ANNEX B1

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

An Integrated Analysis of Government Policies Influencing Innovation in the Agro-chemical, Biotechnology and Seed Industries

Objective I Report

Annex B 1

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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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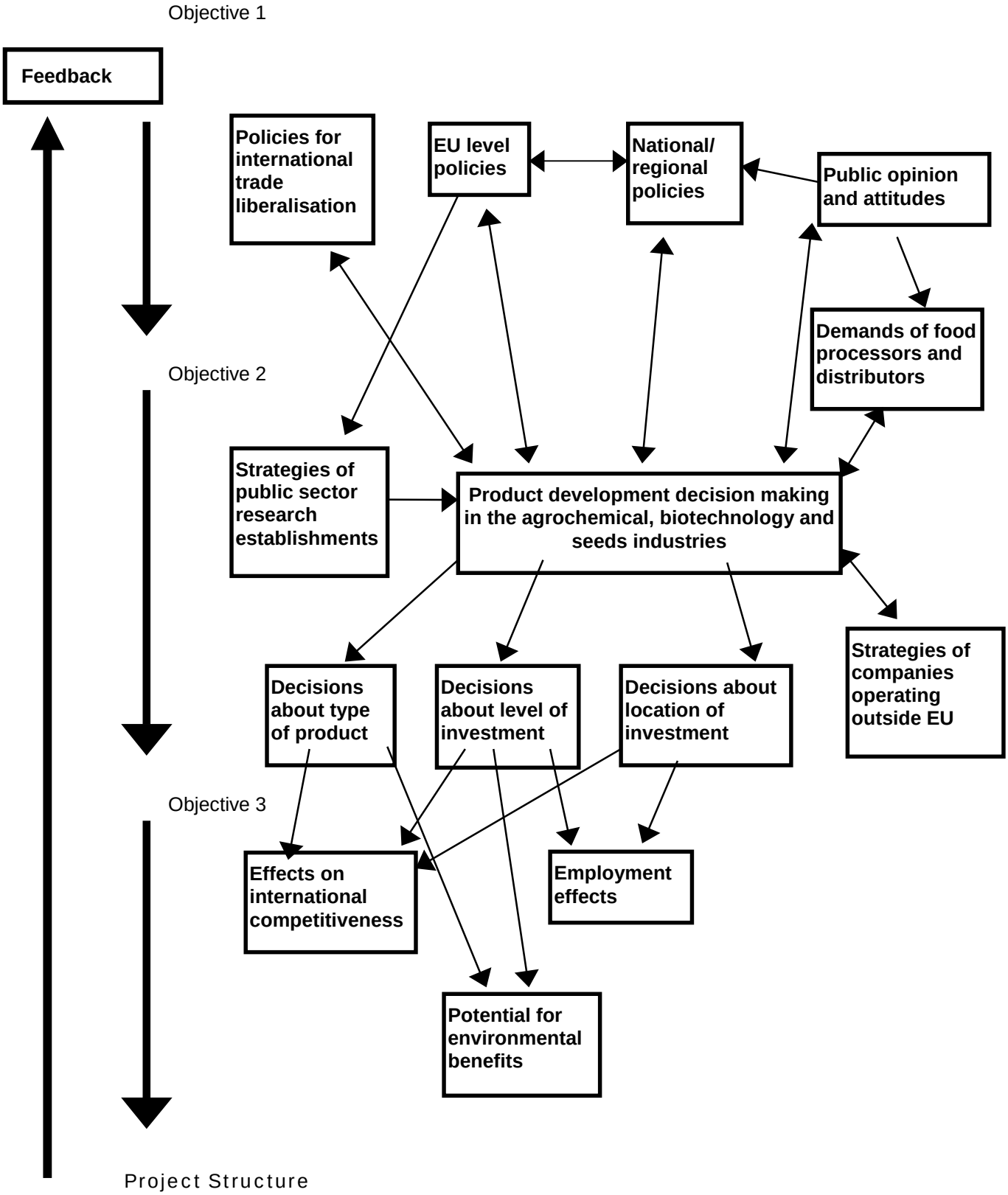
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1. Introduction

Technological innovation in the agrochemical, biotechnology and seeds sectors is the result of an intricate interaction among market opportunities, technological opportunities, firm strategies, and government policies. This paper focuses on how government policies influence market and technological opportunities for the agrochemical, biotechnology and seeds industries. In essence, the development of new seeds and new pesticides is the outcome of the combined effect of market (or pull) factors, technology (or push) factors and state regulation of these factors.

This paper is part of the outcome of the project **Policy Influences on Technology for Agriculture** (PITA). Objective 1 of the PITA project stated the following aims: *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.*

An integrated analysis of government policies and market-related factors serves two main goals. First, to assess how policies relevant to technological innovation in the agrochemical, biotechnology and seeds sectors interact, and how this interaction subsequently influences the impact of the individual policies on innovation. Second, to develop hypotheses about the impact of government policies on strategic decision making for technological innovation in industry and PSREs. A third goal is an assessment of the interaction between government policies and market-related factors in influencing technological innovation in the three industry sectors.

This paper is based on national and EU policy reports[1], which describe and discuss the goals and instruments of the three policy areas mentioned above, for the EU as a whole and for the following countries individually: Denmark, France, Germany, the Netherlands, Spain and the United Kingdom. As these reports were written in 1998, the information was updated for this paper where appropriate.

This paper is structured as follows. In section 2 we will discuss what is meant by an integrated analysis and present four different perspectives. In section 3 we will describe and discuss the main trends in science, technology and innovation policies in the European Union. In section 4 we will do the same for environment, public health and biodiversity policies, and in section 5 for farm support and international trade policies. Next, in section 6, we will discuss some developments in the food processing and food retail industries, as strategic choices by these industries are increasingly important for innovation decisions by companies in the agrochemical, biotechnology and seed industries. Finally, in section 7, we will present potential impacts of policies (individually and in combination) on innovation. Here, the interactions among various policies and between policies and market-related factors will be assessed in an integrated analysis.

In the remainder of this introductory section we briefly discuss the interaction between government policies, innovation in the agrochemicals, biotechnology and seed industries, and cleaner agricultural systems in Europe. The many questions about how public policies and private innovation choices interact have led to setting up the PITA project.

Seeds and agrochemicals have long been important inputs for intensive agriculture in the EU. Since the 1980s biotechnology products have entered the market, initially as tools for R&D, nowadays also as products to be used in agricultural production. Such biotechnology products may be genetically modified (i.e. transgenic) plants, or devices for measuring the incidence of pests. The use of seeds, agrochemicals and biotechnology products in agriculture has significant environmental impacts. The choice of the crop as well as the choice of the crop variety determines the cultivation methods (e.g. whether irrigation is needed) and the use of plant protection products. Switching from one variety to another may

[1] These reports can be downloaded from the PITA web site: http://www-tec.open.ac.uk/cts/pita.

lead to a change in the use of pesticides (qualitatively and/or quantitatively) and therefore in environmental impact. Depending on the physical circumstances, changes in the environmental impact of intensive farming methods can result from changes in seed (crop variety), the kind of pesticide used and the way pesticides are used. The latter implies changes in the skills and knowledge of the farmer and in equipment.

