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An overview of Research Activities 1994- 2002

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ETHICAL, LEGAL AND SOCIO-ECONOMIC ASPECTS OF AGRICULTURE, FISHERIES AND FOOD BIOTECHNOLOGY.

An Overview of Research Activities

1994-2002

PROGRAMMES FAIR AND BIOTECH (FP4)

QUALITY OF LIFE PROGRAMME (FP5)

E. Sachez, M. Ragucci and A. Vassarotti, coordinators
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PREFACE

The creation of a true European Research Area is a priority if the EU wants to become a dynamic, knowledge-based economy that provides for more and better jobs. But I strongly believe that the European Research Area will only be successful and sustainable if it is firmly anchored in society at large.

That is why I attach great importance to encouraging scientists and experts from different disciplines to engage in dialogue among themselves and with the public.

In the agriculture and food areas, for example, the challenge is for economists, sociologists or ethicists to become the natural interlocutors of both the new technology providers and those who benefit from the research, consumers in first place. The whole value-adding process, from the management of living resources, along the food supply chain to the consumer, with his/her particular food habits, needs its own scheme of dialogue, mutual education and consensus.

In the medical area, ethical, legal and social considerations are increasingly determining research priorities. Social sciences and humanities have a crucial role to play to help form and translate society's expectations vis-à-vis the increasing pace of scientific and technological progress that affects fondamental values and beliefs.

The work described in these pages demonstrates that the European Commission has supported many efforts to this effect since the beginning of the 1990s. This is part of our commitment to good governance of science. And it reflects a confidence in the potential that life sciences and technologies have to offer to modern society.

Philippe Busquin

Commissioner for Research

FOREWORD

Research breakthroughs and technological developments in life sciences raise important ethical and social considerations, in particular in connection with **agriculture and food related issues.** Ethical and social considerations have influenced legislative/decision making processes and the public understanding of new scientific and technological developments, e.g. in the case of genetic engineering applied to the agro-food sector.

The Commission has consistently addressed the ethical and social dimensions of research in life sciences within the different Framework Programmes for Research and Technological Development. In particular, the **4th FP** highlighted the bio-ethics dimension through the horizontal **ELSA (Ethical, Legal and Social Aspects)** sub-area, common to the three programmes (BIOMED II, FAIR and BIOTECHNOLOGY). Now that the majority of the projects supported under this sub-area have concluded, with this publication we intend to communicate to the public the main results relevant to one particular application area, namely the agro-food complex.

Basically this publication selects from the **FAIR and BIOTECHNOLOGY Programmes the ELSA** projects funded in the field of agro-food, fisheries and food biotechnology (including animal welfare and biodiversity). Projects dealing with **Public Perception and Socio-economic impacts of Biotechnology** have also been included.

The Commission services have taken advantage of this opportunity to include also results of research projects and accompanying measures funded under the **Bioethics and Socio-economic activities** of the ongoing **Quality of Life programme (5th FP).** Basic information about current projects in agriculture, animal or food biotechnology is included as well.

The publication thus provides an overview of relevant activities carried out over the 1994-2002 period. Among the **topics** covered are: ethical aspects of agro-food biotechnology, public perceptions, the development of biotech companies, animal welfare, animal biotechnology, biodiversity and environment- related aspects and intellectual property. It should be noted that a number of projects focus on education (biotechnology, ethical education within life sciences faculties, etc) and the characterisation of the link between policy making and ethical/ social aspects.

The main results have been extracted from the final reports. The complete results of the projects presented are available in most cases via the website indicated and may also be published via the Internet[1] in the near future.

In conclusion and considering that we are moving close to the date of launch of the **6th FP** for RTD, this publication also presents the **new approach for integrating the ethical, legal, social and wider cultural aspects into research projects.** We hope that this approach, which is fully in line with the actions proposed by the Commission in its communication on

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[1] http://biosociety.cordis.lu; ftp://ftp.cordis.lu/pub/life/docs/catalogue_elsa_qol.zip

"Life Sciences and Biotechnology- A strategy for Europe »[2], will contribute to making the ethical and social debate a natural part of the research and development activities in Life Sciences, involving society as much as possible.

