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

Bayer AG monograph

Annex C6

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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.

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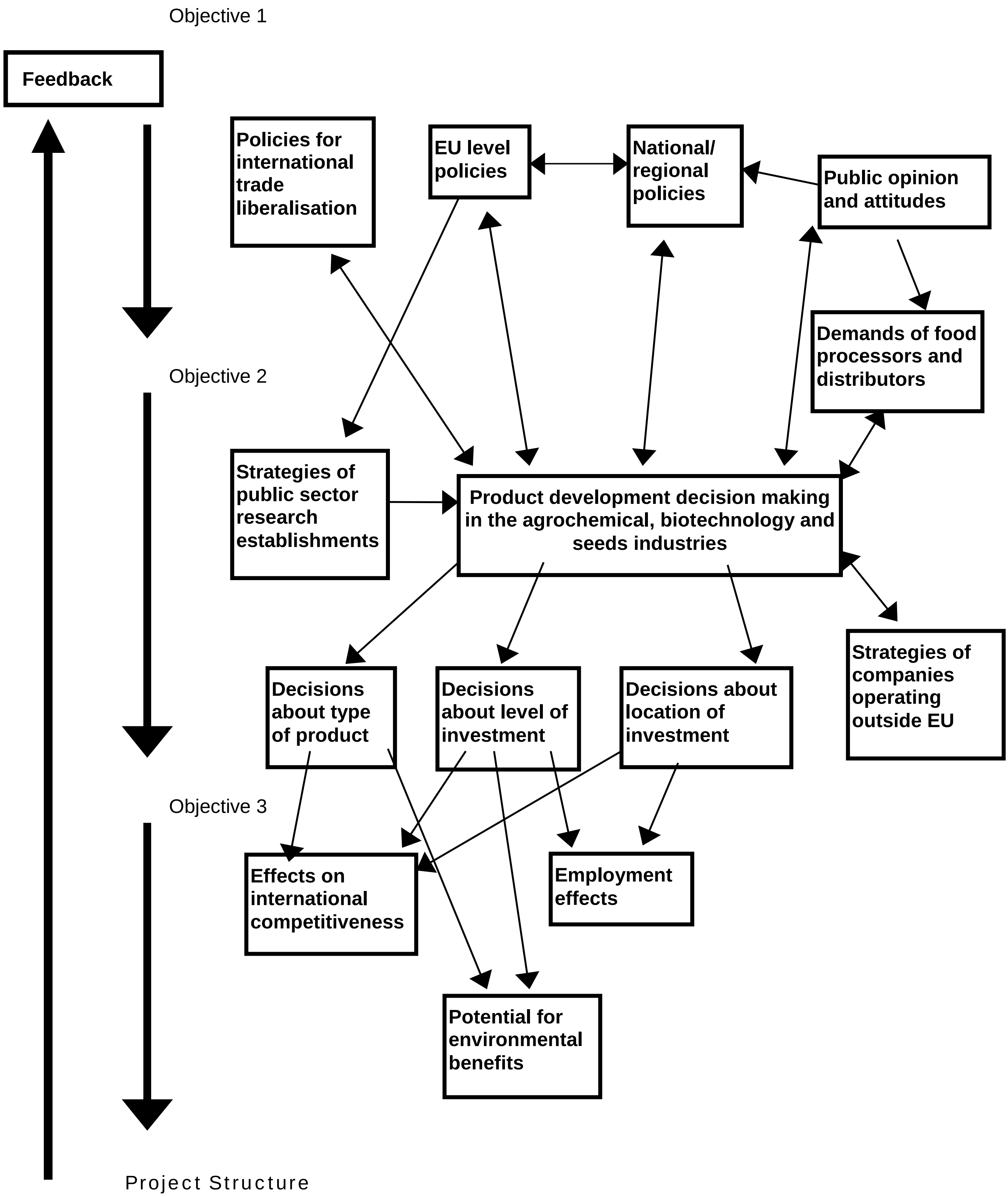

Project Structure

Contents

1. Introduction

> "Bayer is an international, research-based group with major businesses in life sciences, polymers and specialty chemicals. Employing 120,400 people worldwide, the group has operations in nearly all countries of the globe and a portfolio of about 10,000 products. With annual sales of DM 54.9 billion and an operating result of DM 6.15 billion (1998), it is considered a world leader in its sector".

This is how Bayer introduces itself in its Internet presentation. The company has 5 production sites in Germany – in Leverkusen, Dormagen, Uerdingen, Elberfeld, and Brunsbüttel. Bayer is an international chemicals and health care group. The group was founded 135 years ago, and established itself internationally – both in the Far East and South America – before 1900. In 1892 it applied for a patent for Antinonnin, the first synthetically produced insecticide. This marked the birth of the company's crop protection activities.

It is now active in 150 countries throughout the world and controls some 350 companies. Bayer's business activities are concentrated mainly in Europe, North America (the USA) and the Far East. Bayer is headquartered in Leverkusen, Germany, and its largest production facilities are located in Germany.

The purpose of this section is to introduce the company by presenting its major strategic goals and giving an overview of the structure of this large company – the way it has been divisionalised and its presence in various regions of the world. Section 2 presents the organisational goals and innovation strategy of Bayer's agrochemical division. In Section 3 the structure of decision-making on R & D is outlined. Section 4 considers policy influences on technology, and Section 5 summarises the environmental discourse of the company.

1.1 Major strategic goals

The overall aim of the Bayer group is to become "the world's leading integrated chemical and pharmaceutical company with core competencies in health care, agriculture, plastics and specialty chemicals". As with other companies, the concentration on core activities is a recurrent issue across Bayer's business sectors.

However, within the chemical and pharmaceutical industry it is stressed that Bayer wants to "retain our diversified Group Portfolio, with its emphasis on chemical specialties, high-performance plastics, health care and agriculture. By doing so, we not only want to stand out from our competitors, we also want to consistently exploit the many synergies to gain clear competitive advantage." (Annual Report 1998)

> Bayer's "goals are to steadily increase corporate value and generate a high value added for the benefit of our stockholders, our employees, and the community in every country in which we operate. We believe that our technical and commercial expertise involves a responsibility to work for the common good and contribute to sustainable development."
>
> As concerns crop protection Bayer argues that "The amount of arable land worldwide is limited, and the population grows incessantly - by around 250,000 people a day. As a result, intensive, environmentally sound farming is necessary to ensure the basic right of all people to have sufficient food." Hence, the aim of the business group is to develop products that give "accurate and long-lasting crop protection while at the same time being harmless to humans on the environment".

