostic assays to detect plant disease infestations before symptoms occur[22] or to provide more rapid disease diagnosis. These are based on immunoassay and polymerase chain reaction technology. They are important components of precision farming and integrated pest management techniques. Assays are currently available for *Septoria,* eyespot, *Fusarium* and corn diseases. Insight® detects and differentiates between Yellow and Black Sigatoka on bananas.

Fungicides

Novartis describes its fungicide strategy as ' … meeting the short term expectations of our stakeholders as well as the transition to the biotech age'[23]. They are key players in producing fungicides for small grain cereals, vegetables, potatoes, grapes and bananas.

In 1999 Novartis Crop Protection successfully entered the strobilurin fungicide market when the US Environmental Protection Agency granted registration for *Flint* on pome fruit, grapes and cucurbits earlier than expected.

Novartis markets over 28 different fungicide formulations for use on a wide range of crop/disease combinations. The following are particularly important:

- difenoconazole, propiconazole and cyproconazole, three triazole fungicides which act systemically to give curative and protective control of a wide of diseases;
- the phenylamides, metalaxyl-M and oxadixyl, foliar and soil applied systemic fungicides for use on a wide range of crops worldwide, particularly for downy mildews and late blight;
- cyprodinil, one of the recently developed class of anilinopyrimidines, particularly for diseases of fruit crops and cereals;
- thiabendazole, the premium post harvest fungicide acquired from Merck which has a very favourable safety profile.

The top three crops for Novartis' fungicides are small grain cereals, vegetables and grapes; and major markets are in France, the USA and Brazil[24].

An important new product in the pipeline is a plant activator Bion® which stimulates the plant's natural defence mechanisms against disease.

Herbicides

Novartis produced 40 different herbicide formulations in 1998[25]. Best selling established herbicides are:

- metolachlor, a leading broad spectrum, long lasting herbicide, to be substituted by the highly concentrated form, S-metolachlor, which reduces the volume of the compound to be applied by up to 38% and also reduces packaging needs and transportation costs; this product complements the effectiveness of triazines such as atrazine;
- atrazine; and
- triasulfuron, a sulfonylurea herbicide with low application rates and a useful spectrum of activity on economically important weeds.

Promising new products include:

[22] http://www.cp.novartis.com/diagnostics/diag_cont.htm

[23] http:/www.cp.novartis.com/a3_cont.htm

[24] Novartis, Helping Farmers Feed the World: a Portrait of Novartis Crop Protection, p11.

[25] Novartis, 1998. Novartis Crop Protection Products, pp 4-9.

- clodinafop which kills annual grasses and some dicots on cereals and soya; and
- prosulfuron, a sulfonylurea used on maize.

The top three crops for Novartis herbicides are corn, cereals and soybeans; the major markets are in USA, France and Brazil.[26]

Novartis also produces a range of 'safeners' to protect crops against the action of herbicides by inducing enzymes in the crop plant to metabolise the herbicide. Products exist, for example, to protect sorghum against metalochlor, rice against fenchlorim, wheat and rye against clodinafop, and to increase the selectivity of metalochlor on maize[27].

2.2.3 Novartis Seeds

The world wide headquarters of the Seeds business are in Basel, Switzerland and the business incorporates four internationally established brands (originally acquired by Sandoz):

- NK, a global brand for corn, oilseeds and other field crops; established in 1884 as Northrop King Co. in the USA
- Hilleshog, the world leader in sugar beet production; commissioned in 1907 by the Swedish Sugar Company
- S&G, leading supplier of vegetables and flower seeds in Europe, Africa and Asia and world wide for young plants; established in the Netherlands in 1867 as Sluis and Groot
- Rogers, the best known brand name for vegetables throughout the Americas; established in the USA as Rogers Brothers Seed Company in 1876[28]

Organisationally, Novartis Seeds is divided into four major geographic regions (Europe, North America, Latin America and Asia) and five business areas (corn, sugar beet, oilseeds, vegetables and flowers). There are currently five Market Operations (MOs) which result from the intersection of business areas with geographic regions[29]:

- Field Crops Europe
- Vegetables and Flowers Europe
- Field Crops NAFTA
- Vegetables and Flowers NAFTA and
- Latin America and Asia.

Novartis Seeds describes its strategy as being 'customer oriented and technology driven'. The sector employed 5238 staff in 1997. Thirty two percent of seed sales were in maize, 38% vegetables and flowers and 30% other field crops[30]. In 1997 in the North American seed market Novartis had 9% of maize sales and 5% of soybean sales. In 1998 sales increased worldwide, especially Bt hybrid maize in the USA, soybeans in NAFTA region, and sunflowers in Europe. Sugarbeet sales declined in Europe along with acreage reductions.

In 1997, worldwide, maize accounted for 33% of Novartis Seeds sales, vegetables 21%, flowers 15%, sugarbeet 14%, and oilseeds 11%. Novartis Seeds sales reached CHF 1.3 billion in 1997 and almost CHF 1.5 billion in 1998, distributed as shown in Table 2.7.

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[26] Novartis, Helping Farmers Feed the World: a Portrait of Novartis Crop Protection, p 10.

[27] Novartis, 1998. Novartis Crop Protection Products, p 6.

[28] The World of Novartis Seeds, Novartis Seeds AG, Basel, Switzerland, 1997

[29] http://www.seeds.novartis.com/who/business.asp 'Who we are: Business Areas and Market Operations'

[30] Novartis, 1999. The World of Novartis Seeds

Table 2.7 Novartis Seeds Sales by Geographical Area

Sales in:	1997	1998
Europe	48%	41%
North America	44%	47%
Latin America	5%	7%
Asia	3%	5%

Conventional breeding in Novartis Seeds sector has emphasised disease resistance and yield, particularly in corn, sugar beet and vegetables[31]. Genetic engineering R&D priorities[32] have included insect and herbicide resistance. In general, genetically enhanced plants are being developed to improve plant characteristics and also to increase yields and make it easier to tackle difficult agricultural problems. Targets include agronomic and end-use quality enhancements in corn, oilseeds, cereal and vegetable varieties. New technology developed at Agribusiness biotechnology centres (advance breeding and chemical discovery) offer the potential to create proprietary new products. Transgenic biotechnology, through the development of 'output traits', is expected to increase the nutritional value of vegetables and grains or help food products prevent and/or treat human disease.

Marker technology is used to indicate the presence of specific characteristics in plants without costly field or greenhouse trials. For example, the Novartis laboratory in Landskrona, Sweden has identified more than 500 markers in the nine chromosomes of sugar beet to give the largest genetic map in existence for sugar beet.

Agricultural genomics (the study of the location and function of groups of genes in crops and their pests) is another important tool for Novartis Seeds R&D, incorporating gene sequencing, gene mapping, the development of gene libraries and bioinformatics.

Successful launches and sales improvements in 1999 included:

- new corn hybrids launched in the US
- the introduction of disease-resistant sugar beet varieties and improved sales, despite a declining market
- the launch of several new soya bean varieties including a Roundup Ready® variety with excellent stress tolerance
- sunflower varieties with a strong germplasm base and fungal resistance
- vegetables, particularly peppers in Spain and tomatoes in California and the EU
- flowers and young plants in NAFTA and Asia Pacific Regions

Novartis Seeds has focused on key technologies such as marker-assisted breeding, seed and production technologies, output traits and gene technology' [33]. GM corn crops approved for commercial use are all protected from European corn borer, e.g.:

- insect-protected corn (approved for sale in USA and EU)
- insect-protected, glufosinate-tolerant corn (sold in USA)
- insect-protected, glufosinate-tolerant sweet corn (sold in USA)

Following public controversy over marker genes based on antibiotic resistance, Novartis has pledged to phase out antibiotic resistance markers in developing future products as

[31] http://www.seeds.novartis.com/skills/conventional.asp

[32] http://www.seeds.novartis.com/skills/genetic.asp

[33] Novartis Operational Review 1998, pp 20-21.

alternatives become available. It has announced development of a novel sugar-based marker gene system, Positech™. Novartis is currently working with Positech on several crops, particularly maize and wheat and regulatory dossiers for the first commercial release of crops based on this system are expected in 2001-2. The system is being made available to industry and the academic community through simple licensing procedures and will be provided royalty-free for subsistence farmers in developing countries[34].

2.3 Patent Issues

The Derwent Biotechnology Abstract gives the following totals for patents relevant to agriculture held by Novartis and related companies:

Novartis, 41

Ciba, 104

Sandoz, 48

Rogers, 1

Total, 194

Two principal objectives underlie Novartis' recent patents[35]:

1. The establishment of chemically regulatable DNA sequences, and the identification of the chemicals (promoters) which regulate them.
   Promoters of interest are those which permit the gene's expression to be turned on in response to an externally applied chemical. The promotion effect can be associated with genes to control flowering or fruit ripening, effecting tolerance or resistance to herbicides, pests and diseases, controlling the production of enzymes or secondary metabolites, male or female sterility, nutritional qualities, etc.
2. Patenting of the genes coding for proteins that form part of the natural capacity of plants to resist pathogens (insects, viruses, fungi or bacteria), particularly 'systemic acquired resistance' (SAR). These traits can be combined with those in the first category.

Legal disputes over patents have become an increasingly common feature in the biotechnology and agrochemical industries. Novartis noted that, in 1998 the operating margin of the seeds sector was reduced by high litigation expenses for protection of intellectual property[36].

Bacillus thuringiensis (Bt) genes have been the subject of dispute between Novartis and Monsanto. In 1995 Ciba became the first company to introduce Bt maize, using its 'Knockout' gene under the Maximizer name. Following the 1996 merger Novartis introduced under the NK brand another Bt maize using Monsanto's YieldGard gene construct. Monsanto accused Novartis of infringing its Bt patent but the court ruled against Monsanto.