Within this perspective, the Commission activities in this area will also include actions targeted to better communicate the progress in life sciences to society. With this purpose, already in April 2000 the Research Commissioner Philippe Busquin decided to set up the European Group on Life Sciences (EGLS) as a source of high-level advice on the future of life sciences and technologies[3]. In addition, the implementation of the action plan Science and Society [4] will contribute to setting this goal in the wider context of the European research policy.

Bruno Hansen

Director
Direction E Life sciences: Biotechnology, Agriculture and Food

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[2] In this communication it is stated that the Commission will strengthen and focus Community support for socio-economic and ethical issues and that the Commission will ensure that ethical, legal and social implications are taken into account at the earliest possible stages of Community supported research . (Action 14)

[3] http://europa.eu.int/comm/research/life-sciences/egls/index_en.html

[4] http://www.cordis.lu/science-society

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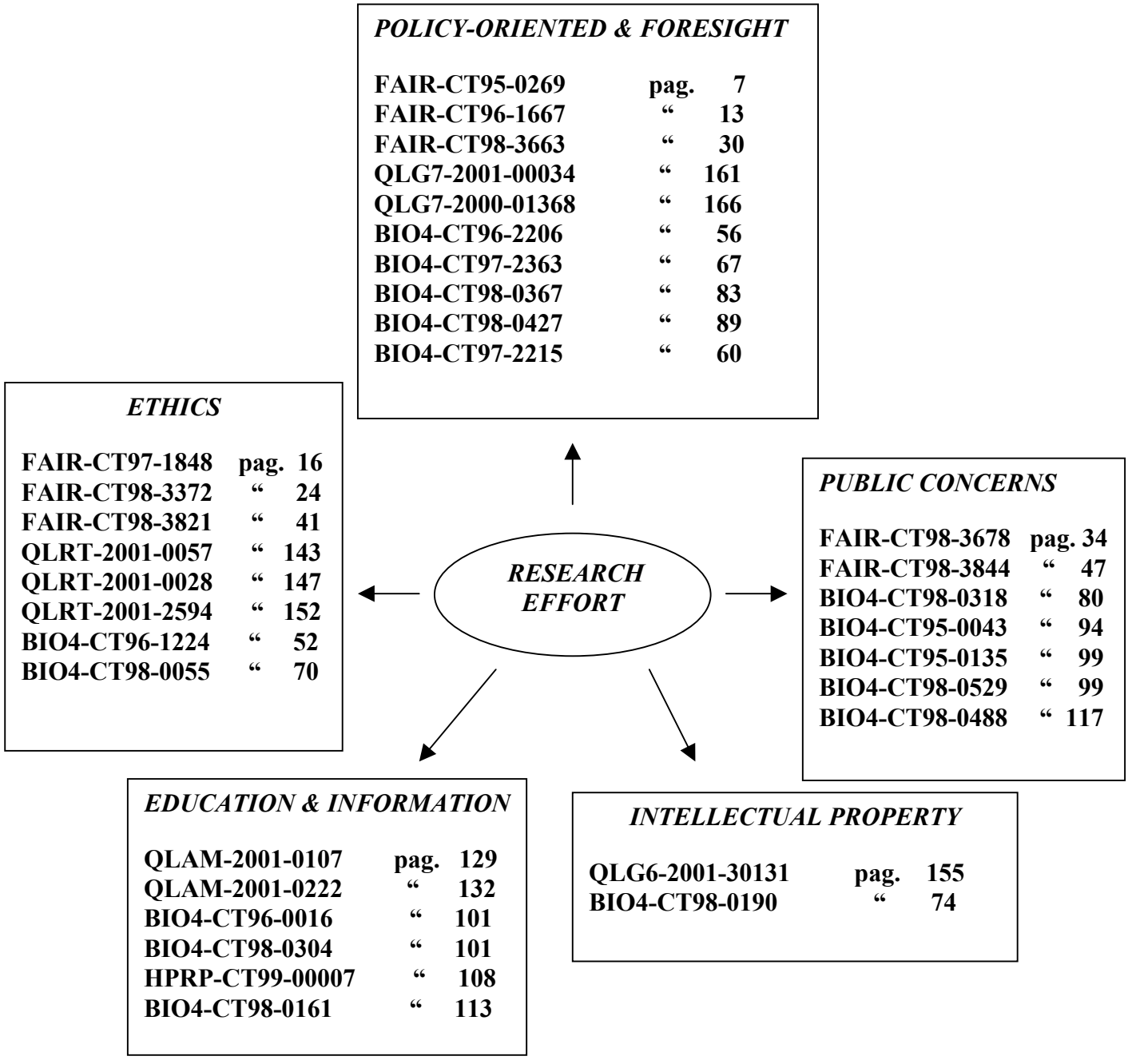