Bayer adopts a life-cycle perspective on waste management. As a means of implementing this policy Bayer has issued Guidelines for Product Stewardship. In Bayer's internet presentation Dr. Pol Bamelis, member of Bayer AG's Board of Management is quoted as saying: "We see it as an important task of our research to develop products that are not only useful but also safe and environmentally compatible, or even contribute to the innovative resolution of environmental problems. The company is concentrating on minimising the production of waste since "what isn't produced need not be disposed of". The growing role of biological products within the chemicals sector is seen as an important part of this process, due to the biodegradability of biological matter.

Bayer is a member of the World Business Council of Sustainable Development – an association of 125 international companies. As such it has adopted the principles of the international Responsible Care Initiative. Under this initiative the company is committed:

- " to implement sustainable development concepts aimed at conserving natural resources for the benefit of future generations,
- to operate a management system that, of its own accord, sets, reviews, and continues to develop targets for improvement in the areas of product stewardship, environmental protection, plant safety, hazard prevention, occupational safety and health,
- to report to all employees and to the public on the current status, targets and results,
- to pursue a dialogue with employees, customers and the public, actively responding to their opinions and requests and taking these into account in developing future corporate objectives."

Bayer has also defined a set of guidelines for the responsible use of genetic engineering, which is seen as a "key innovation for the economic future of [the] company". Genetic engineering is used by Bayer for a variety of purposes, "primarily in research into human diseases", but also in the production and development of "new drugs for the treatment and prevention of diseases in companion and farm animals", "to learn about the development and growth of plants and the organisms that damage them (insects, fungi)", and "to optimize chemical crop protection agents and to develop complementary biological methods".

It is stressed that the company "markets only those genetically engineered products and processes which, according to the latest scientific and technical findings, are known to be safe and environmentally compatible". Finally, Bayer is "committed to increasing public understanding of this technology".

1.2 Internal Structure

1.2.1 Corporate level

Bayer's operations are organised in five business segments: health care, agriculture, polymers[1], chemicals and Agfa (Figure 1.1). These are further subdivided into various business groups as shown in the diagram below. The relative importance of the five business segments is indicated in Table 1.1 below

Table 1.1 Relative contributions of the five business segments 1998

Segment	Health Care	Agriculture	Polymers	Chemicals	Agfa
Percentage of sales 1998	25%	11%	32%	16%	16%
Operating Results 1998	29%	17%	34%	12%	8%

Source http://www.bayer.com/bayer/ueberblick/arbeitsgebiete_e.htm

[1] Polymers are macromolecular compounds used for a wide variety of purposes.

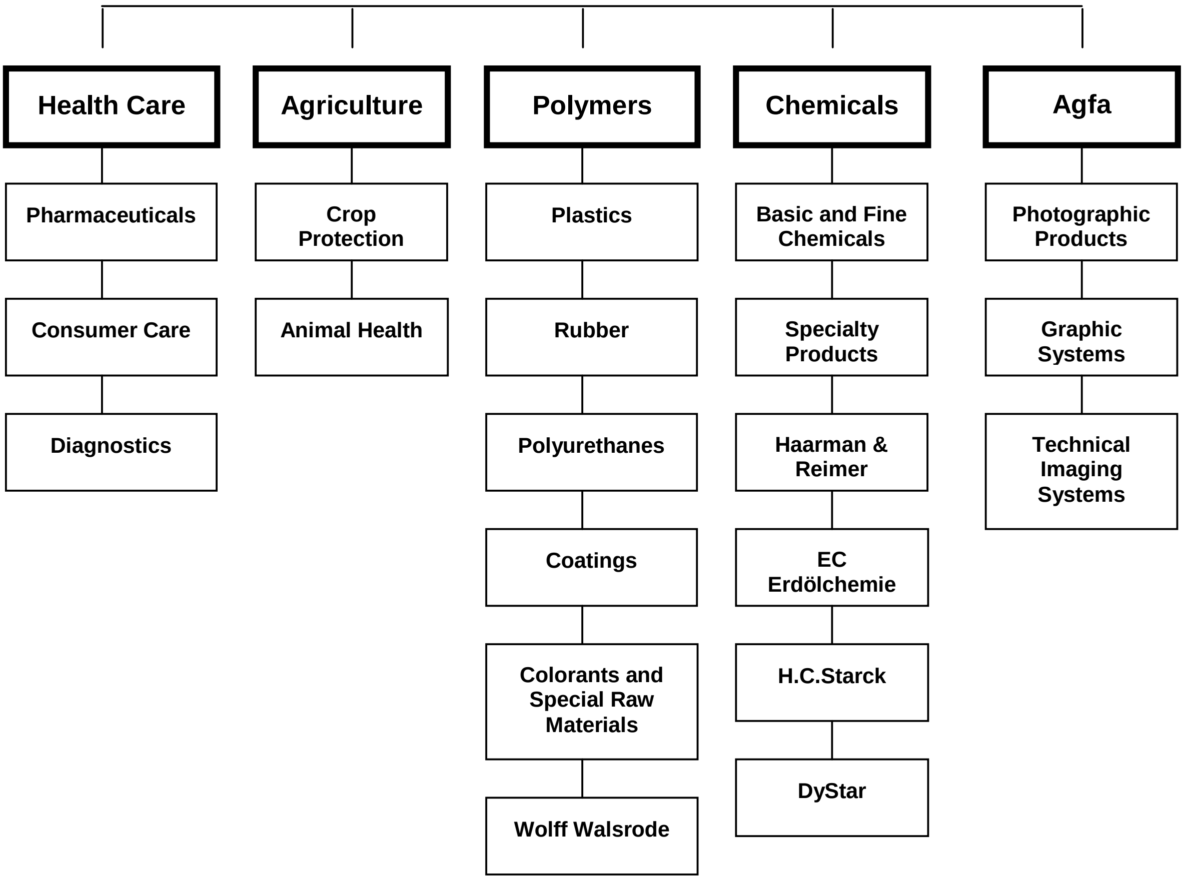

Figure 1.1 Organisational structure of Bayer

1.2.2 Subsidiaries

As shown in Table 1.2 below, Bayer is active in all parts of the world. Bayer's largest subsidiary is Bayer Corporation in the USA with about 23,000 employees at more than 50 locations. Bayer Corporation is headquartered in Pennsylvania.