Innovation in the seeds, agrochemicals and biotechnology industries offers opportunities for the adoption of 'cleaner' agricultural systems in Europe, and the potential to bring social and environmental benefits. Innovation may be induced by technological development, by changes in the market for seeds, agrochemicals and biotechnology or by both. Looking at innovation from an evolutionary perspective, R&D activities provide variation and farmers make up the selection environment. New crop varieties and new plant protection products will only be commercially successful if they yield benefits for the farmer. Thus, economic and technical developments in agricultural production are major determinants of innovation in the seeds, agrochemicals and biotechnology industry. Government policies set the conditions for innovation processes, by supporting R&D, by setting environmental requirements, by stimulating certain types of farming activities, etc.

The PITA project explores the impact of government policies on the development and uptake of environmentally enhanced seeds, agrochemicals and biotechnology products. The first stage of the PITA project involved an assessment of government policies in Denmark, France, the Netherlands, Spain and the UK, as well as EU policies. In the second stage innovation strategies in the seeds, agrochemical and biotechnology industries were studied. By combining the policy perspective and the industry perspective, the PITA project will generate insights into the influence of government policies on the development and dissemination of environmentally enhanced agricultural inputs.

2. Integrated analysis

The development of an integrated analysis of policies and market-related factors is not a simple task as a great number of factors play a role in innovation processes. To facilitate our task, we have distinguished four different perspectives on integrated analysis.

The first perspective deals with the content of the policies. Within the PITA project, we have distinguished and analysed three fields of government policies. Science, technology and innovation (STI) policies are meant to enhance technological knowledge and to promote innovation in private industry and PSREs. Environment, public health and biodiversity policies are meant to protect the natural environment, to protect and improve public health, and to sustain and enhance biodiversity. Farm support and international trade policies are meant to secure a multifunctional, sustainable and competitive agriculture. An integrated analysis will study how policy measures from these three areas interact with each other, and how this interaction influences (e.g., strengthens or weakens) the efficacy of each individual policy.

A second perspective for integrated analysis focuses on the geographical level of policy making and implementation. There are at least three levels of policy making relevant for innovation: regional, national and EU level policies. Particularly in the larger EU Member States in the PITA sample – France, Spain and the UK – regional policies seem to be of growing importance for innovation. Since the introduction of the subsidiarity principle, policy makers in the EU are conscious of choosing the most appropriate geographical level for deciding on and implementating government policies. An additional reason for explicitly giving attention to regional decision making is the increasing attention of the EU on rural development, regional differences in economic development, environmental vulnerability and nature values. An integrated analysis would study the interaction between policies and market-related factors at the various geographical levels, that is at regional, national and EU level.

A third perspective for integrated analysis deals with policy effects on the development and use of agrochemicals and seeds, where innovation process can be conceptualised as a chain of activities: R&D, registration, production, distribution, and use (Figure 1). Even though

innovation in reality is an iterative process, it can be useful to distinguish the various activities that have to be carried out before a new product is successfully developed and commercialised, as well as the various actors that carry out these activities. STI-policies are particularly relevant for the research and development stage. Farm support and international trade policies primarily affect the use of seeds and pesticides. Environment, biodiversity and public health policies are relevant for all stages of the innovation process, with emphasis on testing, registration and use. Different activities in the production and distribution chain are carried out by different companies. R&D, registration and production is primarily done by agrochemical companies and seed companies, often large companies working on a Europe-wide or world-wide scale. Distribution is done by producers, or by independent retailers of seeds and/or pesticides. Finally, farmers are the users of crop protection products and seeds. An integrated analysis describes which policies are most influential at the various stages of the production and distribution chain, and studies the combined impact of the various policies on actors and activities.

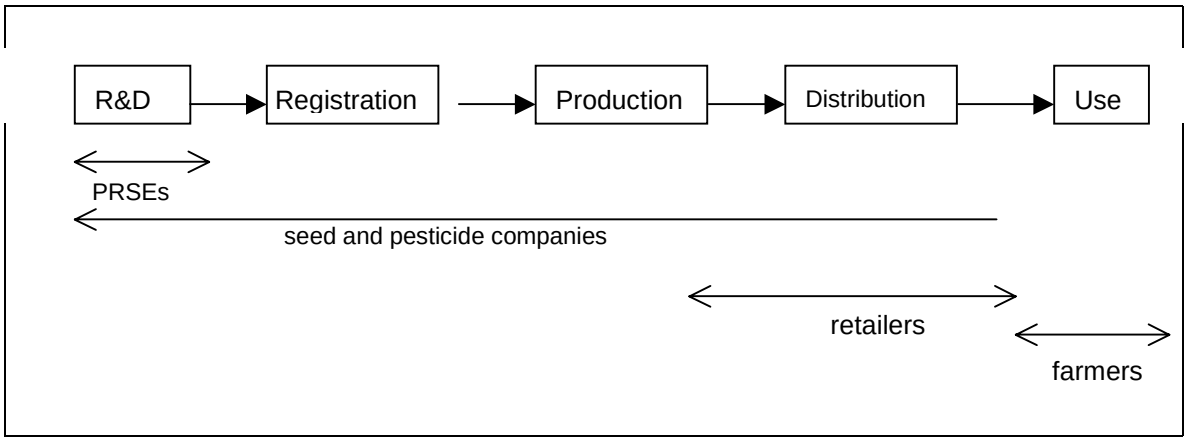

Figure 1 Production/distribution chain for seeds and agrochemicals

A fourth perspective for integrated analysis is the interaction between government policies and market-related factors. Seeds and pesticides are primarily developed, produced and used by private firms pursuing the economic goals of income and profit generation. A major driver for private activities is market opportunity. Government policies affect market opportunities, by creating and reinforcing them, or by redirecting and restraining them. The integrated analysis studies how government policies interact with new market opportunities, in an enabling or constraining way.

An integrated analysis of policies and their impacts will take into account all four interactions. In the last section of this paper we will present the interactions, but first we will discuss the three policy areas individually.

3. Science, technology and innovation policies

Science, Technology and Innovation (STI) policies enable and promote scientific inquiry, technological research and the uptake of new technological opportunities by industry. Indirect goals of STI policies are the strengthening of the competitiveness of industry and the enhancement of the quality of life. The instruments used in implementing STI policies are direct government funding of PSREs, (universities and agricultural research institutes), and subsidising R&D activities of private industry. Also, information transfer is used as a policy instrument, in formal education, publications, extension and advisory services.