In 1997 Novartis claimed a broad patent for exclusive use of all Bt technology in corn. It sued Monsanto and DeKalb for infringement but in November 1998 the court ruled against Novartis. Following an appeal Novartis and Monsanto-DeKalb settled all pending lawsuits between them, securing for Novartis a royalty-bearing license for future sales of Bt corn and also royalty-bearing licenses for glufosinate-resistance in corn (Novartis Press Release, 15.11.99).

In the insecticide area thiamethoxam has also been subject to a patent dispute based on its similarity to Bayer's imidacloprid, first marketed in 1991. Novartis claimed that Bayer's patent

[34] http://www.sees.novartis.com/news/news_article.asp 'Positech breakthrough offers alternative to antibiotic resistance marker genes for genetically enhanced crops' Basel, 5/23/00

[35] A Description of the Novartis Patent Group, RAFI Publications, 1/30/1999. (www.RAFI.org/web/allpub-one)

[36] Novartis Financial Review, 1998, p6.

does not cover this new generation of neonicotinoid insecticides but the European Patent Office ruled against Novartis in 1998. Pending an appeal, Novartis cannot market thiamethoxam in eight European countries but it is being developed worldwide for use on more than 20 crops [37].

2.4 Health, Safety and Environment (HSE) Related Issues

The HSE organisation operates on five levels – site level, Sector company level, country level, Sector level and Corporate level. This respects Novartis' commitment to decentralisation and maintains an over-riding framework for management on a company wide level. Corporate HSE acts on behalf of Novartis Corporate Management, setting Group-wide policies and defining practices and procedures that extend beyond the boundaries of any particular sector. They also maintain the Novartis Emergency Management system and audit the Sectors' HSE management implementation. The Sectors also monitor and control their own HSE performance, conduct site audits and implement and maintain the emergency Management system[38].

Despite precautionary measures, Novartis recognises that any undertaking involves a residual risk. The Emergency Management System is set up to deal with a diverse range of emergencies and has the role of managing any potential physical, chemical or biological incident, product emergency or other critical situation that could affect people, the environment, company property and/or company reputation. It is a Group-wide system, compulsory for all Novartis entities and not essentially a part of HSE[39]. It reflects the company's attitude to risk and commitment to minimising adverse effects and defending and enhancing its reputation.

Through its membership of the World Business Council for Sustainable Development, Novartis subscribes to the concept of eco-efficiency, combining economic and ecological efficiency, creating new and better products and services with less resources and less pollution along the entire value chain.

2.4.1 Sustainable Agriculture

The Novartis Crop Protection vision[40] is to "… strive for profitable growth by providing products and services which support the principles of sustainable agriculture". Sustainable agriculture "… does not mean organic or chemical-free farming. Instead it includes the use of crop protection products in such a way that not only our generation but also our great grandchildren will be able to farm the food they need" [41].

The challenges faced by agriculture are perceived as: world population pressures and increases in income which both increase demands for food and fiber, qualitatively and quantitatively; urbanisation and reduced availability of agricultural land; soil erosion; pests, diseases and weeds; and waste disposal.

As part of the vision (see footnote 41) Novartis is committed to selling only products for which they can demonstrate positive benefit/risk profiles. They comply with all laws and regulations – indeed, included in Novartis' core values is the commitment to exceed industry standards in environmental and safety matters[42]. Novartis Crop Protection sells only products whose active ingredients are registered in at least one OECD country. They acknowledge and manage the risks of chemical crop protection, minimise waste at source through advanced

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[37] Novartis Press Release, Brighton, 17th November 1998.

[38] http://www.info.novartis.com/hse/organisation

[39] http://www.info.novartis.com/hse/organisation/nem.htm

[40] Novartis, 1997. Carta Nova: the Charter of Novartis Crop Protection

[41] http:/www.cp.novartis.com/sa_cont.htm

[42] http://www.seeds.novartis.com/who/values.asp

manufacturing, formulation and packaging technologies and recycling packaging materials, and they communicate complex technical information to stakeholders in an understandable and accessible manner.

As an example of the care taken to ensure environmental safety, a promising new nematicide with a good overall ecological profile was dropped after it was found that one of its major soil metabolites might have reached groundwater[43].

Integrated crop management (ICM) is described as sustainable agriculture put into practice. Its components which include more than just chemical crop protection are summarised in Figure 2.2.

[43] Novartis, 'Helping Farmers Feed the World' A portrait of Novartis Crop Protection, p15.

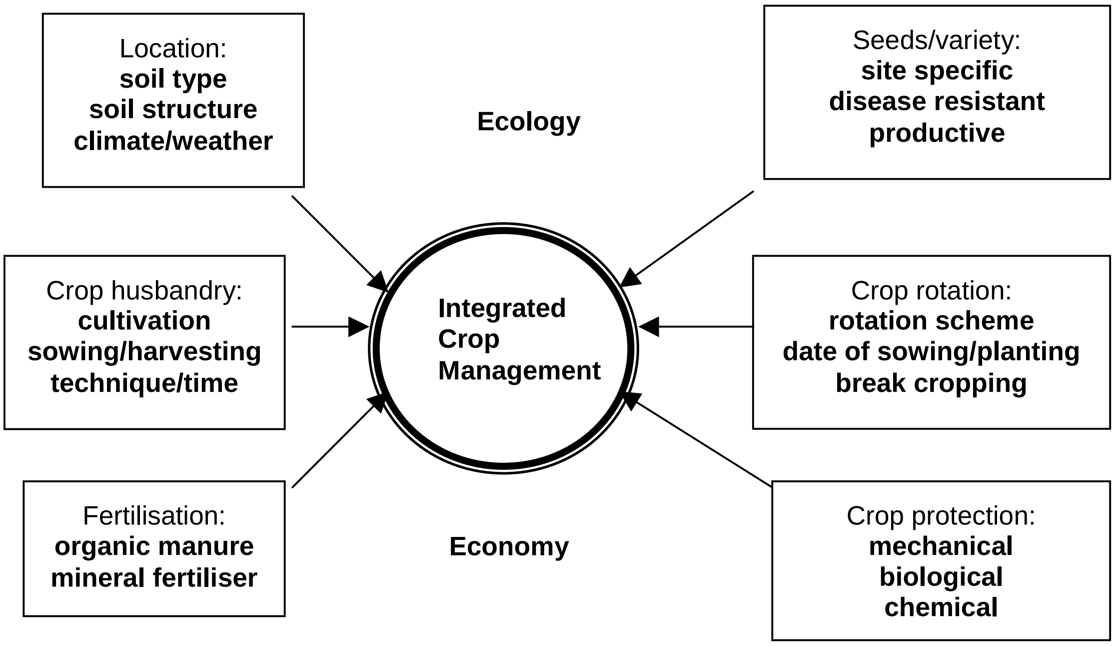

Figure 2.2 Novartis Interpretation of Integrated Crop Management[44]

More than most companies, Novartis' interpretation of ICM thus includes a wide range of techniques and management practices which do not involve the use of the company's products. Most of the techniques involved in ICM can also be seen as components of integrated pest management (IPM), described as 'the farmer's best combination of crop protection measures'[45], in terms of being cost effective, environmentally sound and socially acceptable. For Novartis this involves co-operating with stakeholders such as food processors and supermarket chains. The methods employed in IPM include:

- prevention (e.g. crop rotation and the encouragement of pests' natural enemies;
- observation (e.g. forecasting and diagnosis);
- intervention (chemical, biological or mechanical methods, or any combination of these).

As noted above, Novartis has a particularly useful range of insecticides for use in IPM systems. In particular abamectin fits well with IPM programmes used on high value crops, providing a solution to intransigent pest problems with longer residual control and low dose rates.

Reducing the selection pressure that leads to resistance is also important in the context of sustainable development and Novartis Crop Protection's broad insecticide portfolio allows rotation or combination of products with different modes of action according to optimised crop programs[46].

[44] http://www.cp.novartis.com/icm_cont.htm

[45] Novartis, 'Helping Farmers Feed the World' A portrait of Novartis Crop Protection, p12.

[46] http://www/cp.novartis.com/a2_cont.htm

3. Interviews Conducted for Novartis Agribusiness Study

3.1 Interviews with Novartis managers

Interviews with senior managers in Novartis Agribusiness were conducted in December 1999, including the following functional areas:

- Head, Agribusiness Strategy Planning, Novartis Seeds AG
- Head, Regulatory Affairs and Government Affairs, Novartis Seeds AG
- Head, Issue Management, Novartis Crop Protection Inc.
- Head, Communication and Public Affairs, Novartis Seeds AG
- Head, Issue Management, Novartis Seeds AG
- Head, Support and Communication, Novartis Crop Protection AG
- Head, Basic Biology and Liaison, Novartis Crop Protection AG
- Head, HTS-O and New Methods, Novartis Crop Protection AG
- Head, Biology, Disease Control, Novartis Crop Protection AG

Sections 4 and 5 are based on material gathered in these interviews, including the use of cognitive maps which summarise interview information, following the logic of the explanations given by interviewees.

3.2 Cognitive mapping technique

Rules for developing and interpreting cognitive maps are as follows[47]:

Concepts

Maps consist of concepts linked by arrows or lines. A concept is a short statement covering a single idea or notion, for example assertions about components of a strategy, causes of a problem or means of improving a situation.