Table 1.2 Countries in which Bayer is active

Part of the world	Country
Europe	Austria, Belgium, Croatia, Czech Republic, Denmark, Finland, France, Germany, Great Britain, Greece, Hungary, Ireland, Italy, Latvia, Netherlands, Norway, Poland, Portugal, Russian Federation, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey
North America 23,000 employees	USA, Canada
Latin America 10,600 employees	Argentina, Brazil, Chile, Columbia, Ecuador, El Salvador, Guatemala, Mexico, Peru, Uruguay, Venezuela
Africa	Egypt, Ghana, Kenya, Morocco, South Africa
Asia	China, Hongkong, India, Indonesia, Korea, Malaysia, Pakistan, Philippines, Singapore, Taiwan, Thailand,
Rest of the world	Australia, New Zealand

Bayer intends to expand in Asia, first of all in China and Thailand, and consolidate the company's position in Japan and Latin America.

1.2.3 Subsidiaries within agrochemicals

Bayer's Agriculture Division in the US – the Crop Protection group – has been a leader in the development of crop protection products for the cotton market since the early 1950s. In Latin America Bayer produces crop protection products in Mexico, Guatemala, Colombia and Brazil. Crop protection is also dominant in Bayer's activities in Africa.

1.3 Financial Performance, Employment, and Product Portfolio

Table 1.3 below shows the main operating results for 1997 and 1998.

Table 1.3 Bayer Group Consolidated Statements of Income, DM mio

Net Sales	1997	1998
Net Sales	55,005	54,884
Cost of goods sold	30,999	30,269
Gross Profit	24,006	24,615
Selling Expenses	11,989	12,404
Research and Development expenses	3,878	3,920
Other operating imcome	1,351	1,585
Other operating expenses	1,735	1,815
Operating result	6,018	6,151
Income before taxes	5,108	5,336
Net income	2,941	3,157

Sales of the Agriculture Segment increased by 3 per cent from 1997 to 1998 with an 18 per cent return on sales.

1.4 Core competencies

Bayer spends very large amounts of money in research and development (Table 1.4). "A good 50 per cent of the company's sales are attributed to products developed in its own research laboratories in the last 15 years. Worldwide 14,000 people are engaged in R & D at 25 locations. The most important of these are in North America, Europe and Asia."

Table 1.4 Amounts spent on R & D

Year	1990	1991	1992	1993	1994	1995	1996	1997	1998
Mio DM	2,738	3,007	3,096	3,157	3,177	3,300	3,400	3,700	3,900

Of the DM 3,9 billion spent on R & D in 1998, 65% was spent within health care and the agricultural business segments. The distribution of R & D among business segments is given in Table 1.5 below.

Table 1.5 R & D by business segment, per cent

Segment Year	Health Care	Agriculture	Polymers	Chemicals	Agfa	Total
1997	50	17	14	9	10	100
1998	48	17	15	9	11	100

Source: http://www.bayer.com/bayer/ueberbl…ericht_1998/lage_forschung_en.html

Within its Agriculture Segment Bayer spent DM 0.7 bio in 1998 on R & D. Some of this was spent on the development of new pesticides such as the Herold Terano herbicide and on a new rice fungicide called Win for the Japanese market. R & D is also conducted within the Animal Health Business Group, where a number of new vaccines have been submitted for registration. The Chemicals segment is also active in the development of new means of crop protection, however.

Throughout the Bayer Group's 135-year global history, research and development has always played an important role. Many innovative discoveries from Bayer have strongly influenced the pharmaceutical and chemical industries. Bayer has established a global research and development triangle which includes Germany, the United States, and Japan. Bayer derives its strength in R&D by assigning the research centers responsibility for appropriately targeted projects. Additionally, success is based on an effective system of close collaborations.

In Japan, research and development focuses on the life sciences, which includes health care and agriculture. This business segment accounts for more than half the Bayer Group's revenues within the country, and constitutes a major part of Bayer's activities in Japan. In 1995, Bayer completed construction of its pharmaceutical research centre in Kansai Science City; a facility designed to establish the company's pharmaceutical-related R & D activities in Japan. The crop protection research centre in Yuki has already proven itself to be a successful global contributor to R&D of agrochemical products. These two facilities are expected to make further important innovations in the Life Sciences area.

1.5 Research agreements

Bayer AG has concluded a five-year research agreement with Heidelberg-based LION Bioscience AG in thelife science fields of phamaceuticals and diagnostics. The objective is to make more efficient use of leading-edge genomics and informations technologies to identify and develop innovative drugs and diagnostic markers. This is expected to accelerate the pace of research considerably and enhance product development. In the field of genome analysis of insect pests, fungal diseases and weeds, Bayer co-operates with Exelixis, Lion and Paradigm.

Within the farmaceutical industry, a comprehensive research partnership with the American biotechnology company Millenium Pharmaceuticals was concluded in 1998. The underlying strategies behind these research agreements will be presented in Section 2 below.

> “We do believe that chemical crop protection will continue to be very essential for food production on a worldwide basis, and we have made that statement for several years now – even when other companies were saying ‘well, the future is all biotechnology’, without knowing how to define it exactly. Innovative crop protection chemicals will be a continuing factor for food production which is one of the basic reasons why we continue to invest substantial amounts of money on research and development.”

2. Organisational goals and Innovation strategy

Roughly speaking, it takes about ten years for a chemical compound to reach the market. After its market launch it needs another 8-10 years to recoup the costs of research and development. In these circumstances, R & D strategies must be based on very long-term forecasts concerning market developments and technical change. In Section 2.1 the future vision underlying Bayer's long-term strategic decisions is presented. Section 2.2 goes on to consider the basic strategic options open to the company, and the choice it has made among them.

2.1 The future – Bayer's strategic vision

On the market side, a further rapid growth of world population (with another 83 million people every year), an increasing demand for higher quality food, and a decline in arable land combine to necessitate annual productivity increases of about 2-3% to avoid food shortages. At present, productivity in food production is estimated to grow by around 1.5% per year[2]. The central strategic vision of Bayer is one of helping 'feed the world', therefore. In this respect Bayer resembles the other major players investigated under the PITA project.

To resolve the dilemma of accelerating productivity growth and intensifying food production on a sustainable basis, a broad range of advanced technologies must be harnessed and orchestrated according to the principles of *integrated crop management*. These technologies include satellite-based monitoring of crops and fields, genetic modification, and agrochemicals. These technologies may be mutually supportive, but they may also represent competing solutions to the same problems. More specifically, many observers of the market expected green biotechnology to increasingly take over the role of agrochemicals.