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I. PROJECTS FUNDED UNDER THE 4TH FRAMEWORK PROGRAMME (1994-1998)

INTRODUCTION

At the time the 4th Framework Programme was in preparation the growing recognition of the importance of biotechnology for innovation, growth and employment in Europe was reflected in initiatives aimed to regulate and support the bioindustry and enhance applications needed in agriculture, health care and the environment. The European Commission's Biotechnology programme (1994-1998), provided the framework to reinforce the European science base in biotechnology, and create the links between that science base and established companies while promoting the formation of small firms. The biotechnology programme mobilized research and various actors to meet the needs of European citizens as competitiveness and quality of life must go hand in hand.

A similar process aimed at improving food quality processes and developing environmental friendly agricultural practices was taking place in the parallel R&D programme FAIR (Food Agro Industry Research – 1994/1998).

The ELSA (Ethical Legal Social Aspects) approach, which is a common research subarea for the above programmes, dealt with ethical, social and legal issues raised by specific applications of biotechnology, agricultural, food and fisheries production systems, etc; ensuring that these aspects were taken into account in public policy deliberations. Both the Biotechnology and the FAIR programmes supported projects investigating the real and potential socio-economic impacts of research in the agricultural, food and food biotechnology areas. Some projects dealt with social expectations and public communication strategies, contributing to the public debate. The projects that were considered relevant in the context of this catalogue are presented in the following pages. A total budget of roughly 8 million Euros has been spent on these projects.

I - PROJECTS FUNDED UNDER THE 4TH FRAMEWORK PROGRAMME (1994-1998)

i) FAIR PROGRAMME – Ethical, Legal and social aspects (ELSA)

FUTURE IMPACTS OF BIOTECHNOLOGY ON AGRICULTURE, FOOD PRODUCTION AND FOOD PROCESSING - A DELPHI SURVEY

Contract No. :	**FAIR-CT95-0269**	**Coordinator:**
Contract type:	Shared-cost project	**Dr. Klaus MENRAD** Fraunhofer Institute for Systems and Innovation Research Breslauer Str. 48 DE-76139 Karlsruhe Tel: 49-721 809 62 Fax: 49-721 809 76 **E-mail:** klaus.menrad@isi.fhg.de
Starting date:	01.01.1996	
Duration:	29 months	
EC contribution:	617.000 €	
Website:		

Introduction

Although the first Agro-Food products based on modern biotechnology have entered the EU markets, the application of this technology is still intensively discussed in the European Union. Recent opinion polls indicate as well that consumers' acceptance of genetically engineered food and agro-products is still relatively low, at least in some member states of the EU. In contrast, representatives from politics and industry underline the necessity to apply modern biotechnology in the Agro-Food sector, mainly to ensure the competi-tiveness of the EU agriculture and food industry and for employment reasons.