Concepts involve two contrasting parts or 'poles', i.e. they are bi-polar. Thus, where there is '…' in the middle of a concept, this indicates X 'rather than' Y, as perceived by the person who made the statement (e.g. friendly … distant). If the second pole of this relationship is not specified in a concept it implies 'X rather than not-X' (friendly … not friendly).

Links

Links describe relationships between concepts and together they form a line of argument, a description of a problem or the components of a strategy.

They can include a range of different types of relationship. The most usual are *causal, connotative* or *temporal*. However, *user-defined* links can also be added.

Causal links.

A → B indicates that concept A *leads to, or contributes to,* B or A *affects* B.

[47] Based on the Reference Manual for Decision Explorer Software, pp8-14, Banxia Software Limited, 141 St James Road, Glasgow G4 0LT.

Connotative links

A —— B implies that the two concepts are associated in an unspecified way.

Temporal links

A → B (with a letter 'T' attached to the arrow) implies that B follows in time from A.

Positive and negative links

Unless specified otherwise, links are assumed to be positive, i.e. the first pole of one concept leads to the first pole of the linked concept. Where a negative sign is attached to an arrow this indicates that the first pole of one concept leads to the second pole of the consequential concept. These conventions do not apply to connotative or temporal links.

4. Novartis Agribusiness Innovation Strategies

[Material in this section is based on personal interviews with Novartis managers.]

4.1 Research and discovery (see Map 4.1)

Strategic planning

In strategic planning for new product development the next ten years is irrelevant for R & D decision making. Any decisions taken for research today are for after 2010. In Novartis Agribusiness 'the present day' covers the period up till 2005, mainly the operating companies engaged in product development. 'Tomorrow', covers time lines approximately 2005-2010, roughly, and involves research conducted at Novartis Agricultural Biotech Research Institute (NABRI) in North Carolina. 'The day after tomorrow', covers 2010 and beyond and involves mainly the Novartis Agricultural Discovery Institute (NADI) in California. But these dates are approximate and the technology can surprise a company positively or negatively.

Thus, the real agricultural research strategies are not for the next decade but the decade after that. So inevitably these are discovery strategies, looking at basic components of the environmental status of crops and how to improve it, to improve crop productivity and to consider the value of crops for their intended uses. Beyond this, in the area of nutraceuticals, functional foods, optimising feeds etc., before you can start working on product development you need to know the molecular basis of problems or opportunities.

Location of activities

The location of Novartis R&D facilities is mainly in the US, largely because the biggest skilled labour pool is there, but decisions are taken in Basel, requiring a large amount of travel for staff. There are four biotech valleys, or clusters, in the US–the North Carolina research triangle, Boston, San Diego and San Francisco, and these were the main attraction for Novartis.

Knowledge is transferred throughout the company by personal contact within Novartis Agribusiness, research meetings, project reviews and there are good information flows between the US and Europe. The targeted approach is done in the US at the same site as the seeds-related work and they can use the same techniques very easily. Staff at Stein, the screening facility near Basle, do not need all the basic knowledge of these techniques but there are staff exchanges and they can profit from this knowledge and help in validating new ideas on whole organisms.

Some European countries are seen as making a valiant effort to catch up with the US, particularly Germany which will soon overtake the UK as the leading European biotechnology country. (Germany had a five year gap in the late 1980s when the public debate there was very contentious but they are catching up quickly. They have such a large academic research base that it was inevitable, given the right policies, they would take off.) However, the research taking place in Germany is 95% medical biotechnology.

Novartis considered the US to be ideal for molecular biology projects, because of their different state of mind – the “can do” factor. On the other hand, different skills are needed in other areas where Europe was seen as superior to the US–persistence, perseverance and quality. Although it might be desirable to have all these ‘traits’ together in one place that was considered an illusion. Physical distance was not regarded as a problem–two chemists in the same building may not communicate well.

Having locations in Europe and the US meant that the company could tap into a wider range of different scientific areas, creating more opportunities than other companies could achieve. Also, given that Novartis markets are split equally between N. America and Europe, there is a need for research support for these different markets.

Interactions with SMEs and employment impacts

Novartis has a great deal of interaction with SMEs and many small companies depend on Novartis for their livelihood although they are not directly linked to Novartis’ products. For example the company may develop an assay and then contract out the running of it.

They also use small companies for the robotics needed in their screening processes, to develop and service the specialised robots. Thus, on the employment front, robots do not replace people. The robots need maintenance so the numbers of employees remains the same but Novartis can do more with the same staff.

Novartis also co-operates with research labs to do specific studies which may be too complicated for them or where they do not have the required knowledge, leading to many connections to researchers.

The whole NW area of Switzerland, into France and Germany is very dependent on the chemical industry in Basle (Novartis and Roche), with a range of high-tech and low-tech collaborations. There are even more such collaborations in the US.

4.2 The agribusiness strategy: linking agrochemicals and biotechnology (see Maps 4.2 and 4.3)

The major development in Novartis’ internal organisation in recent years has been a concerted drive to link the crop protection and seeds businesses through a singular strategy, the ‘agribusiness strategy’. Until two or three years ago each sector, crop protection and seeds, had a separate five year strategic planning process so there were sector strategies but no common agribusiness strategy. The development of the agribusiness strategy started in the spring of 1999, and it was mainly concerned with organisational and marketing aspects of the business. It did not penetrate very deeply into functional areas. The strategy is now being moved down through the company for alignment and communication.

Linking market dynamics and organisational issues

In developing its agribusiness strategy, Novartis considered a series of issues in the context of market dynamics. The most important one was the concept of technology which is interwoven through all decision making. It has created a world market that is separated into two clusters. The first includes the companies such as Novartis that have a significant crop protection share and a viable seed base that they can leverage and gain synergies from, and the second includes those that are either pure players in crop protection or the few remaining pure players in the seeds sector. The feeling in Novartis was that they were not gaining the synergies or the leverage from being in that favourable position, in contrast to Monsanto who were doing that very effectively. The strategy is therefore an effort to highlight Novartis’ unique competitive advantages and this in turn created a series of organisational issues. How does Novartis act; how do they prioritise; who prioritises?

Not only was Novartis not capitalising today, but they also were not planning for the future on these synergies and their leverage. Gaining the potential advantages in the future requires joint planning and prioritisation today.

The process has operated by prioritising on the basis of crops, in the management of investments and global strategies. Novartis has created three crop categories in terms of priority:

- *pillar crops*–corn, vegetables, cereals and rice;
- *important crops* including oil seeds; and
- *opportunity crops*, rounding up the portfolio but not of significant volume.

Taking the market for crop protection and seeds together, approximately 50% is in pillar crops, 40% in important crops and 10% in opportunity crops.

Novartis is organising itself around those crops, asking “Within those crops what does the future look like, where is the value going to be in those future crops and then what is the best way to accept the value and integrate it into the business chain?”. Instead of merely selling inputs from the company standpoint, they are asking the question from a crop standpoint, worldwide.

Three major internal organisational bodies form the triangle involved in synchronising and driving this strategy:

- the Agribusiness Steering Team (AST), chaired by the head of the division;
- the Agribusiness Research Board (ARB), chaired by the two heads of research, crop protection and seeds and including other key research people; and
- the Global Crop Teams, one for each of the pillar crops.

The Global Crop Team organisation has then been replicated throughout the regions and countries. Each team includes two 'leaders', one from crop protection and one from seeds, working together along with two others, one responsible for business development and one for business planning. Ideally, by late 2000, it would be possible to look at the Crop Team and forget which leader was ‘crop protection’ and which was ‘seeds’, because they would work in harmony and develop jointly defined solutions to bring back into the development portfolio and research priorities, back into the separate sector organisations.

This bridging of the sectors, which are separate legal entities, enables these bodies to work together organisationally to create a common strategy, in the process defining what is important, what are the solutions, how the business chain will interact or how Novartis should interact with the business chain, the consumers. Novartis are already seeing the benefits of this approach where, when it comes to research priorities, it is the crop team that has to bring those forward and justify how they fit within the crop strategy.

The selection of pillar crops was based on where Novartis thought the future value was going to exist–accessible, attainable value, and Novartis’ ability to capture that value; and at the pillar crops level the company intends to work as much like an ‘agribusiness’ as possible. Prioritisation further downstream still operates more or less separately as ‘crop protection’ and ‘seeds’.

The solution to linking chemicals and seeds may be relatively simple in some cases. For example in the US there is relatively little difference in corn market shares for crop protection and seeds compared to other parts of the world. However, they still do not match. The areas of the US where Novartis have their largest seed market share do not match the areas where they have their largest crop protection market share. So it may be simply a matter of getting the businesses better aligned.

Acquisitions and mergers

So far Novartis has not gone down the road of building up a large portfolio of ownership of other companies, and is unlikely to do so in future. However they have made a few strategic purchases to provide them with more influence, rather than ownership. For example they purchased the seed activities of Eridania Beghin Say so that they now have a close relationship with them and greater insight than they had before. They also have a joint venture in the United States with the co-operative Land o' Lakes (Wilson's Seeds) where they are focusing on quality traits for white corn, for feed and for food processors. They have thus made relatively small, targeted acquisitions or alliances, rather than purchasing right down the line, as some other companies have done, e.g. purchasing companies like Cargills.

Mergers, for example as between Sandoz and Ciba to create Novartis, can take a long time to achieve effective integration and full implementation. Externally, they create some confusion and people are unsure who they will be dealing with. Strategy is immensely important in these circumstances because that is what binds the company together.

In the current circumstances, shareholders are concerned that when they invest a dollar in a pharmaceutical company, 30% of that dollar goes to agribusiness. A de-merger between pharmaceuticals and agribusiness gives people a chance to decide where their money goes. They have to believe that their investment in agribusiness is going to be longer term than in pharmaceuticals. That was seen as the profile of Novartis' investment in future.