Not surprisingly, Bayer have considered the future of biotechnology very carefully. Thus, for about four years, Bayer has had a team look at how biotechnology will develop until the year 2010. The present popular anxiety about biotechnology is expected to fade over the coming years. Two reasons were given for this. For one thing it was argued that a major breakthrough in pharmaceutical biotechnology, e.g. in the treatment of cancer or other serious diseases, might reduce the widespread scepticism about biotechnology in other areas as well among the general public. Thus, 'red' (medical) biotechnology could pave the way for 'green' (agricultural) biotechnology.

Secondly, it was explained that while focus had been on so-called input-trait biotechnology up until now, benefitting the farmer but not the consumer, a shift towards output-trait biotechnology could bring very substantial benefits to consumers in terms of higher quality food products. The possibility of producing healthier food, e.g. by reducing cholesterol problems was mentioned. This ought to have a favourable impact on consumer acceptance. Bayer was convinced, therefore, that agricultural biotechnology would have a significant role to play in future.

Biotechnology was by no means seen as an unequivocal threat to agrochemistry, however. Although the relationship between biotechnology and agrochemistry is often thought of as one of alternative, competing solutions to problems of plant protection, this is but part of the truth, according to Bayer. In important respects biotechnological and agrochemical plant protection are expected to be complementary.

This has been the case with input-trait biotechnology such as the development of herbicide-resistant crops, for example. This technology may have reduced the quantity of herbicides applied, but without herbicides the technology would not have made any sense at all. Bayer anticipated rather different forms of interaction between chemical and biotechnological crop

[2] 'Why crop protection will also be needed in future'. In *Courier Agrochem*, special issue 1998 p. 13.

protection in future, however. For example, Bt cotton may be protected chemically against some early season pests at a highly vulnerable stage of the growth process.

Moreover, it was expected that “with a higher added value of seeds, the need for crop protection will also increase. Although biotechnology (input traits) can to some extent replace chemical crop protection, experience suggests that there is still an important role for chemical substances to play..”(PK). One interviewee added that the price of seeds might even double, which would give farmers a stronger economic incentive to protect their seeds. For these reasons, the assumption that biotechnology will simply replace agrochemicals and make them redundant was thought to be oversimplified.

> MP: “We do believe that chemical crop protection will continue to be very essential for food production on a worldwide basis, and we have made that statement for several years now – even when other companies were saying ‘well, the future is all biotechnology’, without knowing how to define it exactly. Innovative crop protection chemicals will be a continuing factor for food production which is one of the basic reasons why we continue to invest substantial amounts of money on research and development.”

Within crop protection Bayer spends about 12 per cent of turnover on R & D. In terms of money this amounts to about 250 million ECU per year.

2.2 Strategic options

There are basically three options open to Bayer.

1. To invest in classical agrochemicals
2. To invest in input-trait biotechnology
3. To invest in output-trait biotechnology

As for input-trait biotechnology, the development of Roundup-resistance was given as an example. In this case biotechnology is used to improve the plant by adding the feature – or trait – of being resistant to a specific herbicide.

In Bayer’s expectation the focus in biotechnological research will shift towards output-trait biotechnology, i.e. biotechnology improving the characteristics and hence the quality of the final product.

Bayer itself intends *to invest mainly in the agrochemical area* but use biotechnology to develop new so-called lead structures or ‘modes of action’. Lead structures are classes of chemicals (“Zuzuki herbicides”) with a broad range of applications. Glyphosate would undoubtedly qualify as an example.

The decision to stay in agrochemicals is based on promising market forecasts, suggesting that agrochemicals will continue to play an important role in crop protection, on interesting new products coming out of Bayer’s pipeline, and on the premise that fungicides and herbicides are not seriously threatened by competitive solutions.

In practice, the strategy of using biotechnology in the development of new lead structures has given rise to new joint ventures, as explained at Bayer’s website:

> “A joint venture with the U.S. company Exelixis Inc., valued at DM 200 million, will give the Crop Protection Business Group information on new targets related to harmful insects and threadworms; this will be used to develop more selective crop protection agents (insecticides) with new mechanisms of action. A collaboration agreement worth approx. DM 75 million with Paradigm Genetics Inc., also in the USA, aims to decipher the genetic code of weeds and to thus to identify targets for the development of safer and more specific herbicidal agents.

> As soon as targets for new life science products are identified, they enter Bayer's robot-controlled high-throughput screening process in which they are tested for efficacy. This system currently has a capacity of 200,000 tests per day. Bayer's scientists are in the process of establishing one of the biggest compound libraries in the world, comprising a million substances. This is where combinatorial chemistry comes in – an innovative technique capable of synthesizing a large number of substances in a very short time.
>
> Licensing agreements are being concluded with international research organizations in order to speed up the establishment of the research platform. This is giving Bayer access to libraries containing hundreds of thousands of substances. Cooperations with a total value of around DM 120 million currently exist with Genzyme Corp. in the USA and Oxford Asymmetry in the UK. The DM 60 million agreement with U.S.-based ArQule Inc. concluded in 1999 will provide Bayer with hundreds of thousands of substances for pharmaceutical and crop protection research over the next three years".
>
> "Genome research allows us to identify new targets for drugs and crop protection agents; at last we are able to gain a better understanding of how diseases arise and progress and to incorporate this knowledge into the development of very specific life-science products," Dr. Bamelis emphasized."

Seed dressing is a key element of Bayer's crop protection strategy. In Bayer's publication *Perspective on Innovation '97*, this technology was explained by Professor Berschauer in the following way:

> "A farmer using a conventional spraying bar distributes an insecticide across as wide an area as possible and hopes that he will hit the destructive insects in the process. This is an uneconomical approach which is also unacceptable from an ecological point of view since the farmer destroys not only pests, such as aphids, but in some instances also beneficial organisms such as ladybugs. The best way to protect larger plants is really to administer crop protection agents in the same way that medicines are given to people, by injecting them or applying them to the surface of the organism."

It is explained that seeds dressed with Gaucho (an insecticide) have "a number of advantages:

- "The farmer buys seed that has already been protected; he saves a lot of work and does not have to apply crop protection products separately;
- The consumer can be confident that there are no residues left in the crop when it is harvested;
- The environment is protected because only tiny amounts of the active substance are used, and they are delivered directly on the location in which they are needed to protect the crop."