Against this background, there is a need for a scientific analysis of the future impacts of modern biotechnology in the Agro-Food sector of the EU. Recent studies trying to analyse this issue usually comprise extrapolations of status-quo analyses. What has not been exploited so far in this context are systematic technology forecasting approaches which get comparable information on an international level. Therefore, in this project, the impacts of modern biotechnology on the Agro-Food sector in five member countries of the EU (Germany, Greece, Italy, the Netherlands, Spain) have been analysed with the help of the Delphi methodology. The Delphi approach is based on a questionnaire containing possible visions of future developments, which are assessed by selected experts, thereby providing a feedback mechanism, since the results of the first round are included in the questionnaire of the second round. The specific features of this project are the consideration of the scientific and technical development in Agro-Food biotechnology, the development of framework conditions as well as the involvement of different social groups (e. g. farmers, consumers, biotechnology critics), who are not asked in traditional Delphi surveys.

The questionnaire containing 71 statements of possible future developments was created in an interactive procedure between the different project teams and specially established national

expert committees in the five countries during the first six months of 1996. In total, more than 7,800 experts have been asked in the first round to participate in the Delphi survey. The size of the expert panels range from around 1,200 experts in the Netherlands and Spain to almost 2,400 experts in Germany. The questionnaires of the first round were mailed during autumn 1996, the second round followed in March/April 1997. While in Italy and Spain a relatively low rate of response occurred with around 150 participating experts, 522 experts answered the questionnaire twice in Germany. Around 200 experts filled in the questionnaire of the second round in Greece and the Netherlands.

Main results

Differences between countries

In a first step the results of the Delphi survey were analysed on a national level. The experts of the Central European countries (Germany, the Netherlands) are more critical than their colleagues from the Mediterranean countries concerning Agro-Food biotechnology, whereas among the latter the Spanish respondents are by far the most positive ones. In total, more than half of the statements are appreciated, while less than one fifth are opposed by the experts. The most obvious differences between these two groups of countries emerge concerning the application of modern biotechnology in animal husbandry and animal breeding. The German, Dutch and Greek panels estimate this application field rather critically, while the Spanish and Italian panel members regard this area more positively. Negligible differences in the personal attitude of the experts emerge towards biotechnological approaches which contribute to reduce health problems or to develop products outside the food chain. Moreover, the experts of all countries are in favour of monitoring systems based on modern biotechnology.

The German and Dutch expert groups show rather polarised answering patterns, while the expert groups of the Mediterranean countries mostly indicate a relatively uniform response behaviour. In Germany the extreme poles are represented by the rather positive experts from industry and research institutions on the one hand and the rather sceptical consumers and biotechnology critics on the other. The answering behaviour of farmers is placed between these two poles with clear tendencies towards the consumer/critics cluster.

The social and ethical acceptance of modern biotechnology as well as the conditions on the relevant markets got almost twice the weight in Germany and the Netherlands as the three Mediterranean countries, while in the latter R&D infrastructure, technology transfer and the availability of qualified and skilled personnel are seen as rather important constraints. The diffusion of background information on modern biotechnology is regarded as more relevant in the Southern countries as well. In all countries the relatively low relevance of "ecology" and "international collaboration" as influencing factors is rather surprising.

Future scientific and technical developments

The results of the Delphi survey confirm that the number of modern biotechnology-derived products and methods is likely to increase significantly within the next ten years.
In the field of enzyme production, leading companies producing food and feed enzymes have made strategic decisions in recent years to use genetic engineering, as well as other core technologies, in order to drastically shorten the time to market for new enzymes and to make a much larger variety of different enzymes commercially available in future.

In plant breeding and plant production multinational "life science companies" invest heavily in "green biotechnology". Their strategic goal is to transfer the genomics approach from the pharmaceutical sector to the Agro-Food sector. However, the Delphi results indicate that the applied methods still have to be refined in order to allow the engineering of polygenic traits in crop plants.
Genetic engineering of farm animals and cloning by nuclear transfer is mainly in the research stage and, if applied, is predominantly targeted to the pharmaceutical sector. In the coming decade it will most likely become possible to combine these different approaches, thus overcoming present technical difficulties and exploiting synergies between the individual technologies.
In the field of analytical tools and diagnostics based on modern biotechnology, current research activities in elucidating the molecular and genetic basis of economically important characteristics of food, crop plants, livestock and food-relevant microorganisms will provide a multitude of information in the coming decade which can be used for new analytic and diagnostic tests in the Agro-Food sector.