Alignment with other agribusinesses, fighting for agricultural investment was seen as a more robust strategy where Novartis had the capability to be in a winning position, rather than competing for pharmaceutical investment. To give an example, the chemical business which was spun off from the Novartis family at the time of the merger between Ciba and Sandoz, has done very well and been able to do things in their own market that perhaps they could not have done in the context of Novartis.

Policy interactions with the agribusiness strategy

Considering the interactions between the mix of crop characteristics and the policy environment there are a large number of decision sets or decision points, weighted depending on the crop and the point of time in the development pipeline. The ARB is charged with maintaining flexibility, so allocation of research spending in the next five years will involve only a subtle shift toward areas like crop outputs, genetics and genomics, trait regulations, marker systems. In allocating and prioritising research resources, a balance needs to be struck with what else is required for in-house development and crop protection, re-registration etc. The challenge will be keeping the core business running while managing these other areas for potential developments in six or seven years' time, bringing together the products that are already in the pipeline in a solution that offers value under the new Novartis strategy. This is seen as an issue of flexibility, a subtle rather than a dramatic shift, keeping a balance along the vector from current business to the nutraceutical environment.

Competitively Novartis has a great deal of flexibility in its ability to respond to the policy environment, for example through clean, traditional chemistry using lower rate, single isomer products that are more active and also through the newer areas of future business potential involving biotechnology. The decision is not, for example, between an insecticide or an insect resistant gene for a particular deal in France, on a worldwide basis it is a case of providing a longer term balance rather than meeting such short term demands.

Biotechnology is only one element in a whole technology basket. Other elements include chemicals and also in some circumstances organic farming. Novartis should use the various possibilities in the best combination to deliver sustainable development in agriculture. Biotechnology has advantages, including many in the environmental area, but it will not solve all the problems on its own. It has to be combined with other technologies.

The systems approach and the organisation of crop teams

Increasingly a systems approach is being applied to crops, to deliver a crop management system which takes care first of the yield characteristics and composition of the crop, then of its capability to resist environmental and biological stresses and then climatic stresses. Rather than working through a department system, Novartis works with end products and end targets, using technologies to achieve the target, for example control of fungi X, Y and Z, plus the control of insects A, B and C, in a crop and region. The company tries to design a package of items for the farmer that together will do the job. Some parts of the package will involve chemistry and other parts genetics. Some of the genetic components will involve traditional breeding and some gene technology.

Seed and biotechnology development strategies are not seen in isolation from chemical strategies. The relevant question is not pesticides, or biologicals, or seed. The question is low impact, high output agriculture, which is why the systems approach is needed–a low impact chemical may actually be the best solution to a problem.

In the supply chain to the farmer, the only group of professionals that have traditionally worked holistically were breeders who tried to integrate the full range of characteristics for the future crop into one seed variety–to resist disease, cold, heat, etc.. The composition also has to be such that there is a market for the farmer’s product. Thus a breeder is like an architect who needs something that, at the end of the day, is functional in an environment. Now the whole supply system to the farmer is increasingly thinking in this holistic manner and this is certainly creating very significant improvements in the farmer's productivity.

The inputs are organised around the concept of the crop and its environment, through the *crop teams,* organisational entities with a director whose job is integrative, working through specific management strategies. Each crop team involves people from the agrochemicals group, the biocontrol group (Novartis has a company that develops biocontrol systems) and the seed group and it takes on a particular crop worldwide, in all it's growing environments, defining strategic targets for that crop. The division of work depends on which group has the best chance of achieving individual goals within the overall strategic objective.

The high throughput screening facility

The high throughput screening facilities at Stein are part of the agribusiness strategy linking the development of chemicals and GM crops, to allow the company to move into the biotechnology area of research where this is relevant. Portfolio development, for example, predicts from a technical aspect where a chemical should be used and where there are other opportunities. Nature is very complex and solving one problem may create new ones–GM crops may even create problems that Novartis can take care of. Thus, research should not involve an either/or strategy but should have both chemical and GM crop strategies operating in parallel to a certain degree. It is not possible to predict which will be more successful in ten years’ time.

In the facility at Stein, they are linking chemistry and GM plants in weed control and in the herbicide tolerant crop area. Input traits (insect and disease resistance) could have a direct impact on Novartis’ business, and interactions between GM plants and chemical solutions to crop protection problems can be an opportunity as well as a threat. Output traits may make the crop more valuable and this could result in more use of chemical plant protection products. GM plants might solve one problem but there will still be other problems on the same crop which might be solved by a chemical or even a biological approach. Novartis tries to assess the impact of such shifts so that they can modify the screening programmes to take them into account.

By far the majority of the work at Stein is still linked to the crop protection area rather than agribusiness. The filters, the organisms that are used in screening, are linked to the markets the company has targeted in ten years’ time. The first step in high throughput screening already involves organisms and includes the impact of genetically modified crops on these markets, but so far there have not been great changes to the spectrum of organisms in the screen, apart from adjustments in the importance of some organisms.

The focus up till now has been on keeping the resources for research more or less constant, with less emphasis on the more traditional aspects (chemical discovery and the focus on chemicals, on crop inputs and agronomic traits) and moving towards crop outputs, genetics and genomics, chemical trait regulation and marker assisted breeding.

Although modern breeding methods in seeds are a very important component of Novartis strategies, there are other important technologies like marker assisted breeding that will move development forward more efficiently. The focus on chemicals will not disappear but the emphasis will be shifted towards biotechnology. Part of the strategic focus has been to move down the food chain, less on farmers (although they are still very important) and more on traits that are needed by the food processors, customers and feed processors.

There are numerous links between business people in Novartis and staff at Stein who rely on these colleagues to give them an indication of what they are supposed to be looking for. The business section is interested in the flow of new products into the market place and the fit.. A key issue in the next few years will be the ability to register products. In the early stages of product development decisions are based mainly on the spectrum and level of activity to give figures on expected market size; at a later stage factors like toxicology and environmental behaviour are more important.

4.3 Agrochemical product development strategies (see Map 4.4)

The probability of finding new chemicals and modes of action has been declining over the years and this has been a major reason for developing the new facilities at Stein with the capacity to test 100,000 compounds per year on organisms, on 24 different assays, compared to the 15,000 compounds previously tested each year. The decision making processes and the criteria are also different, in terms of the value they have to bring to the company. The success rate is now on average one new product every two years, compared to three per year ten years ago. This change in throughput has been achieved with similar numbers of staff so it is much more efficient.

Fifty percent of the compounds tested are random intake, bought from suppliers in milligram amounts, and for this component Novartis has decided to invest more in their selection and to build up chemi-informatic tools. The remainder of the compounds are supplied by contract labs, universities and in-house chemistry. At least 10% of this capacity comes from natural products, another source of diverse chemicals, through contract labs which do pre-screening to give new chemical leads.

Through the screening process, Novartis also hopes to pick up entirely new leads which were not in the original concept. There are examples where the original work was in weed control and the product ended up as a disease control agent; or alternatively where fungicidal activity was first identified from a random input but the product is now going in the direction of a herbicide.

Some novel compounds have unusual modes of action, for example Bion, a really exciting product which acts by increasing plant vigour. Although it is successful, the concept is difficult for farmers to understand. There are also some new insecticides coming through in Novartis, neo-nicotinamides which could become at least as important as organophosphates. This area of work was initiated by Bayer, and Novartis is developing the second-generation improved version of these products. These are broad spectrum, highly active products with a lot of advantages.

Pymetrozine insecticide is another novel compound which is not well understood by farmers: if they use organophosphates or carbamates the insects fall off immediately after spraying. With pymetrozine it takes 3 – 5 days before the aphids are dead. The aphids stop feeding after 20 minutes so do not cause any further damage but they die slowly from starvation. Farmers want immediate control and this gives Novartis problems in marketing pymetrozine even though it is very safe to beneficial organisms and to workers.

Because of its delayed action, pymetrozine was not picked up in the screening programme as the assays run only 2 – 3 days. They did not at first realise the potential of this compound.

One of the company's chemists asked for it to be checked again – according to his knowledge it should have worked. Similarly with herbicides, the one week test period was too short to discover some modes of action and tests are now run for two weeks.

There are now numerous links between business people and staff at Stein. The business people are interested in the flow of new products into the market place and the fit with strategy and they give staff at Stein an indication of what to look for, for example "We need a similar chemical with less persistence."

A key issue in the next few years will be the ability to register products. In the early stages of product development decisions are based mainly on the spectrum and level of activity to give figures on expected market size; in the later stages factors like toxicology and environmental behaviour become more important. The question for pesticides is not how much chemical is put on the crop, but what it does there, how long it stays there, and whether it has side effects in the field or beyond the field. So there are very legitimate targets for pesticides for many decades to come, but the key new element determining the choice of new pesticides is going to be low impact.

4.4 Biotechnology and seeds development strategies (See Map 4.5)

Replacing chemicals with GM technology

Given that GM technology is cheaper to develop than chemical technology in most respects, it is possible that GM solutions may be found where chemicals are not coming through the pipeline, where problems are not solvable with chemicals. For example with European corn borer, once the pest is in the crop it cannot be controlled by chemical means. In such cases, farmers use pesticides prophylactically and this is one case where biotechnology can lead to a reduction in pesticide use. Bt corn provides a solution where there is no other option.

Chemical trait regulation, the ability to turn a trait on and off, could be very valuable for many different reasons including crop protection and transgenic crops. Also, looking at the genomics of pests can provide you with clues as to how to control them in a very selective manner. Novartis is becoming increasingly selective in the way they treat problems, to avoid the problems of non-selective treatments with unwanted effects. This can be difficult commercially for small scale problems but some problems are big enough to warrant selective treatments, for example the European corn borer or the corn root worm.