> (Perspective on Innovation '97, p. 77-78)

Seed dressing technology was seen as highly promising with substantial gains not only for producers and consumers but for the environment as well.

> "RS: We decided to focus our research on seed dressers. We expect this market to grow and our participation market position is with a share of over 30 per cent, which is excellent. Gustafson is an important player, because Gustafson is the owner of the machinery – the equipment used for seed dressing in NAFTA. In other countries we have very strong positions in France, Germany, and the UK

> where we bought Zeneca's business. We have taken over all the machinery. Bayer has acquired 50 per cent of Gustafson in 1998, which has allowed us an accelerated entry into the market."

A recent newspaper article (Financial Times, September 29, 1999) suggested that Bayer was prepared to spin off its pharmaceutical activities to buy up biotechnology companies. This was denied, however. On the contrary Bayer stressed the advantage of not being a seed-producing company to avoid competing with its own customers. Moreover, the interviewees pointed to the synergies between pharmaceuticals and agrochemicals. There is a continual exchange of knowledge in both directions and the same screening facilities are applied to pharmaceuticals and agrochemicals.

2.3 Conclusions

In conclusion, Bayer expects both green biotechnology *and* chemical crop protection to coexist in the future. This is seen as a necessary precondition for the food productivity growth required to feed the growing population of the world in an environmentally responsible way.

Bayer's own future lies in the field of agrochemicals, however, and the company does not see a future for itself as a seed producing company. Its strategy of focussing on seed dressing requires close co-operation with seed producing companies, which would be hard to reconcile with the competitive relationship that would emerge, should Bayer decide to become a seed producing company.

3. Decision-making on innovation

The decision-making structure is quite complicated "which should not surprise you since we spend over 250 million Euros per year on R & D."

Monheim is mainly responsible for long-term, research-based strategies. Once an interesting compound has been identified, it takes about ten years and costs some DM 290 million before it has been registered and can be brought to the market. This means that todays candidates will reach the market by the year 2010. In order to identify interesting candidates, Bayer must forecast market conditions (at least) ten years ahead, therefore.

More short-term strategies are the responsibility of the operative units, where e.g. the mixing of two compounds could be done in a couple of years, for example.

R & D is divided into two parts in the agrochemical division of Bayer. There is a more research oriented part whose main activity is synthesis. Connected to this part are three biological screening facilities, where greenhouse testing is conducted. After having identified interesting candidates, the field part of the R & D can take over, which is where the development starts.

Bayer co-operates with genomic firms to search for new lead structures, i.e. new classes of compounds that could provide a future market platform for the company. At its Monheim Agricultural Center Bayer is setting up a new building "in which our researchers will be able to conduct over one million individual tests a year by automated methods, starting in spring 2000. We are also setting up a computerised substance library for about 1.2 million potential active ingredients." (Annual Report 1998, p. 44)

The top five mode of action herbicides represent 70 per cent of herbicide sales.

A key issue is to shorten development time.

Research guidelines lay down which areas are seen as important to success. These guidelines are dynamic, examined continuously by the so-called *Business Group Commissions*, which have participation of all business units (insecticides, herbicides and fungicides). Each of these units have their own commissions reviewing these issues on a regular basis. The research guide lines give the chemist an idea of what to look for.

Within agriculture, Bayer has two *Business Groups*: crop protection and animal health. These are subdivided into business units. For example, the crop protection business group consists of the following business units: Insecticides, Fungicides, Herbicides, and Garden/Professional Care.

Once a product has been tested in the greenhouse, the Management Committees of the Business Groups decide which products are candidates for further development (in company jargon, products are classified as either L or F2 products, the latter being candidates for further development). These decisions are based on the research guidelines mentioned above.

This decision is the starting point for the more expensive development stage. Strategic Decision Analysis is done for the compound. The market value – in terms of a net present value of the product – is assessed very carefully from many different perspectives to provide the best possible background for the decision made by the management committee on whether or not to continue the development of the compound.

Bayer has set down a Market Research Group with a world-wide responsibility, which is in contact with different subsidiaries, bringing together information on the world market. This is the basis on which the Business Units look into the future and lay down Research Guidelines.

The criteria for screening compounds were not discussed in any detail. It was mentioned, however, that in the initial screening, Bayer would not look for a specific herbicide for potatoes, potatoes being too small a crop worldwide. Instead the initial screening will be based on cereals (wheat, rice, maize, etc.). Later on, if a herbicide turns out to be successful in the cereals area and proves to have a good compatibility with potatoes, it may be developed specifically for potatoes as well.

The above refers to routine decision making. The Management Committee is also responsible for major strategic decisions, however, such as that of going into biotechnology, not as a seed producing company but as an agrochemical company co-operating with the seed business. The Management Committee of the Agriculture Division is composed of representatives from all functions (R & D, marketing, production, etc.) as well as the heads of the regional units.

To sum up, Bayer's subsidiaries are responsible for gathering information on expected market conditions around the world. This intelligence is brought together in Germany by the Market Research Group, and it informs the Research Guidelines formulated and reviewed by the Business Group Commissions. These Commissions have representatives of all relevant Business Units.

Based on the Research Guidelines, the initiation of new research projects is the responsibility of chemists in the laboratory. Once new compounds have been synthesised, they have to pass a number of tests to decide which substances will be candidates for further development. Strategic Decision Analysis is applied to assess the market value of the compound, taking account of a broad range of risk factors. The outcome of this analysis is an estimate of the net present value of the product, which allows the Management Committee to decide whether or not to continue the development of the compound.

As mentioned above, the divisional Management Committee is responsible for major strategic decisions.

4. Policy influences on technology

> "PM: When you talk about policy influences on R & D, two things come to mind spontaneously. One very important issue is: what will be the regulatory environment by the time the product comes to market. We don't have a playing field where we know exactly what will be the requirements that will have to be – rightly or wrongly - met by the compound. With the tremendous amount of money involved, this sometimes raises the question: is it worthwhile doing certain

> activities not knowing what the requirements will be. And here we are talking not just about Europe but worldwide."

As indicated by the above quotation, predictability was an overriding concern to Bayer. The general view was that regulation and safety margins should be based on sound science rather than political judgements to establish a more predictable regulatory environment. In this section the impact of science, technology and innovation policies, environmental regulation, CAP reform, and intellectual property rights on R & D at Bayer will be reviewed.