Impacts on consumers' health and on the environment

In the public debate on Agro-Food biotechnology in the EU, potential risks of this technology related to the health of consumers as well as to the environment play a prominent role. Modern biotechnology is seen by the respondents as a factor of aggravation but at the same time as a possibility to reduce negative health (like allergies) or environmental effects for the contribution of genetic engineering to prevent allergies. There are strong convictions and expectations, especially. The same relates to biotechnology approaches to reduce organic waste in animal husbandry as well as its conversion into marketable products. But at the same time, there are clear concerns about harmful health (e. g. additional allergies in employees) or environmental effects (e. g. horizontal gene transfer, negative impacts on biodiversity or the loss of traditionally used varieties and organisms) of the same technology. In total, the experts asked express higher expectations in technical solutions (e. g. the development of new monitoring and test systems) than in organisational approaches (like enhanced information activities).

Future acceptance and regulation of modern biotechnology

In line with the results of population surveys recently carried out, Spain and Italy are the most "optimistic" countries in the Delphi survey. Germany confirms its low degree of acceptance and the Netherlands appears to have an intermediate position. This finding is rather surprising, as it shows that the level of knowledge and the familiarity with the concerned issues (which are assumed to be higher in the Delphi survey) are not so decisive in shaping the main attitudes. Instead, cultural factors seem to prevail. In addition, the perception of possible risks of modern biotechnology expressed in the Delphi survey suggests that the social acceptance of biotechnology is also linked to the satisfying the public demand for control.

All developments involving a broad diffusion of gene food products receive a moderate consensus. Positive attitudes seem to be linked to the indication of clear and specific benefits for human health and the environment. This confirms that the existence of ethical purposes is a key factor in order to obtain the social acceptance of genetic modification. This expectation,

however, is accompanied by a feeling of the inevitability of the final adoption of genetic engineering techniques in food production and processing.

Economic impacts of modern biotechnology

An important argument for the promotion of modern biotechnology is the expectation that the application of this technology will contribute to additional employment possibilities and the competitiveness of European industry. However, the results of this survey indicate that within the next five to ten years only limited job growth is to be expected in the specialist biotech service companies and in supplying companies of the food industry. It is also expected that a decrease in the traditional jobs in agriculture will take place, partly due to the widespread use of modern biotechnology, but also as a result of structural changes in this sector.

The experts express some uncertainties and concerns about a strong market penetration of gene food products. Nevertheless, the experts expect considerable market shares and a kind of "habituation" of the consumers to this type of products in around ten years. In addition, the experts have high expectations in the market opportunities of biotechnology-based products for non-food purposes which are expected to be realised in the medium to long term. This relates to renewable resources used in the chemical industry and for energy production, to pharmaceutical substances produced with the help of transgenic animals or plants, as well as to the use of biotechnology approaches to reduce agricultural waste.

A clear regulation of the market approval procedure for gene food products is required for economic reasons as well. On the other hand, a considerable proportion of the experts sees little chances for clear regulation procedures due to practical reasons and other intentions of industry and policy.

Recommendations for further activities

Based on the results of the Delphi survey the following main recommendations have been formulated by the project team.
The current regulations in the field of Agro-Food biotechnology focus on the potential risks of this technology related to the health of consumers, users and employees as well as to the environment. Taking into account that ethical and cultural factors gain increasing importance in shaping the acceptance of modern biotechnology a need might arise for a stronger focus on ethical concerns as driving forces for the design of regulatory frameworks in addition to the present risk-driven approach.
Further research activities are recommended, focusing on the development of practicable ways to include ethical aspects in regulation and decision-making concerning Agro-Food biotechnology.
The implementation of the passed "Novel Food Regulation" in each EU member country is recommended as fast as possible, thereby ensuring clear and realistic control and monitoring activities.
Politicians and the responsible authorities at EU and national level should take effective measures in order to minimise adverse health and environmental effects of modern biotechnology in future thereby considering regulation, research and information activities.
Public research policy should focus to a higher extent on the analysis especially of the long-term impacts of modern biotechnology in future.