The R&D stage of the innovation chain consists of fundamental research, applied research and development activities. Although large companies, particularly those in agrochemicals, carry out basic research themselves, still most of this kind of research is done by PSREs like universities and large technology institutes. Applied research is carried out by PSREs as well

as by private industry. Most of development work is done by the individual companies, or by public and private research centres with industry funding.

Five developments are relevant for technological innovation in the agrochemical, biotechnology and seeds industries.: intellectual property rights, special support programmes for biotechnology research, support for small biotechnology companies, special R&D programmes for crop protection, and restructuring of public agricultural research.

The pharmaceutical, chemical and biotechnology industry (including seed companies with biotechnology research) have long lobbied for strengthening intellectual property protection of biotechnology in Europe. They claimed that better protection of the biotechnology inventions was needed to provide sufficient incentives for investing resources in both fundamental and applied biotechnology research. They also claimed that protection in the EU was lower than in the USA, leading to a competitive disadvantage for the European biotechnology industry. However, an EU proposal for strengthening legal protection met with broad opposition, particularly in the European Parliament. Opponents criticised the ethical implications of genetic engineering and the appropriation of life forms by monopolistic corporations. After ten year of debate, in which the European Parliament played a major role, the European Directive on the Legal Protection of Biotechnology Inventions (Directive 98/44/EEC) was approved in May 1998.

The Directive seems to be a key tool to secure biotechnology investment in Europe and also to achieve the objective of harmonisation of the European market. As such, it may contribute to reducing the technological gap between US and European companies (Joly and De Looze, 1996). However, controversies and uncertainties remain. First, there continues to be a debate on the economic efficiency of a patent system for protecting and promoting biotechnology research. Second, the agricultural and seed industries are uncertain over the effects of patenting genes on the free circulation of genetic resources. Will compulsory licences sufficiently address the problem of access? Third, national opposition has lead to unwillingness of some Member States to implement the Directive.

Since the early 1980s, promotion of fundamental and applied biotechnology research has been one of the specific targets of STI policies, both at the EU and the national level. Biotechnology was considered a key technology (together with information technology and new materials) that would form the foundation for new economic growth. Adherents of the theory of long waves in economic development –Kondratieff waves - stressed the importance of new technologies for new business opportunities and thus income and employment generation (Freeman and Perez, 1988). While in the 1980s promoting of biotechnology focussed on fundamental research, in the 1990s more attention was given to the transfer of knowledge from PSREs to private industry, to commercialise the scientific expertise. Governmental technology programmes have put more emphasis on the transfer of basic knowledge into technological innovation. The ultimate goal was to stimulate the international competitiveness of national and European industry.

Private industry has been strongly involved in decision making on biotechnology support programmes. Particularly large national so-called ‘technology champions’ like Rhône-Poulenc in France, Gist-brocades in the Netherlands, Zeneca in the UK and Novo Nordisk in Denmark, have advised government officials on setting up biotechnology policies. However, both policy makers and industry managers continue to complain about the gap between public research and private R&D, and the lack of collaboration. In most countries ministries of economic affairs have set up special programmes to bring people from industry, academia and government together, to identify trends and opportunities and to guide research that supports the competitiveness of the domestic industry (e.g. foresight in the UK).

A special instrument of STI policies has been financial support for small dedicated biotechnology firms, based on the idea that small biotech companies would be the fastest way to turn scientific knowledge into commercially viable new products and processes. In line with the general idea that small and medium-sized companies account for the largest share of employment creation, it was expected that small biotechnology firms would generate a substantial number of new, high quality jobs. Most European countries continue to have special subsidy programmes for small dedicated biotechnology programme, but most of the

new companies are working in the area of human health biotechnology and not in the area of inputs for agriculture (Chataway and Tait, 1993).

During two decades of biotechnology support programmes, growing attention has been given to the socio-economic aspects of developing and applying biotechnology products. National and EU STI programmes increasingly make funds available for research on factors that influence the commercial success of biotechnology, like public acceptance, approval policies and intellectual property rights. In EU R&D programmes, special subprogrammes for socio-economic impact studies have been organised.

While biotechnology has received large government funding, there are hardly any STI programmes specially for seeds and pesticides. Research on plant breeding and plant reproduction is carried out at agricultural universities and agricultural research institutes. Development of new plant varieties is primarily the responsibility of private companies. Since 1990, France has had a special programme to facilitate the transfer of (bio)technology from public research institutes to private seed companies. This *contract de branche* programme has stimulated collaboration of public research institutes like INRA with various private plant breeders. In the Netherlands, the Organisation for Scientific Research has a S&T programme for fundamental and applied research on plant protection. The absence of special programmes for seeds and pesticides does not mean that the seed and agrochemical industries are excluded from national and EU R&D funding. Many companies are involved in biology and chemistry R&D programmes that aim at developing fundamental insights relevant for crop breeding and crop protection.

With the share of agriculture in the economy steadily declining, greater public attention on environmental impacts of intensive agriculture and the loss of political support for the agricultural sector as a whole, government funding of agricultural research has been steady or declining in most countries except Spain. As a result, public research institutes have been privatised or have expanded contract research for private industry and this has raised the question whether they can still be considered as ‘public’ institutes, and whether their research agenda is targeted at public or private interests. The reorganisation of agricultural research in the 1990s has lead some agricultural PSREs to focus more on basic and strategic research and less on development research. For the seeds sector this has meant that seed companies have to do a larger part of the R&D effort themselves, requiring a larger commercial base. Thus, government retreat from agricultural research has contributed to consolidation and specialisation in the seed industry.

4. Environment, public health and biodiversity policies

Numerous policies that deal with the protection of human health, the environment and biodiversity are relevant for technological innovation in the agrochemical, biotechnology and seed industries. Here we focus on pesticide and GMO regulation.

The precautionary principle (PP) is now the leading concept regulation for the protection of the environment, human, animal and plant health and it will be invoked for all safety assessments of new pesticides and GMOs. Some EU Member States already used the PP for regulation on environment and food safety issues. At the EU level, the PP was used particularly for environmental protection. For instance, in Directive 90/220/EEC on the deliberate release of GMOs into the environment, a case by case approach was used, requiring a separate risk assessment for each product application. Because many uncertainties remained about its scope, particularly in food safety issues of GMO crops, the European Commission has published guidelines for using the PP (CEC, 2000a). The PP, as part of a risk management strategy, covers cases where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU.