Within the company, however, the implications of substituting chemicals with GM crop technology requires changing attitudes among staff who have believed for twenty five or thirty years that, in developing chemicals, they were doing the right thing. This is a very difficult challenge for these people but it is the way of the future.

Input traits

Using GM technology to degrade pesticidal chemicals in plant tissues, for example in herbicide resistant crops, could be cheaper than developing a new herbicide. However, overall, the eventual cost could be similar, taking account of the process to develop the specific plant. Thus, if the company has a new herbicide they would now look for tolerant crops in parallel from a very early stage (an example of an integrated project). However, the tolerant crop may have some lowering of yield–all possible negative effects have to be checked. The end result may be that there is little difference in the benefit-cost ratio between GM crops and chemical solutions. The time from discovery to marketable product is also similar in both cases (8 – 10 years) and there will not be a big difference in profit for the company.

Novartis is also working on mycotoxin avoidance, an important issue for animal feed and for humans. Although this was not the primary objective of Bt corn, there is some evidence that Bt corn has significantly less mycotoxin contamination because there is less *Fusarium* present.

In GM crops input trait development is not new. What is new is the technology to make the processes more precise. The process of development of GM crops so far has been relatively simple because the technology involved has been known for approximately 40 years (Bt technology, Round-up Ready). Even so, companies have not made much money from this technology and the next generation of technology will be much tougher to achieve.

Output traits

The first round GM technology was attractive to farmers but less important for consumers. It might be different for output traits. However, there will still be a need for crop protection and so GMOs can create opportunities for chemical crop protection.

Often quality traits are taken to mean factors such as flavour enhancement. This is one potential but other factors like better processing and feed quality are also important, as are agronomic traits.

In crops such as vegetables and rice, the research focus is, for example, to improve nutrition (rice with additional vitamin A and iron, a Brussels sprout with high vitamin C content or even more active health properties such as traits that would lessen the incidence of heart disease). These are likely to be further in the future because they are more difficult to accomplish technically. They are also more difficult to put on the market because health claims will require clinical trials. This is one place where the synergies with pharmaceuticals would come into play, but almost nowhere else.

The importance of germplasm

The core technology for Novartis is still the seed and without strong germplasm the rest is secondary. Then there is a range of other supporting technologies, including plant biotechnology. Seed treatments and seed technologies, marker technology and genomics all make conventional breeding more efficient.

Acquiring the germplasm is a significant organisational issue. In most cases it would be driven up through the crop teams, coming to the AST and then the ARB and the decision would depend on what Novartis has in the pipeline and how this fits within the context of the strategy that has been approved for these crops. This draws a boundary around what Novartis would and would not seek to acquire. A pillar crop team tries to create comprehensive solutions so they would aggressively try and fill any gaps to provide complete solutions.

4.5 The life sciences concept

Within the Novartis group of companies, the vegetable group works closely with the consumer division, but they could equally well work closely with any consumer or functional food organisation. There is just as much opportunity to work with a company outside Novartis as there is within Novartis, including other pharmaceutical companies or other functional food companies.

The concept of ‘life science’ was originally a good idea but in the real world of analysts and investments and managing portfolios, it does not make sense from a straightforward business perspective. If a company can capture the synergies and gain the value or the leverage of the ‘life-science’ concept then it makes sense but individual investors can invest in agricultural stocks or pharmaceutical stocks more efficiently than Novartis can manage those businesses.

There are multiple levels of ‘life science’. A nutraceutical grown on a single acre can satisfy a specific need worldwide. On the other hand there is an agribusiness life science where concerns are about what is grown on an acre in Europe or the US and the politics or public opinion relevant to feeding the world through agriculture.

Considering life science issues on a technological level, there is a knowledge base across the company so that work in one area might have an impact in another area. A chemical screen may pick up something that is more relevant to be worked on in the GM plant area. To capitalise on such aspects it is vital that there is a research level network.

There are relevant aspects of life science–based synergies at the chemical level in natural products. All divisions use the same equipment and are interested in the same topics and there may be synergies that managers are not aware of. Areas of overlap include the joint access to libraries and overlap in target assays, for example a series of chemicals with fungicidal activity arose from the pharmaceutical area; and in the azole fungicides some leads were optimised for the control of human diseases while others were more relevant to plant pathogens.

5. Policy and other external influences on R&D strategies

[Material in this section is based on personal interviews with Novartis managers.]

5.1 General responses to policy issues (See Map 5.1)

Novartis screens the external policy environment and if they detect a development that could be a potential concern they monitor it in depth. If they identify a potential issue a decision is then made on who will take it further within the company.

Environmental policy is one issue which has been there for a long time. Previously, the Common Market and Free Trade were key objectives for the EU but that changed some time in the beginning of the 1990s, when they began to focus strongly on environmental programmes, consumer health and sustainability. This has already had, and will continue to have, a very direct impact on agriculture.

There are many factors underneath this very broad view which influence Novartis' business and the company wants to anticipate these changes. They then have two options: to shape whatever comes along; or if they cannot influence it then adapt internally. There will also always be situations where the company cannot adapt and also cannot prepare, in which case the issue is 'on the table' from one day to the next and they have to cope with it through 'issue management'.

There is a strong focus on looking at developments and trends, not only in Europe but also in other parts of the world, to see how Novartis would have to adapt or what strategies and action programmes would be appropriate. This includes changes within the industry and changes in markets. For example, the focus of the Commission on food safety affects, not just the ag-biotechnology industry, but also agricultural production and the processing and distribution of food, which are also items that Novartis is concerned about.

If Novartis wants to create opportunities in Europe, they have to position themselves in the context of the long-term strategies of European society. The industry as a whole has not done that in the past although it is now in the process of trying to do it. How do they help to achieve society's objectives of an essentially emission-less agriculture, an agriculture that is also a source of leisure for the 95% of the population that is not employed in agricultural production and is a keeper of biodiversity?

The education process needed here is two-way–changing the EC and changing Novartis. Most people in the biotechnology sector still firmly believe that they are in a technology-driven sector and it is a challenge to explain to them that wherever they are working in the food chain they are in the consumer business. This is a basic paradigm shift for people who have never had reason to doubt that their products would be received with open arms.

5.2 Policies to stimulate innovation (See Map 5.2)

Some Novartis managers felt that the EC decision making process about innovation needed to change. EC papers on the future of agriculture do not include the words 'science', 'technology' or 'innovation'–European institutions have not been able to see a role for innovation in their long term agri-food strategies. If one goes to a political decision maker in Europe with an innovation one goes with a problem. In US, Canada, Argentina, Brazil, Australia, China, they say 'Innovation! Yes! But how do we do it properly?' In Brussels they say 'We already have too much food. Don't bother us with your problem.'

European society's view on agriculture is thus totally different from America where it is a pillar of the economy and one of the biggest export sectors. In Europe agriculture is first of all a social policy, second an environmental policy, third a keeper of values, and fourth it produces a very disturbing side-product called food of which there is too much. It is therefore not surprising that the European public and policy makers look upon agricultural innovation in a different way and that is the debate the industry has to address. In the EC, policy makers do not seem to have a place in their philosophy for what industry is doing. So industry has to take several steps back and ask the Commission what they see as the role of agriculture in Europe in the next 25 years. This debate has to be changed before industry can begin to have an impact with its long-range R&D strategies. Otherwise public acceptance will never be there.

If policy makers were to redefine their strategic objectives and, through the regulatory process, give incentives to develop products that are working towards their overall social objectives and to phase out other older products, then industry could work towards this. Industry feels much more comfortable if it gets a clear signal from society of what it wants but they are not getting clear political information on the direction in which to steer their strategic research.

5.3 WTO and CAP (See Map 5.3)

Impacts on Novartis decision making from the external operating environment (eg WTO talks or CAP reform) are dealt with through the AST. This defines the point where the strategy is developed, based on agreement on the current situation, the future outlook, and issues (including external influences) that will have an impact on it. Once the strategy has been created, it defines a boundary and the groups drive through the strategy. If things change dramatically and require quick action, if it is not a regional issue, it is dealt with by the AST.

What happens in Europe is very important for Novartis for various reasons. There are 270 million people living in Europe so it is an enormously important market. Also, whatever Europe does has repercussions throughout the world and if Novartis were to withdraw from Europe they would not be able to make up for what was lost. They will certainly defend Europe, but it will take a long time to recover from the public opinion backlash (for example the demonstrations in Seattle).

In Europe, the industry is in a difficult situation. On the one hand there is a surplus, too much food available, although there are already much lower levels of surpluses than ten years ago as a result of the first CAP reform. On the other hand, agriculture is the biggest economic sink for the EU and this requires action from a financial point of view. All areas of company decision making have to estimate the effect of CAP 2000. It is a huge influence on company planning. Novartis develops scenarios and bases its research on these estimates. Its approach to screening looks at factors likely to affect the market (GMOs, WTO, CAP2000 and other influences). CAP reform could depress or increase markets depending on the balance in relation to world prices.

5.4 Pesticide regulation (See Map 5.4)

The European regulatory system

During the early development process Novartis looks at the properties of a new compound and predicts what the market is likely to be. Then the company has to decide whether it is worth undertaking the further high development costs.

No matter what the final size of the market certain aspects always have to be covered, for example human toxicity studies. However, environmental studies may not require coverage of all geographical areas in Europe, or the number of residue trials could be reduced. It may also be possible to adapt the dossier that has to be submitted for approval, although the EU always insists on a complete dossier.