4.1 Science, technology and innovation policies

Bayer is not directly involved in any such programmes at the moment. In Germany, substantial amounts of public money is being spent on biotechnology programmes intended for start-up companies, which explains why Bayer is not directly involved. At the moment, STI policies in Germany do not appear to have any noticeable influence on Bayer's R & D, therefore.

4.2 Environmental policy

In relation to environmental policy, three factors were stressed.

- Predictability, and the need for science-based regulation
- The precautionary principle
- The harmonisation of environmental policy at European level

As will be shown in this section, the three issues are closely related and therefore will not be treated separately.

The first issue addressed was that of harmonisation at European level. Bayer was clearly in favour of having a harmonised set of core requirements at EU level.

> "PK: Before bringing a compound to the market we have to answer questions with respect to side-effects etc., where we feel (as a company) we can justify bringing it to the market. On top of this we have to fulfil all the official requirements, and this is actually a moving target. As you know, from PPM[3] we can now analyse from PPB to PPT to PPQ – that we find molecules in the environment, and whenever we find them, even in minute quantities, the question of risk comes up. So when we were faced with all these requirements at national levels, we thought it would definitely be a good idea to harmonise these on a scientific level – to come to a list of requirements which (if we could actually fulfil them) would imply entry into the European market. What we have realised during the last years is that there is an effort at least to harmonise requirements, but at the same time there are very creative efforts by Member States to create new ones.
>
> Now if you add up all the strictest requirements from all the Member States, it will be very, very difficult to find compounds that can actually fulfil all of them. We ask for requirements based on sound science, and we are not arguing against safety margins, but these should also be established on a scientific basis that we can follow."

[3] PPM, PPB, PPT = Parts per million, parts per billion, parts per trillion, etc.

Applicant assembles all required documents on the active ingredient (dossier)

↓ Submission of the documentation to member state

Member State compiles an evaluation report (monograph)

↓

European expert meetings

(ECCO peer review-meetings)

Experts from Member States discuss each active ingredient on a scientific level

↓

Consultations at EU level in Brussels

with all member states and the European Commission: working groups and committees (e.g. on consumer protection)

specify e.g. exact conditions of use or make comments

↓

Decision on the inclusion of the active ingredient in Annex 1 of Directive 91/414/EEC (the positive list)

Inclusion in the positive list is a precondition for national registration of crop protection products with the active ingredient examined

Source: Bayer: *Courier*, Special Issue 1998 on Farming in the Future, p.9

Figure 4.1 Tests on active crop protection ingredients in the EU (new active ingredients)

The political process at EU level was felt to contribute to this. While Dutch and Danish concerns about the quality of ground water were thought to be perfectly legitimate, it was not found reasonable that Denmark, for example, could object to the approval of a product intended for the protection of olives in Greece.

> "PK: If we tailor a product for, say, citrus production in Spain, Denmark – for example – should not object to it, for if we are developing a compound under the EU 91/414/EEC Directive, we have to be accepted in the Annex 1 listing which needs the approval of all Member States. And apparently some of the Member States feel that we don't want to allow compounds for eventually they might reach

our Member State. But this is not our intention. Our intention is to solve problems not for a specific State, but for a specific crop. Olives are not grown in Denmark, but in Spain, Italy and Greece."

The process of registration has been described graphically in a special volume of Bayer's magazine *Courier*, cf. Figure 4.1 above. Bayer felt that this process was often unnecessarily time consuming (thereby detracting from the patent life time of new products in the European market). Also, the outcome of the process was seen as highly unpredictable.

Moreover, it was felt that national governments were often prone to yield to the pressures from interest groups and invoke the precautionary principle to hedge themselves against absolutely negligible risks, as indicated above. Apparently, there was a tendency to forget that the company would always be held accountable, if something were to go wrong.

"PK: If we develop a compound, first of all we have to answer ourselves: is this a safe compound. We must do this, for in the end we would be responsible if something goes wrong. It would be very shortsighted to produce chemicals which we do not believe would be safe for the producer, the consumer, and the environment."

From Bayer's perspective, there were two ways of improving regulatory predictability. First of all, it was stressed that regulation should be based on "sound science" rather than more or less well-founded political pressures.

"RS: The addition to safety obtainable is very very small, because we are already on a very high level… Agencies are coming up with new proposals for new tests, etc. – we don't get more information but we lose time. This is our biggest burden, and we don't think it makes much sense for the people or for the environment. "

Secondly, the companies should be given a time frame for adapting to new and tighter regulations (except, of course, in emergency situations).

PK: When it comes to policy influences, the time frame is a very important part. When the Food Quality Protection Act was voted for in 1996 in the US, there was no transition time, which means the new Act was requiring things that were not planned before, which had not been started in terms of coming up with results. The whole industry and the authorities, the EPA, is still struggling after four years. In Europe – after a very, very slow start implementing the reevaluation of all the active ingredients of Europe, the EU is realising that time is running out, they would like to finish the reevaluation in a very short time. This forces companies to prioritise, because we don't have much time. We therefore have to cancel a number of active ingredients, which might make both economic and scientific sense. If we would know that a product which is right now in the market, and where we do not see an immediate threat forcing us to withdraw it anyway – if we could have a time-frame which we could calculate on, it would be much, much easier for us to say, we can phase out this product, because we have products coming out of our pipeline, which would have smaller side effects and a better profile. So phase-out and sell-out periods are very, very important.

Another significant problem was the time consuming approval process of the EU authorities.

RS: To us it is not just a legal problem, but also a financial problem that the approval authorities are short of people. Bayer is speeding up its R & D. A lot of effort has gone into this, and after this the approval time may take 18 months which takes away time from the life time of the patent.

MP: Especially keeping in mind that a patent life-time of 20 years may sound like a long period, but if you look at the time elapsing from the original screening and

> patenting to the commercial introduction of the compound (in the very best of cases 8 or 9 years), the actual life time of a patent is quite short.

A final issue related to environmental taxes. It was specifically mentioned that taxes at the same level as in Denmark (a level ranging from 37 per cent) is really heavy and complicated in administrative terms. In the first place it was argued that there is no need to load any taxes on pesticides (since farmers do not apply larger quantities than necessary), and secondly it was felt that tax revenues should be rebated to farmers[4].

4.2.1 The EU moratorium on biotechnology

Bayer expected the current popular resistance to biotechnology to disappear, which would remove the political basis for the EU moratorium on biotechnology. Two arguments were advanced.