Measures based on PP (CEC, 2000) must be:

- proportional to the chosen level of protection;
- non-discriminatory in their application;
- consistent with similar measures already taken;
- based on an examination of the potential benefits and costs of action or lack of action;
- subject to review in the light of new scientific data; and
- capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

This clarification of the Commission's interpretation of the PP will be very helpful to regulators but seems unlikely to meet the expectations of environmental pressure groups (Greenpeace, 2000). Also the clear reservation of the rights of the EU to unilaterally set more stringent standards for its territory could presumably be challenge under WTO rules.

Pesticides

The main goals of pesticide policies are the protection of human health (of industry workers, farmers and consumers) and the protection of the natural environment from pollution by producing and using pesticides. Consumers are protected by setting maximum residue standards. They are also protected from pesticides and their residues through water quality policies, like maximum levels of pollution in drinking water supplies.

Governments that want to influence the use of pesticides can use three categories of policy instrument (Vedung, 1998): regulation, economic instruments and information. Regulations are measures undertaken by governmental units to influence people by means of formulated rules and directives which mandate receivers to act in accordance with what is ordered in these rules and directives. Economic policy instruments involve either the handing out or the taking away of material resources, be they in cash or in kind. And information includes attempts to influence people through the transfer of knowledge, the communication of reasoned argument and persuasion. Instruments in pesticide policies in the EU are primarily regulation, along with some information. Economic instruments are rare; only some Member States use them, notably Denmark.

Pesticide registration in the EU is now a combined responsibility of the European Commission and national governments. EU Pesticide Directive 91/414 requires that all new active substances (introduced after 25 July 1993) have to be approved by the European Commission. Only after an active ingredient is put on the positive list, can it be used in plant protection products in the EU. Also, all active substances that were introduced before 25 July 1993 have to be re-examined and have to enter the positive list to be allowed to be used after 2003. Once an active ingredient is registered in the EU, national authorities can register the actual plant protection product for particular crops and modes of application. In this national approval process Uniform Principles, established under Directive 91/414, have to used. Once a plant protection product is registered in one Member State, other Member States have to grant registration on the basis of the original approval. However, each Member State maintains the right to set additional requirements for use, for instance relating to the vulnerability of some agro-ecological areas.

Re-examination of the 800 old active substances has been slow, due to difficulties in designing clear criteria for examination, as well as difficulties in decision making among all Member States about criteria and procedures. Major problems are the lack of agreed indicators by which the potential environmental harm from individual pesticides can be judged and administrative problems at EU and national levels. By early 2000, only 2 active ingredients had entered the positive list and 10 had been rejected (Nefyto Bulletin, March 2000).

Two recent developments are expected to speed up the re-examination process. Regulation (EC) 451/2000 contains detailed prescriptions on how to carry out the re-examination process, which criteria to use, which procedures to follow and by which date individual active substances have to be re-examined (or which date the re-examination has to be started by presenting a full dossier). Another development that should speed up the re-evaluation of process is restructuring of tasks among the EU Directorates-General and the greater role of DG Health and Consumer Protection (SANCO, by its French name). SANCO is now responsible for the re-examination of active substances. Previously, DG Agriculture, was not effective in speeding up the process. Given the recent food safety crises, the European Commission has stepped up its efforts to protect the consumer, as well the environment.

Traditionally, Northern European countries had a more stringent regulation of plant protection products. For instance, Denmark and the Netherlands have adopted formal pesticide use reduction plans: the 1987 Pesticide Action Plan in Denmark and the 1990 Multi-Year Crop Protection Plan in the Netherlands. The Dutch plan has three goals: reduction of dependence on chemical methods, reduction of the use of chemical methods, and reduction of emissions to the environment. These programmes also contain provisions for the re-approval of all (Denmark) or some (the Netherlands) currently used pesticides. Results of these programmes are mixed. Reduction in the use of pesticides in quantity terms has often been reached, sometimes just by substituting low dose for high dose products. Emissions to the environment have been reduced for some pesticides, but not for others. And generally, the dependence on chemical methods has not been reduced. Not reaching the goals for the Pesticide Action Plan was reason for the Danish government to implement a tax levy on pesticides. Since 1996, there is a 15 per cent levy on herbicides and fungicides and a 37 per cent levy on insecticides and soil disinfectants.

Besides the formal registration procedures, all countries have implemented policies to encourage farmers to reduce pesticide use (Oppenheimer, Wolff & Donnelly, 1996). These policies include extension and teaching programmes to improve farmer knowledge of pesticides and pesticide use, support for development of innovative plant protection techniques, encouraging the fine tuning and maintenance of spraying equipment, and support for research on integrated pest management

A recurrent theme in discussions on how public policies can support sustainable development, public health and biodiversity is the need for better indicators. The development of indicators of sustainable development, including effects of pesticide use, is needed for measuring the environmental impact of farming methods (OECD, 1997). Such indicators can be used by farmers to select appropriate pesticides, by policy makers to target cross-compliance measures, by food processors and retailers in setting quality standards for the raw materials they purchase, and by producers of plant protection products to substitute newer, less polluting products for old, heavily polluting substances.

In recent years, governments have stepped up their attention to water quality as a response to pressures from environmental organisations and from producers of drinking waters. Although EU and national standards for water quality are becoming more strict, there is also a clear regional element in policies for protecting water supplies. Because of major variation in natural condition among regions, regional policy makers have designed environmental policies attuned to conditions in the specific region.

Policies to protect human and environmental health have become stricter over the years. Most deal with the effects of using pesticides, although regulation of manufacturing and distribution has also been tightened. More stringent regulation has made developing new plant protection products more expensive. Higher costs for developing new plant protection products reinforces the trend towards consolidation in the agrochemical industry as companies need a larger scale to be able to recoup the investment in R&D and the costs of registration and testing of new products. However, according to Tait and Williams (1999), risk regulation has largely been beneficial to industry, particularly to multinational companies. It has opened up markets for new high value added products when older, off-patent products are banned. Compliance with regulations absolves companies from liability that could otherwise result from product defects. And competition may have been eased as the high

financial cost and considerable knowledge resource required to comply with regulations has created a barrier to entry.

The development and use of pesticides is not only influenced by pesticide registration policies, but also by other policies at the EU and national levels (Oskam et al., 1998). The Fifth European Environmental Action Plan, launched by the EU, states a reduction in chemical use as a major objective, although no actual aims or limits are defined and currently Member States are largely free to address their own priorities. The only EU-wide action taken so far that could reduce pesticide use is agricultural policy reform.

GMOs

The goals of EU policies regulating the introduction of genetically modified organisms (GMOs) are to protect the health of EU citizens, to protect the environment, and to create a unified market for biotechnology (CEC, 2000b). The main instrument for giving consent to experimental releases and for placing on the market of GMOs is Directive 90/220/EEC on the deliberate release of GMOs. This horizontal Directive complements specialised vertical sectoral legislation like the Regulation on novel foods and novel food ingredients (Regulation (EC) 258/97). The latter sets out rules for authorisation and labelling of GMO derived food products and other novel foods.