New instruments should be developed in order to get a more realistic view concerning the employment effects of Agro-Food biotechnology. Furthermore, sound scientific studies in this area should be initiated by national governments or international organisations.
Many non-food applications of modern biotechnology can only be speeded up in a "concerted action" of science, industry and policy, taking into account the interests of other groups (e. g. farmers) as well. It should be checked if the network between the different actors is sufficient or if building up or optimising such a network should be publicly supported.
Taking into account the existing technical constraints in animal biotechnology as well as the genetic modification of polygenic traits in crop plants, emphasis should be given to an advancement of R&D infrastructure and additional funding for broadening the knowledge basis, if the use of modern biotechnology and potential commercial applications in these fields are desired by society.

Partners

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CONSUMER ATTITUDES AND DECISION-MAKING WITH REGARD TO GENETICALLY ENGINEERED FOOD PRODUCTS

Contract No. :	**FAIR-CT96-1667**	**Coordinator:**
Contract type:	Shared-cost project	**Klaus G. GRUNERT** MAPP - Centre for market surveillance, research and strategy for the food sector The Aarhus School of Business Haslegaardsvej 10 SE-8210 Aarhus V Tel: 45-89 48 64 87 Fax: 45-86 15 01 77 **E-mail:** klg@hha.dk
Starting date:	01.12.1996	
Duration:	36 months	
EC contribution:	619.756 €	
Website:		

Introduction

Over a three-year period (1.12.96-30.11.99), the project has investigated consumer acceptance of genetically modified food products through established social science methods.

Objectives

The objectives of the project have been the following:

- to gain an understanding of the concerns and benefits relevant to societal actors associated with the use of genetic modification in food products in selected EU countries
- to gain an understanding of how consumers in selected EU countries form attitudes, positive or negative, towards genetic modification in food products
- to gain an understanding of how such attitudes interact with other factors in determining consumers' purchase decisions
- to gain an understanding of how various strategies for informing consumers about benefits and risks associated with genetic modification affect their attitudes and their purchase decisions
- to derive, based on the understanding obtained, conclusions for the development and marketing of food products based on genetic modification, for the regulation of the use of genetic modification in food products, and for strategies for informing consumers about use and consequences of the use of genetic modification in food products

Methodology and research tasks

The objectives were achieved through the development of models, building on existing consumer behaviour theory and a review of comparable research, and through four empirical studies. The first two studies were qualitative and aimed at eliciting risks and benefits that consumers associated with the use of genetic modification in food products. These were executed as expert focus groups and semi-structured consumer interviews, called laddering interviews. The expert focus groups also formed the basis for identifying possible ways of informing consumers about genetic modification. The other two studies were quantitative. One was a cross-national survey investigating the formation of consumer attitudes and purchase decisions, and one was an experiment to investigate attitudinal and choice effects of information provision.

All empirical research was conducted in four countries: Denmark, Germany, Italy and the United Kingdom.

The project was performed partly with two examples: yoghurt produced with genetically modified starter culture resulting in a fatfree product, and beer brewed on genetically modified yeast resulting in a product with price and environment benefits. Both products are examples of the application of genetically modified microorganisms in food production, with the genetically modified material present in the final product in the one case (yoghurt) and absent in the other (beer).

Main results

Results show consumer attitudes and purchase decisions with regard to genetically modified foods to be a result of complex processes. The following main conclusions can be extracted from the research:

- Consumers' attitudes towards genetically modified food products are very negative. This holds at the general level, as shown in the survey attitude measurements, and at the product level, as shown in the laddering study and in the survey purchase intention measurements.
- There are national differences in the degree of negativity. Danish and German consumers were generally found to be more averse towards genetic modification in food production than British and particularly Italian consumers.
- The negative attitudes are linked to uncertainty and a host of diffuse negative risk perceptions. The laddering study showed that genetically modified foods were associated with attributes such as unwholesome, unfamiliar and unnecessary and were perceived to lead to undesirable consequences such as harms nature, less healthiness, cannot trust and morally wrong. These associations do not seem to be product-specific.
- The negative attitudes are linked to more fundamental, underlying attitudes. These more general attitudes include attitude towards technology, attitude towards nature, alienation from the marketplace and food neophobia. This suggests that present attitudes towards genetically modified foods are quite strong, despite their lack of basis in actual product experience.