For some crop protection problems there will be no solutions in future particularly given the EC programme to reduce, say by 50%, the number of active ingredients on the market. It could be that for certain problems in Southern Europe or Scandinavia, no company would want to develop a pesticide. Sometimes ideal compounds from a range of different perspectives are not developed because the market is not big enough.

Whenever the company brings a new active ingredient onto the market they have to meet the same European standards, no matter what the final size of the market. However, if a Government or local authority sees a need for a certain compound they can notify such a compound and push it through the system. Some type of burden-sharing with a multinational company could be helpful to them but it would depend on the company’s capacity to deal with small-potential products at the time. Alternatively, such a compound could be sold to a smaller company to develop for a niche market.

Pesticide residues are an important topic and Novartis works with the food chain to help farmers to reduce residues as much as possible, maintaining the quality demanded for agricultural produce while also assuring that it is available in the right quantities. Farmers have overused agrochemicals in the past and now society is are going to the other extreme, rejecting agrochemicals. It would be better to try to find a compromise, not just to defend the company, but because agrochemicals and biotechnology will be needed in the right combination to produce our food. It is no solution for EU countries to say “We will produce organic and whenever we do not have enough we will buy it somewhere else.”

New developments in insecticides

The organophosphates (OPs) are still the biggest class of insecticides and they have the disadvantage of high acute toxicity. Also OP insecticides are used in tropical areas where it is very difficult to enforce precautionary measures. Because of these disadvantages companies have been trying for some time to find alternatives and Novartis took the opportunity to buy the Merck range of products (see section 2.2.1). One of the big benefits of the ivermectins is that they are used at very low rates. Novartis also has a compound (thiamethoxam), comparable to the Bayer insecticide imidacloprid, which opens up the opportunity to replace a number of their OP insecticides.

They believe that R&D based companies should, when they have better and newer technology, replace the old technology. However, one problem is that the OPs are very cheap and so there will be pressure from farmers to keep them on the market. The real difficulty will be, as Novartis moves out of OP insecticides, to introduce these new technologies in a very competitive market. Otherwise, if Novartis moves out and generic producers fill the gap, nobody benefits.

The better toxicity spectrum of these products is certainly an advantage but farmers are likely to be resistant to change, to take on something new that they do not know, given that they have been using OPs for thirty or forty years. A regulatory incentive might encourage change and if there is something better on the market the company should have the chance to promote it properly, but this could be seen as incompatible with the concept of an open market.

Another important question is whether all uses of the OPs will be covered by the new products. A case by case approach will be needed and some OPs may need to be kept for certain uses. The OPs will therefore still be there but their use may be reduced significantly.

Conflicting regulatory instruments

Novartis managers referred particularly to two regulatory instruments which often had conflicting impacts on product development, the EU Water Quality Directive and the US Food Quality Protection Act.

The EU Water Quality Directive was seen as too crude an instrument and Novartis would prefer to see a more scientifically-based approach to water quality. There are examples where Novartis is having to make some difficult decisions on whether to progress a compound or not. Chemicals with potential problems for the environment are screened out at a very early stage in development but rejected chemicals may include some with useful properties compared to current products. A different approach by regulators to the water quality issue would change the way the company looks at this. However, this is regarded as part of the innovation process–new products are needed today because the old ones cannot cope with these limits and because pathogens and pests develop resistance. These are the two major driving forces for innovation.

The approach of the Food Quality Protection Act in the United States was given strong support, although there were reservations that, if the basis for prioritisation among chemicals is too narrow, the selection of chemicals may not be justified. The EPA basis for such decisions takes account of both environmental and human health factors and its fast-track system is now built into Novartis' decision making processes. They consider at an early stage the register-ability of compounds, including the opportunities presented by 'reduced risk' chemicals.

The EU approach on the other hand is that of developing environmental indicators and trying to classify pesticides, preferably on the basis of a single indicator such as bee toxicity, fish toxicity, soil degradability or water solubility. This does not do justice to the real situation and if the criteria are too narrow, the selection will not be sustainable. In Novartis there was therefore support for a system that allowed a fast track for compounds with a clear advantage over others, but concern that the basis for selection had to be a reasonable one.

5.5 Biotechnology regulation (See Map 5.5)

The European regulatory system

A regulatory framework is expected to provide the citizen with assurance that his or her concerns are adequately and comprehensively dealt with and to provide the producer with the confidence that his products are going to be expertly and fairly dealt with. Currently, the European regulatory system for biotechnology in agriculture is doing neither because the regulators are totally unsure about what society wants from them. It is a very difficult situation for industry.

The European regulatory system is a translation of political action, as a consequence of public concern, into an administrative implement. The files Novartis submits in the United States, Canada and the EU for environmental safety assessment are at least 98% identical. This is not surprising as they are all based on the OECD guidelines agreed ten years ago. On both sides of the Atlantic the application files are examined by independent government and academic experts, people who talk to each other regularly and respect each other. There is no difference in competence level yet the outcomes are completely different, so there is clearly a non-technical factor in operation.

From industry's point of view, the regulatory process has to be transparent and predictable. Where there is a scientific process for the evaluation or risk assessment and superimposed on that there are political decisions, a company cannot predict whether it will be able to bring particular products to the market.

Novartis staff want to assure themselves that a product is safe, partly to protect the company. Once they are convinced that they have a good safety file, they take that file through the regulatory process. The company has no interest in bringing an unsafe product to the market. The damage in such cases, financially and in public image terms, goes far beyond the product itself. Novartis is a company that makes its money from saving people's lives.

For environmental regulation of GM crops the UK is pioneering the SCIMAC biodiversity trials which for the first time are explicitly not looking for zero risk. They are comparing the new technology with existing agricultural systems to see whether or not they deliver a contribution to a lower impact agriculture. However, the European regulatory framework is set up as a device to prove zero risk. The questions are put to industry as 'try to prove that this is safe.' and the public mind is very receptive to this, mainly because of dioxin and BSE scares. However, science cannot deliver zero risk, even by doing infinite numbers of experiments.

Considering how the system could deal with risks that cannot be unearthed during experimentation, there is a lot of experience in industry with lifetime monitoring of products, cradle to grave. The safety testing before launch is a very important part of this process but this is then followed up by a system which monitors the product until it goes out of the market. Seed companies have been doing this for some time to monitor the spread of new diseases. A system of agricultural extension agents monitors developments and sends information back to national agricultural research centres, to the EU and to companies.

Given this system of monitors already in place with decades of proven experience, they could be given additional training and a mandate to monitor public and environmental safety. Experienced people in the field will be the first to see anything untoward. Because of food scares in Europe, the public has gone into a general mode that unless we can prove zero risk we should not do anything innovative. The industry has to address the issue of comparative safety versus absolute safety, and perception of risk versus risk, monitoring and mitigation.

Patent issues

Patent people are trained first to claim and then to fight and this has always worked well in the past. The problem in the GM case is that they are making claims about things that some people see as very close to their hearts, leading to objections. The reasons for objections are not logical but they are very important. We need, in Europe and in North America, a debate on what the life sciences are going to do to our future, looking at the opportunities and the threats; and patents are one of the *small* threats. For the issues within the life sciences explosion that are now claiming public attention, it is a matter of "let's look at the molehills and the mountains will hopefully go away by themselves." We are not having that ethical debate.

We need another five to ten years of public, political and legal debate about what you can and cannot patent. There is ignorance and a lack of public understanding of what intellectual property rights are about and as a result the debate suffers in the same way as that on safety in GM agriculture. The debate is also fed by a very oppositional climate where nobody takes the time or the trouble to inform the citizen.

In relation to developing countries, Novartis needs to take into account a number of social and ethical concerns to see if they can adapt the system to these new demands rather than throw it away and start again from scratch. Compulsory licensing does not solve the problem, but a long term strategy of integrated technology transfer could do so. A rapidly expanding number of developing countries are moving into the knowledge society. Both China and India have biotechnology, in both academic and industrial sectors, that is only a few years behind Europe and is ahead, for example, of the former Soviet Union. At least eight countries in Africa, fifteen in Asia, and more than half of the countries in Latin America have laboratories that generate genetically modified crops on a routine basis. This is a technology that moves fast and has low entry barriers. Novartis' licensing department licenses state of the art technology from these countries. Twenty years from now, most of these countries will be competing in the knowledge production market place and they should not throw away their future for short term gain.

On the other side are those developing countries who cannot pay. How can Novartis create an incentive system so that they get access to biotechnology on an equitable basis? All the agbiotech companies, including Novartis, have agreements with the Consultative Group of International Agricultural Research (CGIAR) Centres, where they donate licenses on genes, including training. Novartis refuses to donate a gene without inclusion of training on safety and regulatory affairs. For example, their donation of a Bt insect resistant gene to IRRI came with an agreement where a number of scientists would be trained among staff in the regulatory affairs department on how to do a biosafety assessment and how to prepare files for submission to the authorities in their countries. Novartis, along with all the other big companies in this area, does not want a two-tier system with respect to safety so they all have this kind of agreement. The model is by no means perfect but it is important to find out which aspects work and which do not and to find a way to generalise it. Before we have explored a range of such solutions to the IP problem, it is premature to say that patents do not work.

Containment issues

When people think about containment, in the context of preventing the spread of ‘genetic contamination’ among crops or into the wider environment, they tend to think of walls. However, biological walls tend to be much more effective than, for example, the walls of a building. Industry would love to have better tools available for biological containment, and gene switching technology (‘terminator’) is such a tool.