In recent years, particularly after 1997 when protest against GMO crops and foods erupted EU wide, Directive 90/220 has received increasing criticism (Von Schomberg, 1998; Open University, 2000). Major elements of criticism include the lack of efficiency and transparency in the decision-making procedures, the lack of requirements on labelling, traceability and monitoring of approved organisms, and the absence of guidelines for risk assessment. Also the limited notion of environmental and health effects lead to dissatisfaction, particularly among environmental NGOs, but also among some Member States. As a result, national interpretations of agri-environmental effects and sustainable agriculture were used. As these aspects bear upon how national Ministries apply the precautionary principle, it often lead to conflicts within and across Member States, and thus to long delays in the approval process. Member States have objected to applications for placing GMO products on the market for several reasons, including health concerns about the use of antibiotic market genes and concerns over the suitability of herbicide resistance in sustainable agriculture.

Since October 1998, no GMOs have been approved for commercial release in the EU, while there are currently (as of July 2000) 14 applications pending approval at various stages in the procedure (CEC, 2000b). These applications are either still being evaluated by the respective scientific committee or discussed in the Regulatory Committee (which is composed of Member States and decides by qualified majority vote). Some Member States have invoked the Article 16 ‘safety clause’ of Directive 90/220 to temporarily ban the placing on the market of GMOs. In June 1999, Environmental ministers from Denmark, Greece, France, Italy, and Luxembourg agreed to block any new authorisation for GMOs in the EU until the European Commission brings forward rules that ensure labelling and traceability. This implies that until the revision of Directive 90/220, there is a *de facto* moratorium on GMOs in the EU.

In February 1998, the European Commission presented a proposal for a revised Directive 90/220. This proposal was amended after the first reading in the European Parliament in February 1999. In December 1999, the European Council reached a political agreement (the Common Position) on the nature of the revision. The most significant differences from the existing Directive are its insistence on the labelling and traceability of products, the monitoring of releases, and the imposition of a time limit on consents given. Also, the decision making process between the Member States is improved by further harmonisation of risk assessment standards. The Common Position passed the second reading in the European Parliament in April 2000, with 29 amendments. Now, Parliament and Council have to find a compromise. Even if they come to a decision soon, it would take at least until Spring 2002 before a revised Directive 90/220 comes into force, as it has to be implemented in national legislation.

In the meantime, the European Commission is attempting to lift the *de facto* moratorium by presenting a "proactive approach" (Hodgson, 2000). This means that all new applications for GMO products are authorised in line with the revised Directive 90/220. The Commission also aims to ensure that applications pending approval and those that have already received authorisation under the existing 90/220 rules meet the new requirements.

The laborious decision making process in the EU on biotechnology issues can be explained by political pressures on parliaments and governments from two conflicting directions: on the one hand pressure from environmental and consumer NGOs to restrict the introduction (for some even the development) of GMOs, in combination with low public confidence in GMO products (see section 6 below); on the other hand pressure from industry to support innovation (by letting biotechnology companies commercialise their products) and to support trade liberalisation (by enabling the import of GMO food and feed products).

5. Farm support and international trade policies

Farm support

In the 1990s, the goals of the Common Agricultural Policy (CAP) of the EU were broadened and new instruments introduced. Previously, the CAP concentrated on the goals set out in Article 39 of the Treaty of Rome: securing a fair standard of living for the agricultural community and ensuring security of supply at affordable prices. In implementing these goals, the EU has been managing internal markets for many agricultural products, particularly cereals, milk and beef by establishing guaranteed internal prices above world market prices. As a result, import restrictions had to be put in place and export subsidies were made available for products in excess of internal consumption. Since the early 1990s, a new approach has been taken in the CAP by lowering institutional prices and making compensatory payments. These measures were partly a response to international pressure to reduce world market distortions.

From targeting farmers and food production, the CAP has been broadened to focus on integrated rural development and Agenda 2000 decisions have institutionalised the new goals of the CAP (European Union, 2000). The 1999 Berlin European Council affirmed that the content of CAP reform would be to secure a multifunctional, sustainable and competitive agriculture throughout Europe: to maintain landscape and countryside, make a key contribution to the vitality of rural communities and respond to consumer concerns and demands regarding food quality and safety, environmental protection and animal welfare standards. By lowering institutional prices and making compensatory payments, the EU can achieve several goals at once. First, it increases the competitiveness of European agriculture and strengthens the EU position in the coming WTO round of trade negotiations. Second, it is a step in the direction of CAP reform necessary for the accession of Central and Eastern European countries. Third, it enables Member States to make direct aid payments conditional on compliance with environmental provisions.

With decreasing price support and increasing focus on environmental issues, the national and regional implementation of agricultural policies will show greater differentiation. Nature conservation at local and regional levels requires a decentralised implementation of EU policies. Given the large differences in soil, climate and geography among EU Member States, reform of the CAP leads to a gradual regionalisation of farm policies. Already differences are evident between Member States: in the amount of (additional) funds for nature and landscape, in the environmental conditions for income support and in choosing priorities in agri-environmental measures. In Spain, for instance, measures to solve the problems of drought, erosion and overexploitation of ground water supplies will have much more impact on agriculture than in other countries. At the same time, Spain is emphasising farm modernisation and strengthening competitiveness. In Northern European countries the focus is less on improving productivity, and more on animal rights, landscape and the combination of farming and recreation.

Short term market and policy fluctuations are less relevant to innovation by companies in the agrochemical and seeds industries as they have a lead time for new products of 10 to 15 years. However, the fundamental shift in agricultural policies towards the combined strategy of improving competitiveness (by reduction of institutional prices) and protecting the rural environment is of great importance to these industries. This shift may have major implications for crop production in Europe leading to expansion or reduction of certain crops and in certain regions. These shifts can create market opportunities for the industries supplying agrochemicals and seeds to these farmers. As each crop and production region requires specific seeds and pesticides, expansion of cultivation of a crop beyond traditional cropping areas leads to innovation in the seeds and agrochemical industries. Also policy instruments like cross-compliance and agri-environmental programmes may have an impact on pesticide use as they provide governments with instruments to control the environmental impact of farming methods.

The relationship between the level of internal EU prices and negative environmental effects of EU agriculture is not straightforward. While several authors have stressed that high prices lead to more intensive agriculture and thus to higher use of imports per ha, Brouwer and Van Berkum (1996), in a survey of the literature on this issue, concluded that lower prices have complex implications for the agricultural system and environmental benefits for one aspect may be offset by others. The OECD (1997) has a less reserved opinion on this issue. They state that, in general, “policies that provide income support decoupled from commodity production minimise incentives for additional pesticide use. (...) Commodity, or production-linked programmes can contribute to overproduction, increased pesticide use and resulting negative environmental side effects as they increase output prices and reduce uncertainty” (p. 10).