- The negative attitudes have a strong effect on purchase intentions. The cross-national survey showed that attitudes towards the use of genetic modification in food production, attitudes towards purchasing a specific genetically modified food product and purchase intentions are strongly related. This suggests that at present consumers evaluate genetically modified products on a case-by-case basis, but rather reject the technology overall.
- Perceptions of benefits are hindered by the perceptions of risks. The survey showed that to a large degree perception of benefits is determined by risks associated with using genetic modification in food production. The laddering study showed that even though explicit benefits are built into the products, communicated and sometimes even perceived as relevant, they are not mirrored in product preferences.
- Information mainly activates existing attitudes. The experiments showed that information provision increases the relationship between prior attitude and choice behaviour, regardless of the kind of information or information source. Likewise, the experiments showed that giving information decreased the likelihood of choosing the genetically modified products.

Partners

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ETHICAL ASPECTS OF AGRICULTURAL BIOTECHNOLOGY (BABAS)

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Starting date:	01.03.1997	
Duration:	18 months	
EC contribution:	483.000 €	
Website: http://www.kluyver.stm.tudelft.nl/efb/TGPPB/Home.htm		

Introduction

Recently, biotechnology has been brought to the forefront of public attention. Because the applications of modern biotechnology impinge upon some of the most fundamental of human situations - our health, our food, our environment, even our very nature - they raise serious ethical questions. The intention in this project has been to produce a clear, concise and balanced distillation of these studies in non-technical language for ease of understanding and use. It begins with an introductory discussion of ethical and legal questions followed by more detailed analysis of the ethical implications of biotechnological applications in the various areas.
The project is the work of leading scientists, ethicists and experts in the patenting and regulatory fields concerned with applications of biotechnology in the agricultural and food areas from throughout Europe. The main body of the work was carried out by five Working Groups encompassing the food, industry, medicine, environment and developing countries areas with ethics, patenting, regulation (safety) and economic/political issues integrated across the five areas. It was used as working document at the European Conference held on 16-19 May 1999 in Oviedo, Spain which was organised by the Parliamentary Assembly of the Council of Europe. The conference was organised with the aim for preparing the way for determining the desirability of a European Convention covering bioethical aspects of biotechnology applied to the agricultural and food sector.

Objectives

The objective of this project was to coordinate a network of leading experts throughout Europe in carrying out a series of studies on the bioethical aspects of biotechnology applied to the agricultural, fisheries and food sector. These studies review the state of the art, identify problem areas and deficiencies in research, and carry out any necessary further research. Each of the studies will draw up a report of its findings which will be combined as an overall final report. Composing the overall final report involves three steps:
A) Description of the bioethical aspects in respect to the following - agrofood related - areas:
(1) Food, (2) Industry, (3) Medicine, (4) Environment and (5) Developing Countries.

B) Integration of general ethics, patenting, regulation (safety) and economic/political issues across the five topics in A).
C) Description of ethical aspects with respect to (1) sciences, (2) technology, (3) safety (risk/benefit), (4) socio-economics, (5) intellectual property rights and patenting, (6) regulatory framework and (7) social acceptability and education. These will be dealt with by each group concerned with one of the five identified topics in A), leading to bioethical conclusions and recommendations.

Main results

The final report can be found at the above-mentioned website. The following keypoints, with respect to the areas covered, can be extracted from the report.

1 Ethics

Ethics can usefully be defined as the branch of philosophy concerned with how we should decide what is morally wrong and what is morally right.
Ethical conclusions need to be based on reason, take into account historically well established ethical principles, be based on consensus, take account of minority interests and be open to the possibility of change.
A useful tradition of ethical reasoning in the European Union and elsewhere is beginning to accumulate about moral questions concerning biotechnology.
The simplest approach to deciding whether an action would be right or wrong is to look at what its consequences would be. Controversy exists as to whether that is all which is needed.
Traditionally, ethics has concentrated mainly upon actions that take place between people at one point in time. In recent decades, however, moral philosophy has widened its scope by taking into account interspecific and intergenerational issues.
Ethical decisions can be taken at a number of levels from the individual to the international.