The technology has a number of advantages on the bio-safety side, but public acceptance is an enormous problem and there is a need to find a new name for it. There is a danger that the technology will be rejected for all uses, even although industry has no intention of blocking the farmer from doing his job, and it is important for industry to be able to use this technology. For example if companies are going to make pharmaceuticals in plants, biological containment is an excellent technology to ensure that they cannot spread, and it is being thrown away. It is very difficult for industry to design strategies in such a climate.

5.6 Public opinion (See Map 5.6)

Public concerns

The immense public and political uncertainty about what to do with this new technology is affecting the confidence of the public in industry’s products and also their confidence in the role of the state in assuring their safety. And thereby it is also affecting the investment climate for the agricultural innovation sector. The questions go beyond biotechnology (“Is this GM food safe to eat?”). This is one way in which people who have concerns on a wide range of issues can package their concern and ensure that authorities will listen to it.

The public response to intensive farming systems in the developed world is understandable– industry’s products in biotechnology and intensive farming have been directed to the benefit of the farmer or the grower and the public has seen very little benefit from that. However, in less developed areas of the world there is a lot more concern about food supply and quality.

Factors which may have increased the European public reaction include: intellectual property rights particularly as they affect Third World Countries; the beef dispute between the US and Europe and the implication that Europeans should always accept what the US chooses to export; and the view that developing countries should accept what large biotechnology companies choose to produce.

An analysis of the UK situation showed that several things came together at the same time: tabloid newspapers looking for a headline, especially those that were against the Labour government; an opposition looking for an issue; a highly competitive retail sector looking for every small competitive advantage; BSE; and a lack of comfort with intensive agriculture. There is also anxiety about change in the world, coinciding with the end of the Millennium– things are moving very quickly and people feel threatened. Organic agriculture is increasing in popularity because people see it as a return to a simpler, healthier past. They do not like intensive agriculture, and biotechnology is seen as a symptom of intensive agriculture.

The labelling issue was also very contentious in Europe. There was no mechanism in place to deliver it and no one wanted to be the first to label. However, Holland did do this and it did not seem to affect purchasing decisions. It is important to provide people with choice but currently they do not have choice as GM products are removed from supermarket shelves.

It is impossible for companies to engage in the process of informing the public. If a company such as Novartis or Monsanto tries to provide factual information people say ‘OK, that alone is a piece of information, but we need something from elsewhere as well.’ It is important for industry to find out who are their allies and in the UK the scientists have been good allies. They have been put in a very difficult position because scientists normally communicate about science and it is more difficult for them to discuss values or emotion.

For Novartis staff, if someone says ‘I think plant biotechnology is morally wrong’, they can only say ‘I have a different opinion.’ There will always be a portion of the community that does not like any new technology and it will be a different sector depending on the issue. For those who are uncomfortable with biotechnology, industry will never be able to change them. For the larger portion of the population who say ‘I don't know’, some do not care and do not want to know how their food is produced. There is also a portion of the population who are very interested and really do want to know and are also fairly well educated about it.

It is hard to see how agriculture can live up to current consumer expectations. It has to be environmentally friendly and sustainable, to produce enough food at acceptable prices and of the right quality, it has to be healthy and to be in line with international agreements (e.g. WTO). The economic factor is also an important element because, when something is not sustainable from an economic point of view, industry and farmers will not adopt it.

Some consumer groups are trying to stay in the middle of the road in terms of the debate and are merely asking for people to be informed. In Canada, a coalition of farmers and the Consumers Association went to Government together, an excellent example of how things can work well. The Consumers Association said they could actually see some benefits in the future, but they wanted to make sure that consumers are protected. It would be good to turn the clock back ten years and do that in Europe, to bring some of the stakeholder groups on board. What has happened here is that environmental groups claim to represent consumers. Resistance to GM crops is also emerging in the US, but there it is grower-driven whereas in Europe it is consumer driven.

Industry responses

Novartis likes to believe that the technology will survive when its value is demonstrated to consumers, which will require time and testing. If it does not survive the company will come back to the idea of flexibility. The opportunity for biotechnology in vegetables is different from the opportunity in corn. The opportunity in rice which feeds a huge amount of the world’s population, in a different region, is different again from the impact in vegetables. Novartis’ approach can be flexible enough to attack these differently. In addition, as political issues are increasingly raised against GMOs, the more this may open up opportunities for chemicals. A company has to find a balance.

Considering consumer responses in 5–10 years time, Novartis cannot fail to prepare for what they think is inevitable – that there is value in GM crop traits in the consumer market. It takes seven or eight years to develop a product and it takes a great deal of effort from a business standpoint to prepare yourself to capture the value from that. Novartis cannot just produce a tomato with a high vitamin C content and expect it to have value to the company. They have to create a business structure around capturing the value from it, and whether it is creating a Novartis brand, or consolidating down the food chain, or partnering, that process has to work in parallel with the development of the product so that when or if it is accepted they will get the value back.

So far ag-biotech, like any technology-driven sector of the economy, has worked on the assumption that industry will develop the technology and the advantages will be so obvious that it will sell itself. Most managers come from ‘the roaring eighties’ when industry was rushing out the technology, together with medical biotech and information technology, and society was scooping up everything from medical biotechnology and information technology. However, ag-biotech has become the one target more despicable than tobacco companies and the nuclear industry and this affects decision making.

Most companies did not realise that such resistance could build up against the technology and their communication policies were not what they should have been. They did not do enough to prepare the market for what was coming. Monsanto for some time was too aggressive and wanted to achieve things which were just not feasible. Industry now does realise that this is important and they are adopting a more strategic approach, to start communicating about new technology at an early stage, tell people what they are doing instead of confronting people with it when they are not prepared. However, five years ago, journalists did not want to know about GM crops; it was not a public issue.

The situation in Europe is not going to change quickly. It will take several years to convince the public that there are also benefits from biotechnology. The current public benefits are indirect but the direct benefit today is for the farmer and the environment, not the consumer. Where products show a direct benefit, for example output traits or increased vitamin or mineral content, it is easier to communicate and this could help to change the situation.

The turbulence currently being caused by public pressure could eventually be beneficial but at the moment it is causing disruption in the company's focus and organisation. To cope with this and to take account of public opinion in R & D planning, regulatory affairs management sit in on research planning from the earliest stages to look for potential problems. They are more involved in the strategy than used to be the case. Previously they began to work with a product at a later stage in the research process, see if there were any issues, to do research to resolve the issues, and then to help management to decide whether to take the product forward or not. That traditional view of regulatory affairs in pharmaceutical and crop protection companies has disappeared. Novartis now has a structure for bringing up new research projects where there is an obligation on the scientists to do two things: to look at existing intellectual property and to discuss with regulatory affairs staff whether their project is viable. New biotechnology products are currently handled by the Seeds sector, rather than Crop Protection.

GM crop segregation

There are segregation issues with GM crops but that is true for any quality traits. Examples include good quality malting barley which commands a very good price compared to feed barley; and sweet corn which, unlike field corn, is not a commodity crop. Where a particular variety is grown for a specific processor and purpose it is segregated. This is already a routine process for identity preservation for many crops but in commodity crops it is very difficult to achieve because, to a certain extent, it defeats the purpose of commodity crops. The price premium on a crop is needed to justify segregation.

The role of food processors and supermarkers

There is a need to improve the trust that people have in the process of risk regulation itself, not only in companies. The ag-biotech industry is not well equipped to reach the portion of the population that is uncomfortable with biotechnology and to provide them with information and ideas that make them more comfortable. They have no experience of speaking to consumers and they are learning something very new. To some extent this then becomes a case of building alliances with people who are trusted, and who do know how to communicate, for example food companies and food manufacturing companies.

Food processors and supermarkets have the most power in the food production system. In the end they are the ones who say to consumers 'What we offer is safe.' They are probably stronger than regulators because regulators have set certain standards and as long as industry meets these standards they are complying with the law. However that is no longer good enough – industry also has to meet public expectations by working with food processors and supermarkets.

Some food companies focus on organic products but the more realistic ones realise that it will not be possible to produce affordable food in the required quantities just by organic production. Chemicals and also the whole technology basket have to be used in a way that is acceptable to the consumer.

In practice there is a difference between retailers and food processors. Novartis has had good co-operation from food processors and has been involved in EuropaBio and in their own Food Biotechnology Communications Initiative. Both Unilever and Nestle have been very involved and very supportive, and they have also taken the initiative proactively.

However, the food retailers have a different attitude because they have a different business and in some countries they have decided to hold back for the moment. They may believe that biotechnology will come forward eventually but in the short term it is not the retailers that will benefit. In the longer term, benefits will come through to the retailers but they do not see that yet. Also, even food processors may have to draw the line if something threatens the brand.

Looking at current trends, the more markets are segmented the more room there is for adding value, and Novartis will capture some of that value at some point. As Novartis Seeds, they provide seeds to everybody, from the organic farmer to the biotech farmer, and they provide products for all of those segments. More quality traits will lead to more segmentation and therefore more value that will be captured by the whole food chain. It is a question of who gets what part of it.

5.6 Environmental discourse

In discussion with Novartis staff, environmental issues were closely interwoven with other aspects of decision making, as indicated above throughout sections 4 and 5. The company had looked introspectively to see what were the relationships between environment, consumer health and agribusiness and to see how they could play a part.

For example, there has been a discussion about the roles and benefits of biotechnology and chemicals in crop protection. The company now accepts that a reduction in the use of agrochemicals is a positive element for biotechnology but it is not yet clear how much the environment will benefit. It can be described in terms like ‘the loading of the environment is reduced’, but if agrochemicals are damaging the environment then they should not be on the market. There is a strict regulatory processes to assess these products and if they are not acceptable or the risk involved in their use is not acceptable, they should not be on the market.