Falconer and Oskam (2000) have calculated that the 1992 MacSharry reforms of the arable crops regime has lead to a reduction in total EU pesticide use of 3.2%. This percentage is a combination of several effects. The set-aside measure under the MacSharry reforms lead to a reduction in pesticide use of 2.2%. The price reduction under the reforms lead to a 7.5% decrease in pesticide use. Together this is a reduction of 9.7% in pesticide use for arable crops. As the share of arable crops in total pesticide use is around one-third (Brouwer et al, 1994), the total reduction is only about 3.2%. Falconer and Oskam (2000) emphasise that these figures are only rough indications, as there are many uncertainties in methodology and information. However, they have estimated the effect of further reform of the EU arable crops policy as stated in the Agenda 2000 proposals. With a 15% price reduction and (on average) 5% set-aside, implementing Agenda 2000 will reduce total use of pesticides by an estimated 0.8%. Such a change would be very difficult to observe in practice. One reason for the limited reduction of pesticides use is that price decreases and reduction of set-aside (from 15% under ‘MacSharry’ to 5% under Agenda 2000) work in opposite directions. The effect of either component by itself is rather small, and taken together they tend to cancel each other out.

Kleinhans (2000) has analysed the economic and environmental impacts of Agenda 2000.[2] The core of Agenda 2000 for arable crops is a reduction of intervention prices for cereals, decoupled area-based payments and the abolishment of obligatory set-aside. The reduction of intervention prices may induce lower intensities in crop farming. The decoupling of compensation payments will affect the distribution of crops. As a result, set-aside and oilseed production will be reduced in favour of cereals. Moreover, Member States will be allowed to tie compensation payments to environmental conditions (the principle of cross-compliance). Overall, Kleinhans projects a reduction in the use of crop protection products of 2% on cropping areas (excluding set-aside). This change is mainly induced by the substitution of cereals for rape-seed.

The impact of changes in farm support policies on pesticide use seems likely to be small. However, as the shift in set-aside policies have shown, for individual crops and therefore for

[2] The analysis was based on the original 1998 proposals, not on the final decisions. Although the final decisions did not go as far as the proposals, the author claims that the environmental impact for the arable crops will be more or less the same.

individual pesticides, the impact can be more pronounced. For innovation by the agrochemical industry, changes in specific crops may be more important than overall changes.

International trade

In the new WTO round of international trade negotiations, the EU will emphasise and defend the special European model of agriculture based on multifunctional farming. "Multifunctionality is the word we have found in Europe to describe the fundamental link between sustainable agriculture, food safety, territorial balance, maintaining the landscape and the environment" (Dr. Franz Fishler, speech at the 19th European Agricultural Outlook Conference, London, 9-10 March 2000). Although international trade continues to be an important issue for the EU which is the world's largest importer and second largest exporter of agricultural products, it does not favour a fully liberalised farm trade system. Instead, it wants to take into account public concerns for the impact of globalisation on the environment, health, social standards and cultural diversity.

International trade issues relating to GMO products have become much more important in recent years. Multilateral agreements on regulating trade in GMOs may influence the kind of products that can be traded. In addition, differences in regulatory regimes between the European Union and its trading partners may give rise to trade restrictions and conflicts.

Von Schomberg (2000) lists four relevant issues of biotechnology and international trade:

- The Biosafety Protocol (see below).
- The Agreement on Trade Related Intellectual Property Rights (TRIPS) will be crucial for agricultural diversity and may stimulate the use of biotechnological innovation as it provides for protection of intellectual property rights.
- Particular labelling practices may by challenged under the WTO agreement on Technical Barriers to Trade (TBT);
- Trade and environment issues and the WTO Agreement of the Application of Sanitary and Phytosanitary measures (SPS). The SPS agreement is essential for resolving trade conflicts among signatory parties which have the right to choose their own level of sanitary protection but must avoid unjustified barriers to trade.

In January 2000 the Biosafety Protocol, as part of the Convention on Biological Diversity, was concluded (Cosbey and Burgiel, 2000). This Protocol provides for world wide regulation of transboundary movements of living modified organisms (LMOs) that may have adverse effects on biodiversity and human health. It establishes an Advance Informed Agreement procedure for imports of LMOs intended for the introduction into the environment and an alternative procedure for mass movements of LMOs intended for food, feed and processing (commodities). Its sets out a detailed basis for decision making on imports, incorporating the precautionary principle and specific documentation requirements for the movement of all LMOs. The Protocol also contains provisions on confidential information, information sharing, capacity building, and financial resources, with special attention to the situation in developing countries, which lack adequate domestic regulatory systems.

The reference in the Biosafety Protocol to the precautionary principle could help to restore public confidence in the way public authorities deal with GMOs (Von Schomberg, 2000). However, it could also lead to trade conflicts with the USA (and other commodity exporting countries) as they do not favour the invoking of this principle for regulating trade in agricultural commodities. During the negotiations these exporting countries have tried to make the Biosafety Protocol subordinate to the rules of the WTO (which does not accept the precautionary principle). The negotiations were finalised after a compromise had been found which positions the Protocol side by side with other international trade agreements.

6. Developments in the food processing and food retail industry

In understanding the dynamics of developing and marketing new seeds and pesticides, it is not sufficient to look only at the markets for these products. As agricultural production is one of the first stages in the food production and distribution chain, the dynamics of this whole chain have to be taken into account in decision making on innovation in the seeds, agrochemicals and biotechnology industries. Companies in these industries increasingly watch trends in the food industry, food retailing and consumer markets. The innovation chain for agrochemicals and seeds is thus complemented by the chain for producing, distributing and consuming food products (Figure 2).