Bayer distinguished between 'red' (pharmaceutical) and 'green' (agricultural) biotechnogy. The interviewees expected red biotechnology to pave the way for agricultural biotechnology.

> "RS: If someone reduces the stroke rate by 30 per cent or whatever – nobody will ask: is it biotech? "

Secondly, it was argued that the shift of focus towards improving output traits (rather than input traits such as herbidice-resistance) would enhance consumer acceptance.

> PK: "Right now the consumer does not see the benefit of a herbicide-tolerant crop or a insect-resistant crop. If he could choose, he would rather do without a technology he does not understand. If, however, there was a dietary value, that would shift his position."

The emphasis placed on input traits so far was not seen as a strategic mistake, however.

> PK: It was not a question of making a strategic mistake. In the beginning of biotech, companies looked for traits where they were able to transfer them - small units of proteins, which was simple. Output trait improvements are much more complicated. They started with the easy aspects of biotechnology, for they could not handle the output traits in the beginning."

The interviewees were basically in favour of labelling genetically modified food products to allow consumers the freedom to make their own choice.

4.3 The CAP reform

One of the major policy changes affecting European agriculture is the gradual reform of the Common Agricultural Policy. As described in Chapter 7 of the report on *European Union Policies on Agrochemicals, Biotechnology and Seeds*, agricultural support is increasingly decoupled from production and oriented towards environmental protection and rural development.

> JH: As concerns the reform of the CAP we expect farmers to be paid more and more for environmental value – for keeping a certain length of hedges or for keeping a biotope. This is a development which we cannot judge at the moment, but which we have to observe. What we clearly see is that farmers will have to apply good agricultural practices in order to be eligible for subsidies … Farmers

[4] It has been argued that paying the tax revenues back would have no effect on the demand for pesticides, since farmers could just spend the rebated tax on pesticides. This is not quite correct, however, unless the rebate is linked with the purchases made by the individual farmer. A tax rebate based on acreage, for example, would still give the farmer a stronger incentive to economise on the use of pesticides.

> applying the principles of integrated crop management – of which the good plant protection practices are elements – should be entitled to a higher level of support. This would fit very well into our policy, but at this moment of our time we are not sure about the outcome."

Bayer would strongly oppose a policy of supporting farmers for not applying chemicals, however. Such a policy was not thought to be viable in the long-term "because the farmer has to compete in the market-place and has to produce not only yield but quality. And we do not think production without chemicals will be possible for us in Europe."

4.4 Intellectual property rights.

There were only a very few remarks on this issue. Intellectual property rights differ considerably across the world, and it was mentioned, for example, that "in Latin America there is hardly any exclusivity, and domestic producers are free to copy our products and may even get a registration."

Bayer does not expect to have exclusivity for ever, "but we would definitely want to extend the period of protection".

4.5 Concluding remarks on policy influences

To sum up, the policies of science, technology and innovation and the EU moratorium on biotechnology were felt to be of only marginal relevance to Bayer. When asked which policy area was seen as most important, the interviewees mentioned "the increasing requirements and the avoidance of any risk, which means that authorities are very eager to add risk factors, but these are not based on science." The administrative delays due to the approval procedure was similarly seen as an important problem.

There was still some uncertainty concerning the consequences of reform of CAP, but Bayer would welcome a policy supporting integrated crop management.

5. Environmental Discourse

As mentioned above, the strategic vision of Bayer – like that of many other large companies within the agribusiness industry – is one of 'feeding the world'. Moreover, production has to be environmentally sustainable, and production cannot be increased by simply expanding the agricultural area: In Bayer's view the only possibility of boosting productivity on a sustainable basis lies in integrated crop management:

> "The use of highly intensive agricultural methods must ... be expanded above all in the countries where most of the world's food is grown today. This means good technical practice combined with all possible modern techniques, such as the planting of high-yield varieties, the use of special fertilizers, chemical crop protection within the framework of integrated crop management, and application of biotechnological methods".

At *The Agricultural Centre Monheim* there are two institutes studying the effects of crop agrochemicals on the environment (The Institute of Metabolism Research and Residue Analysis and the Institute of Environmental Biology).

In 1998 the Bayer group became a member of the World Business Council for Sustainable Development. This organisation comprises 120 major companies from 35 countries who are campaigning for sustainable development.

This initiative is known as the *Responsible Care Initiative*, which "obligates Bayer to operate a management system that, of its own accord, sets, reviews and continues to develop targets for improvement in the areas of product stewardship, environmental protection, plant safety, hazard prevention, occupational safety, and health." (Bayer, *Responsible Care Report 1999:* p. 8).

An integrated management system – so-called HSE management, HSE being short for Health, Safety and Environment – has been under development since 1998. The management system defines guidelines on "15 different elements, including plant safety, environmental protection and product stewardship as well as leadership, training, organisational culture and behaviour management, producerement and services, communications and emergency preparedness."

In an interview with Dr. Attila Molnar, who is responsible for safety and environmental protection on the Board of Management, it is explained that

> "The formula for success is ... in-process environmental protection. In the past, we used to talk primarily of add-on environmental protection, in other words disposing all the residues at the "end of the pipe". At that time, many people regarded environmental protection purely as a job of waste disposal. Yet the problems associated with this have long since been solved, and our goal is to take the necessary precautions in advance rather than have to clear up the mess afterwards. In other words, we have been directing our attention for many years not only at what comes out as undesirable waste at the end of the production processes, but on the processes themselves. Our research teams and process engineers have a clear mandate to minimise the amount of undesirable by-products generated during the production phase. In an ideal case such by-products would be avoided altogether or be entirely recyclable."
>
> (Dr. Attila Molnar, Responsible Care Report 1999, p. 10)

The notion of recyclability is key to most perceptions of sustainability. Waste which cannot be recycled (either in terms of entering into a new round of production or in terms of being biodegradable so as to 'return to nature') has to pile up higher and higher. This process may eventually deplete natural resources used in the production process and lead to ever higher concentrations of harmful substances.

While this line of argument has led advocates of the organic movement to completely dismiss the use of chemicals as being unsustainable by definition, Bayer stressed the possibility – and necessity – of using agrochemicals responsibly. In order to reconcile the need for higher productivity with environmental sustainability, it will be necessary to apply a broad range of technologies, as illustrated in Figure 5.1 which sums up the line of argument.