It would also be wrong to say that, because the biotechnology products could eventually replace agrochemicals, that is their only benefit. That is perceived as a good thing at the moment, but eventually it may not be so. The industry will also develop further chemical products which are more environmentally sound or might have additional environmental benefits.

The agrochemical business is in the process of re-defining its strategic objectives. The problem is that, especially in Europe, there is very little policy guidance. The European political superstructure has said ‘Our agriculture is polluting too much – let’s go organic’. But people tend to forget that organic farming pollutes a lot – it is just a different kind of pollution.

There is also the question of how to define organic farming. It can be defined on a philosophical basis or on a scientific basis and at the moment in Europe it is being defined on a philosophical basis. An organic farming approach, defined on a scientific basis where the objective is sustainability and minimising impact, is one where there will be a very important place for agrochemicals.

6. Conclusions

6.1 Novartis strategies and planning processes

Novartis was much more international in outlook than some other multinational companies located in Europe, but it still retained its roots in Europe. The main locus of long term discovery strategies for Novartis, basically how to improve the environmental status of crops, was in the USA, up to 2010 at NABRI, and beyond 2010 at NADI, although the decision making function was still located in Basle. Managers recognised that this added to the organisational costs but also felt that there were advantages to be gained by having a dual location, partly because of the important component of their markets that was located in Europe, but also to capitalise on the perceived strengths of the two continental traditions –

the ‘can-do’ culture in the USA which was particularly important for biotechnology development and the perseverance and quality which they saw as characteristic of the European tradition. The existence of ‘clusters’ of SMEs was seen as important in deciding the location of activities within the USA, and Europe was regarded only as ‘making valiant efforts to catch up’ in this respect.

While there was no suggestion that Novartis would consider relocating its headquarters from Europe to another part of the world, the gradual loosening of European ties and strengthening of those in other parts of the world would certainly make this easier to accomplish if public and policy pressures were to encourage such a move. The implications of such a move for employment in Europe would be considerable, given the large numbers of SMEs, technical and non-technical, located in Switzerland and adjoining regions of France and Germany that owe their existence to Novartis.

Novartis saw itself as one of the companies that had not engaged significantly in the process of ‘buying down the value chain’ as some other companies had done. However, as indicated in section 2.2 they had made significant acquisitions across the value chain to which many of their current strengths in both seeds and agrochemicals could be attributed. The four internationally recognised seeds brands, originally acquired in the merger with Sandoz, have been supplemented by purchases of a number of other smaller seed companies as part of the overall focus on the seed as the core technology and hence on the need for strong germplasm. The merger with Merck led to the acquisition of a set of insecticides which was particularly important for Novartis’ focus on improved, more environmentally sustainable agrochemical strategies in the context of integrated pest management.

Despite long term recognition by companies of the need to link agrochemical and biotechnology strategies in their decision making, in general they are only now beginning to implement this approach. Novartis is one of the furthest advanced in this process, through its agribusiness strategy. The current focus is on organisational and marketing aspects and this is being extended more deeply into functional areas, as could be seen in Biostein, where staff were aware of the strategy but not yet heavily involved in its implementation.

The key components of the agribusiness strategy, AST, ARB and Global Crop Teams bring together staff from agrochemicals and biotechnology areas with the aim that they will rapidly become indistinguishable in their approach despite their different backgrounds. In dealing with interactions under the agribusiness strategy the emphasis is primarily on flexibility, getting the most appropriate combination of possibilities to deliver sustainable development and at the same time maximise the returns to the company.

Novartis agribusiness strategy was based on a structuring of the world industry players into two clusters of companies:

- those with both a strong and viable seed base and significant crop protection activities; and
- the ‘pure players’, mainly in crop protection, along with a small number of players who are still purely seeds based.

Novartis is in the first category and saw itself as being in a very favourable position to gain leverage from chemical/biotechnology synergies, but felt it was not achieving this as effectively as some of its competitors, particularly Monsanto. The ‘pillar crop’ strategies arose out of this analysis.

The main emphasis of the agribusiness strategy, as delivered through the crop teams, was on flexibility and long term balance, keeping the core business running while managing new developments. The overall aim for each crop and region was for a low impact, high output agriculture, considering in a broad way which mix of technologies could achieve this most effectively. Chemical and GM strategies were thus looked at in parallel, in the full realisation that some GM strategies would be a threat to chemical strategies and others would create opportunities. This aspect of the strategy was still causing difficulties for some staff who saw themselves as ‘chemists’ or ‘biologists’ and who were in the process of making a transition to a more holistic perspective.

The need to maintain a flexible approach to the direction of the agribusiness strategy in the future was partly a result of the uncertain policy and political environment for GM crops in Europe. As a result, the focus on input characteristics would be extended gradually and opportunistically to genomics, the development of marker systems and output traits.

The agrochemicals strategy itself, apart from the obvious need for products that will have a viable global revenue stream, was driven by the need to have chemicals with low environmental impact and this was linked to the ability to register the product (see 6.2). Associated with this point was the need to adapt the screening process to detect novel modes of action which could be characteristic of new and more environmentally sustainable products, for example by running tests for longer or including new tests in the battery. With novel modes of action, particularly for some of the new insecticides, there was also a need for new marketing strategies, to persuade farmers of their effectiveness and their added value for the environment and for human health, particularly in the face of competing products which are cheaper.

While there are some large scale problems such as European corn borer and corn root worm that can provide a big enough market to make these more selective treatments commercially viable, in general smaller scale problems will not be addressed by multinational companies.

The concept of 'life sciences' originally seen as the linkage between pharmaceutical and agrochemical strategies in multinational companies, through the adoption of biotechnology techniques, was no longer regarded as particularly relevant by Novartis, except in the context of the knowledge base itself where discovery strategies can operate synergistically, or further down the development trajectory where some nutraceutical products may require clinical trials testing. However, Novartis did recognise multiple levels of what could be regarded as life science strategies involving, for example, the production of pharmaceutical products in field crops and the development of strong linkages with food production and distribution companies. In a sense the whole agribusiness strategy could be see as 'life sciences' even though Novartis did not refer to it in those terms.

In the planning processes within Novartis, there was no real separation of environmental, biodiversity and sustainability discourse from other aspects of strategic and operational planning. Such issues were seen as an integral component of the business planning process and it was assumed that incorporating them into business planning was going to be essential to the future commercial success of the company, and therefore that Novartis has to find a way of turning these publicly demanded goods to its commercial advantage.

6.2 The policy environment and its impacts

Many of the innovation and product development strategies described by Novartis were strongly influenced by the policy environment, particularly the CAP which was seen as a cause of market uncertainty, and the regulatory uncertainty surrounding the development of GM crops.

The regulatory environment for pesticides on the other hand was seen as much more stable and predictable and hence as less difficult to manage. The differences in mode of operation of various regulatory instruments and the resulting differences in impact on industry decision making were noted. For example, the EU Water Quality Directive was regarded as too crude an instrument which could be improved by a more scientific basis for decisions. On the hand, the US Food Quality Protection Act was more positive in its impact, encouraging the development of pesticides with an improved environmental profile. Novartis was well able to accommodate both types of regulation in its R&D decision making – indeed it saw regulation as one of the main drivers or innovation. Managers were also slightly concerned about the extent to which the criteria of the Food Quality Protection Act were scientifically based, but saw the current approach as acceptable.

There is a limit to the extent to which a company can work towards improving the environmental profile of its products, in advance of what is demanded by the regulatory system. For example Novartis' new suite of insecticides is more acceptable from environmental and public health points of view than the currently widely used and much cheaper OP insecticides, but farmers will probably need an incentive to adopt them. Some thought needs to be given to achieving such changes in farm practices without creating what could be seen as restrictions of trade.

The EC response to innovation for agriculture was also seen to be problematic for industry who would prefer to see a stronger recognition of the need for innovation, to protect food supplies, to generate profitable exports and to improve the environmental performance of the industry.

Novartis had developed a range of pragmatic responses to the turbulent policy environment and the evolving EU societal position on intensive farming systesm:

- anticipate change;
- influence it where possible;
- adapt internally to change and have flexible strategies;
- involve regulatory affairs people in the R&D planning process at a much earlier stage than before;
- forge new alliances with the food and retail sectors.

The point about flexibility of strategies was particularly important, allowing future developments to focus on a mix of chemical and biotechnology solutions to agricultural problems, tailored to the social, regulatory and agronomic requirements of different regions and crops.

There was strong concern in the company for the needs of developing countries, some of whom were seen as being well on the way to having successful biotechnology industry sectors, and some of whom were unlikely to be able to adopt this technology in the short term. The former were seen as sources of opportunity for collaboration with multinational companies; the latter were seen as being in need of assistance from them; but the point was made that neither should be encouraged to throw away their future for short term gain. The issue of intellectual property rights was addressed mainly in this context. It was seen as a strong focus of public attention in the developed world, but of relatively minor importance compared to other moral and ethical issues raised by the new life science trajectories.

Addressing the environmental risks of GM crops was seen as problematic mainly in the context of demands by the European public for zero risk. Biological containment was seen as the most effective way to deal with questions of the spread of genes in the environment rather than conducting numerous series of crop trials. Where crop trials are undertaken, the UK SCIMAC approach, based on consideration of whether GM crop technology can deliver improvements over current farming systems, rather than delivering zero risk, were seen as a useful way forward. Novartis managers also saw the development of life long monitoring of the new technology in use as another useful safeguard.

Overall however, in the context of policy and regulatory developments, there is an overwhelming need for relative stability and consistency and for clear signals to be given to industry.

Appendix : Cognitive maps