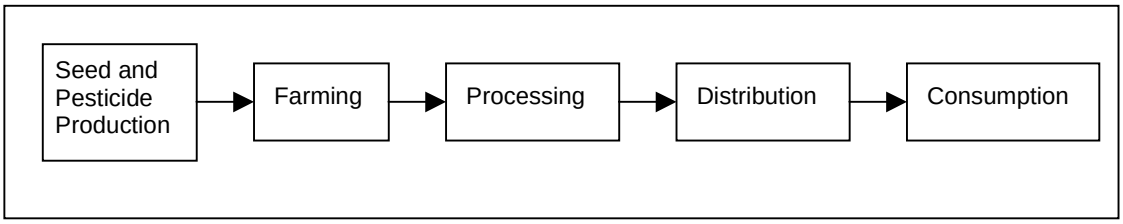

Figure 2 Production and distribution chain for food products

The food production and distribution chain consists of farmers, processors, wholesalers, retailers and consumers. Developments at processing, distribution and consumption stages of the agrifood chain influence decisions by the farmer, and thus, indirectly influence the market prospects for seeds and agrochemicals. If the consumer does not accept genetically modified foods, the farmer will not grow genetically modified crops, and the seed company will not develop genetically modified crop varieties. If a seed company has already developed such varieties in anticipation of favourable public acceptance, the current poor market prospects for transgenic crops may cause the company financial problems. Similarly, if consumers demand more environment friendly agricultural products, farmers will introduce changes in their cultivation practices in order to use fewer or alternative pesticides, or even shift to production systems that do not use pesticides at all. Changing cultivation practices often also bring changes in the crop varieties used by farmers and this is a signal to the seed industry to develop varieties with the required characteristics.

European consumers are demanding higher quality products, more convenience products and more variety in food products (Grunert et al., 1996; Gordon, 1998) and are increasingly concerned about issues like food safety and quality, environmental sustainability and ethically appropriate methods of production (Blandford and Fulponi, 1999). One concern relates to the use of plant protection product in the production and storage of farm products. In the Netherlands, for instance, a survey among 15,000 consumers showed that plant protection products are their third most important concern in relation to food (Consumentengids, September 1999).[3]

Consumer concerns about food safety and quality are the result of a combination of several developments. On the one hand, there is the increasing income and the subsequent decreasing part of income spent on food (“The law of Engel”). As a result, people can afford to purchase more expensive foods (for instance, they consume less cereal products and potatoes and more fruit and vegetables) and to be more critical towards the quality of the food they purchase. In the same line, people want more variety and more convenience. On the other hand, several recent food safety scares (BSE, dioxin, salmonella) have made consumers more aware of the health risk of food consumption. The use of plant protection

[3] Genetically modified food ranks first, and labelling second. The impact of environmental pollution on food quality came fourth.

products and particularly the presence of pesticide residues, is one of the issues that consumers are increasingly concerned about.[4]

In assessing the quality of food products, environmental issues and food safety issues combine. Consumers have a negative perception of plant protection products, both because of (perceived) health effects of residues in food products and because of the (perceived) harmful environmental effects of the production and use of plant protection products. For a large part, the growth of organic production can be explained by the dual concern over the health and environmental impact of the use of plant protection products.

As a result of consumer concerns about health and safety, governments at national and EU level are pressed to implement more stringent regulations, for instance on pesticide use. Food processors and retailers are increasingly paying attention to these consumer concerns and have developed private quality schemes in collaboration with their suppliers, often with strict rules on pesticide use (Brouwer and Bijman, 2000).

Another consumer concern that has a major impact on the choice of farm inputs deals with genetically modified food products. A large and increasing majority of Europeans are worried about transgenic foods. Data from the fourth Eurobarometer survey carried out in November 1999 suggest that Europeans have become increasingly opposed to GMO foods (Gaskel et al. 2000). Between 1996 and 1999, the percentage for respondents supporting GMO foods decreased from 31 to 22, while the percentage of opponents grew from 39 to 53.

In response to decreasing consumer support as well as to pressure from consumer organisations, food processors and food retailers had started to label GMO food products. When this led to blacklisting of products and companies by environmental pressure groups, many food processors decided no longer to use GMO ingredients while food retailers asked their suppliers to leave out all GMO ingredients. Food retailers with a large private label assortment in the top market segments have responded rapidly to consumer concerns. Various retail chains in Europe have formed consortia to develop common practices and criteria regarding inputs, e.g. non-GMO ingredients and lower pesticide use. This co-operative approach has several aims: to maintain consumer confidence in product quality, to establish Europe-wide supply chains which meet common or minimum standards, and to avoid competition for ‘non-GMO’ or low ‘pesticide’ products (for more information on the role of food processors and food retailers, see Levidow, 2000).

7. Potential impacts of policy on innovation

Public policies have diverse impacts on innovation in the agrochemical, biotechnology and seed industries. Government policies set the conditions and the boundaries within which private firms seek to exploit market opportunities and technological capabilities. In every stage of the innovation chain –R&D, registration, production, distribution and use – public policies play a role, either in an enabling or in a constraining way (see PITA Final Report). Moreover, public policies interact with social and economic developments in the food industry, the food retail and food consumption sectors. In this concluding section we will present potential impacts of various state policies as well as trends in the food markets on innovation in the agrochemical, biotechnology and seed industries.

STI Policies

Science, technology and innovation policies are most relevant in the R&D stages of new product development. These policies enhance fundamental and applied knowledge in the field of biology, chemistry, genetics, biotechnology, with the objective to guarantee, in the long run, competitiveness and variation. Also support for applied research and

[4] Product quality is a broad concept with diverse interpretations. While consumers are concerned about the presence of pesticide residues on fresh fruit and vegetables, at the same time they demand products that have a spotless appearance.

implementation of integrated pest management (IPM) methods may indirectly influence innovation, as IPM methods may require different pesticides than are currently available. STI policies relevant to agrochemicals, biotechnology and seeds are faced with the ubiquitous dilemma between supporting fundamental research on the one hand and on the other hand directing government support to research that is induced by short term political demands.

STI policies signal to private industry and PSREs that biotechnology is an important technology and give incentives for investment in biotechnology research. Similarly, strengthening intellectual property rights of biotechnology inventions is intended to lead to more private investment in biotechnology research.

The relative decline in public expenditure on agricultural research has encouraged PSREs to increase the amount of contract research the undertake for private industry with the result that the development of expertise will be more focussed on current and future needs of private clients. As the multinational agrochemical and seed companies are the main users of plant biotechnology expertise, expansion of biotechnology research of PSREs may lead to a stronger focus of PSREs on those companies.

Policies that support the establishment of small, dedicated biotechnology firms are most beneficial for large multinationals in the agrochemical and seed industries. Small, dedicated biotechnology firms target their strategy at the large companies, because they are strongly dependent on the large companies for the commercialisation of their techniques and products or because they hope to be taken over by one of the large companies.

Policies promoting the enhancement of practical knowledge of crop protection strengthen the development of integrated pest management. This may induce the development of new crop protection products to be used within integrated pest management systems. In addition, policies promoting organic farming and integrated crop management strengthen farmer knowledge of crop protection methods, as compared to industry knowledge of agrochemicals. Policies that support farmers in trying and testing new agrochemicals, new seeds, as well as new crop protection methods may speed up the dissemination of these new products and methods. Such policies can use both economic instruments like subsidies and information instruments like public research and extension services.