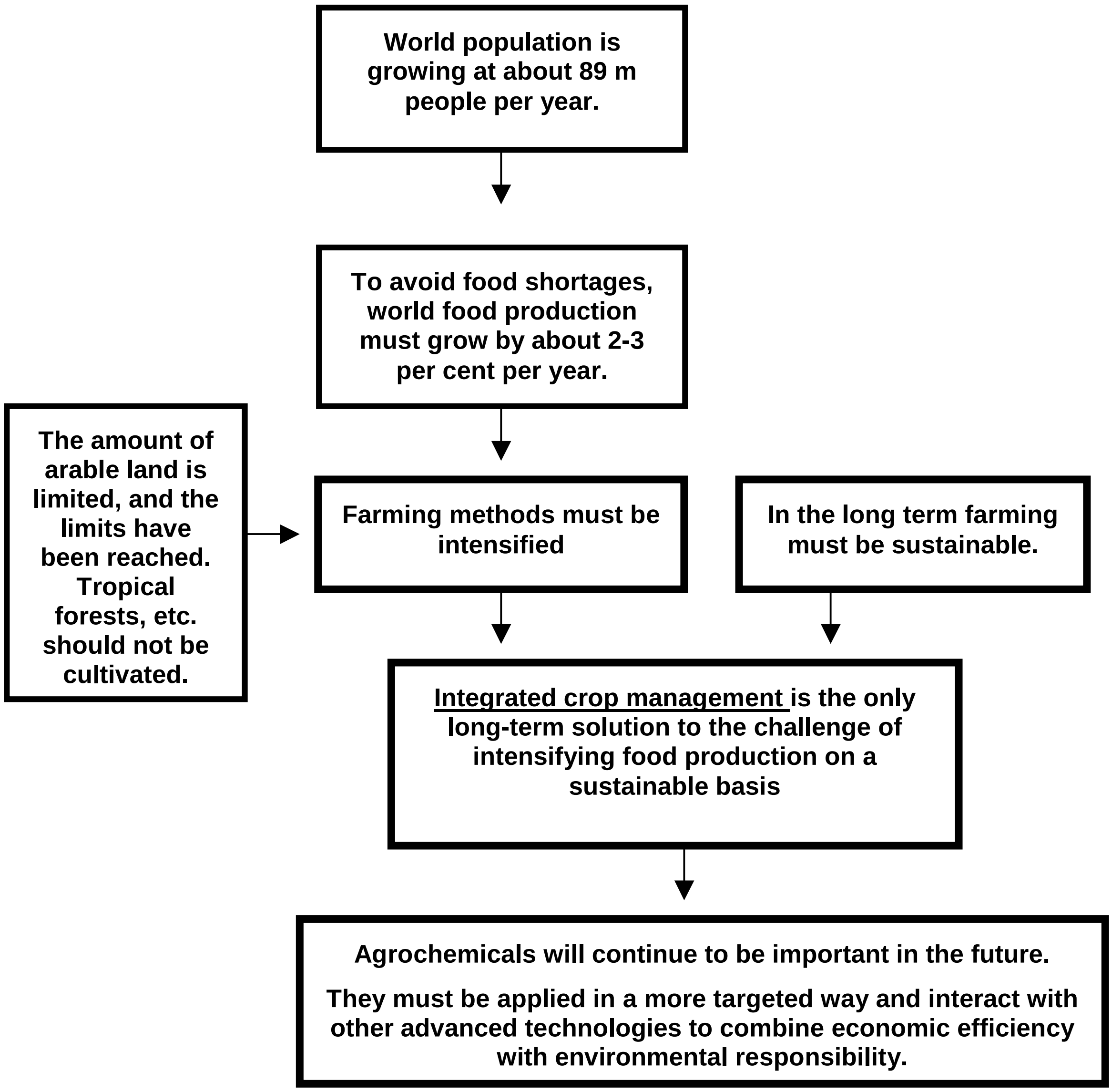

Figure 5.1 Environmental Discourse at Bayer

The agrochemical industry may contribute to this by developing chemicals which are less toxic, which can be applied in a more targeted way (as with the seed dressing technology, for example), or which could be combined with biotechnological crop protection to improve the efficiency of plant protection while reducing its environmental impact.

6. Conclusions

During the postwar period agrochemical industry has been developing a technological trajectory which has contributed enormously to the modernisation and productivity growth of European agriculture. With the increasing awareness of environmental problems, especially since the 1970s, agrochemical industry has come under pressure to improve its environmental performance (and image). Environmental concerns relating to the use of chemicals have spurred the development of organic farming in many countries, but the additional costs of producing entirely without chemicals have prevented the organic sector from seriously challenging the agrochemical industry on a commercial basis. The development of agricultural biotechnology during the 1980s and 1990s was seen by many as a promising alternative to the use of chemicals and is occasionally still heralded to be the future alternative to agrochemicals.

The present monograph presents the views and long-term perspectives of a company with serious stakes in this development. With its solid position in agrochemicals, Bayer obviously has a vested interest in protecting its investments. Yet, it should be clear from the above that the time perspective of an agrochemical company is so long – and the investments in research and development so substantial – that it would be commercially senseless to continue to invest on this scale if these investments were doomed *a priori*.

Bayer's strategy is based on the premise that the growing demand for food and the very limited possibilities for increasing arable land will necessitate a further intensification of food production on an environmentally sustainable basis. The company's analysis of the prospects for biotechnology suggests that biotechnology – and especially output trait biotechnology – will be of growing importance. It does not suggest, however, that biotechnology will ultimately outperform agrochemicals for crop protection. On the contrary, by adding to the economic value of seeds this new range of technologies are expected to add to the economic incentives of farmers to protect their seeds.

The development of seed dressing technology was the main example in Bayer of a technological trajectory (or sub-trajectory) which could give agrochemical crop protection a new and more interactive role in crop protection in the future. This technology allows the application of agrochemicals in lower doses than the ones applied using conventional spraying technology.

Not surprisingly, the strongest policy impact on R & D appeared to emanate from environmental regulation. From Bayer's perspective there was a need to qualify the use of the precautonary principle, to speed of the process of approval, and to support the harmonisation of environmental regulation at EU level. Also, the use of time frames to allow companies to develop alternatives to those compounds which would no longer be acceptable, was seen as essential.

7. List of interviewees

Dr.Rüdiger Scheitza, Senior Vice President, Bayer AG Crop Protection Group

Martin Petersen, Leader of Business Planning and Administration

Dr. Peter Kraus, Head of Regulatory Affairs.

Jürgen Hartmann, Information and Communication Europe

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