Pesticide Policies

Environment, public health and biodiversity policies provide protection from the adverse effects of producing and using pesticides and other potentially harmful products and specify maximum acceptable levels of effect on the environment and human health. New products must comply with these requirements. In recent years the requirements have become more strict, reflecting improved knowledge of the health and environmental effects of pesticides as well as greater concern among citizens about their adverse impact. This may lead to the development of fewer plant protection products but with improved safety characteristics.

More stringent regulation of pesticides leads to higher costs in developing, testing and registering a new product. The minimum market size needed to recoup this investment becomes larger and for some small markets (i.e. minor crops) fewer new plant protection products will be available. As only large companies can afford the necessary investment, more stringent pesticide regulation leads to concentration in the crop protection industry and a reduction in the number of companies could lead to fewer innovations.

At the same time, terminating registration for currently used crop protection products – for instance if they no longer comply with environmental impact criteria – may give an incentive for the development of new products. Reduction in the availability of plant protection products (particularly for minor crops) will encourage plant breeders to develop varieties with better pest and disease resistance.

The shift of pesticide registration authority from the national to the EU level may open more markets for specific pesticides, as registration in various countries should become easier and cheaper once EU approval is granted. At the same time, this shift may lead to a slow down in

the introduction of new products if decision making procedures and evaluation criteria are not clear and give rise to controversies among Member States.

Policies setting quantitative limits on use and residues do not provide incentives for structural decrease in pesticide dependence, or for the adoption of alternative pest control methods. However, the development of unambiguous indicators for sustainable development will help farmers to select plant protection products that have lowest adverse environmental impact. It will also help policy makers to target cross-compliance requirements under reformed agricultural policies. This may induce producers of plant protection products to develop more environmentally friendly products.

Policies that require all farms to apply integrated crop management (ICM) methods and to obtain a certificate of compliance may induce agrochemical and seed companies to develop new pesticides and new plant varieties that fit in an ICM system.

The barrier to entry in the pesticides industry presented by strict regulation interacts with public policy to support small biotechnology start-up firms and other SMEs in the plant biotechnology area. Because of the high costs and the considerable time needed for testing and registration of a new biotech product, the only viable strategy for an SME is to make itself attractive for a take-over by a multinational company (Chataway and Tait, 1993). This has at least two implications for innovation (Tait and Williams, 1999). First, the support for SMEs and university spin-off companies in the biotechnology area is *de facto* supporting the development costs of multinational companies. Second, the need for SMEs to make themselves attractive for acquisition seriously constrains their innovation strategies, particularly in agriculture-related areas, restricting them to products that are compatible with strategies of multinational companies, rather than potentially competing with them.

GMO Policies

Throughout the 1990s, European and national government policies have been characterised by two central themes: strengthening innovation and protecting the environment. Both themes were given an institutional foundation in the Treaty of Maastricht (1992). At the end of the 1990s, a third theme has become more prominent: protection of consumer health. The latter development has resulted, among others, in putting the precautionary principle at a centre stage of EU policy making on food safety issues.

Introduction of the precautionary principle in all EU and national regulation of GMOs may prevent political controversies among Member States and thus may minimise delays in approval of GMO products. Introduction of the precautionary principle may also enhance public acceptance of these GMO products and thus give rise to more commercial opportunities for new products.

The two trends of promoting innovation and protecting environment and human health can have opposing impacts on innovation. By supporting innovation in private industry, governments are helping to strengthen the competitiveness of domestic and European industry. Promotion of innovation is a generally accepted instrument of government policy to support private industry. However, more stringent requirements for protection of health and the environment may pose a barrier for certain innovations. This does not mean that it hampers innovation per se; it may close markets for certain products and provide an opportunity for others. As suppliers of the ‘old’ products are not necessarily also producers of the ‘new’ products, some companies can experience negative effects of more stringent regulation.

Unclear and time-consuming registration procedures lead to high costs for developing and registering a GMO variety and only the largest companies can afford these investments. For transgenic crop varieties with herbicide-resistant traits, a strong interaction exists among pesticide registration, GMO-crop approval and seed registration. First, the transgenic variety has to be approved for deliberate release (under Directive 90/220/EEC). Second, a new field crop variety has to be accepted in a national and/or EU catalogue (or list) of varieties. Third, the pesticide has to be approved for use on the particular crop and for a particular application method. These three procedures for approval are not linked in the policy domain, and each

procedure has its own time scale and decisions making structure. As a result, differences can occur between approval schedules under the three procedures.

Farm Support and International Trade Policies

Reduction of price support for agricultural products may lead to lower pesticide use or a shift to cheaper products as farmers cut input costs. Also, set-aside requirements lead to a reduction in land under cultivation and potentially to a reduction in pesticide used. A decreasing market for and profitability of pesticides may lead to a slow down of innovation. Finally, greater support for organic farming will have a similar effect.

A shift in agricultural policies from price support to direct income payments and support for rural development gives governments the opportunity to tie support to environmental performance (cross-compliance). Farmers may be required to apply crop protection methods with fewer adverse effects for the environment. This may hold an incentive for the agrochemical industry to develop new pesticides that are compatible with ICM.

Agricultural support and international trade policies influence production decisions by farmers and thus influence the purchase of pesticides and GMO seeds. Although innovation strategies of seed and pesticide companies do not respond directly to short term changes in farm support and international trade policies, they do react to the gradual shift in the CAP from market intervention to direct payments conditional on environmental performance of the recipient farms.

Implementation of international regulation of trade in GMO products, like under the Biosafety Protocol, removes trade barriers and this may support biotechnology innovation in the seed industry.

Concluding Remarks

The market and legislative environment for firms developing pesticides, biotechnology and seeds has significantly changed in the 1990s, and will continue to change in the first decade of the 21st century: registration requirements have become more strict; all active substances of pesticides have to be re-examined; the precautionary principle is now fully incorporated in EU policies; GMO-policies have been under continuous criticism; and long delays have occurred in approval of pesticides and GMOs. Although harmonisation of national policies has lead to a shift in legislative and executive authority to Brussels, particularly for GMOs, national governments continue to set important targets in response to political pressure. As a result, companies developing new products for a European market continue to be faced with differences among Member States in interpretation and implementation of common regulation.

There is substantial difference in transparency and predictability of policies for agrochemicals on the one hand and GMOs on the other hand. Pesticide regulation and GMO regulation follow two completely separate decisions making procedures, both at the national and the EU level. However, for companies developing these products as well as for farmers using these products, such distinction is not very functional and therefore hampering innovation. Also from a consumer protection perspective, an integrated analysis would be more useful (see PITA Final Report). The recent formation of DG Health and Consumer Protection (SANCO) and the shift of some authority from other DGs to SANCO is a first step in the direction of an integrated assessment of the effects on human and environmental health of pesticides and GMOs.

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