Some general ethical questions which relate to all applications of modern biotechnology include:
How to weigh the potential benefits against the possible costs?
Do the processes themselves constitute an "unnatural" interference with Nature, particularly in breaching natural species boundaries and violating the integrity of species?
What is ethically wrong with interfering with Nature?
Do the processes involve the taking of ethically unjustifiable risks?
From a religious viewpoint, is modern biotechnology to be interpreted as "playing God" or as collaborating in the on-going work of creation?
Do these questions suggest any significant ethical differences between modern biotechnology and more traditional techniques?

2 Food

Agriculture has always depended on plant and animal breeding and modern biotechnology provides new possibilities.
Public perceptions of agro-food biotechnology are more critical than of its applications in healthcare. This probably results from the cultural and symbolic functions of food together with most people's relative ignorance about modern agriculture and food production.

The most important areas where biotechnology can provide benefits for European consumers can be in improved price, quality and nutritional value of foods.
Regulation has been mostly directed to the safety of foods. Labelling is still a controversial issue at the international level. The EC regulation on novel foods and novel food ingredients (258/97) includes a labelling requirement for a material not present in conventional equivalent foods which "gives rise to ethical concerns" to inform population groups with "well established" food practices. In the USA the Food and Drug Administration considers that no special labelling is required.
Ethical considerations of agrofood biotechnology relate to the environment, biodiversity, sustainability, animal welfare and its socio-economic impacts.
Consumers rights concerning biotechnological food products relate to the rights to health from safe foods, to be informed and to choose genetically engineered products or not.
It is crucial that balanced information is provided to the public. Communication strategies should bring together the scientific, industrial and general communities to promote openness, dialogue and mutual understanding.

3 Environment

The current environmental problems that arise from agriculture stem from modern, intensive agricultural practices and not from the use of genetically modified crops, as the latter are only currently being introduced into European agriculture. The use of biotechnology may either exacerbate or ameliorate these effects depending on how it is applied.
It is therefore important, before applying new biotechnology, to consider the precautionary principle, the need for sustainable development and the need to maintain and possibly enhance agriculturally-important biodiversity.
The latter is emphasised in the two case studies, one on the introduction of GMO crops into their centres of origin (frost tolerant potato) and the other on the importance of mediterranean biodiversity, taking the case of Greece.

4 Medicine

Biotechnology offers many opportunities for the production of medicines, vaccines and other medical products using agricultural sources for further improvement of human and animal health.
New products can be developed using this technology, or the production of already existing products made more cost-effective.
The disadvantages of the use of biotechnology must not be overlooked: although safety regulations do exist unforeseen and unwanted consequences may still occur.
The continued development of biotechnology in relation to the use of agriculture for medicine will undoubtedly raise new ethical questions and controversies. However, there is good reason to expect that the very considerable body of expertise that exists in relation to medical and other areas of ethics will help to give rise to some degree of consensus in many of these novel areas, though it must be recognised that ethical debate is characterised by conflicting arguments and viewpoints.

5 Developing Countries

The issues that are identified need to be addressed regardless of the technology used to manufacture or market a product; these need to be within the context of (agricultural) need and/or food resources.
The view in countries where there is enough to eat, and where choice of what to eat is assumed may be significantly different from that pertaining in other countries. Choices need to be made by those who have to live with their consequences.
Many of the issues identified which are of ethical concern are not specific to developing countries, but occur within parts of countries considered to be developed. The developing world is much too diverse to be treated as a whole. The issues which result from moving from "traditional" agriculture to industrialised agriculture are those which need consideration.
Biotechnology *per se* does not lead to a loss of biodiversity; all modern agricultural techniques contribute both positively and negatively.
Technology has the capacity to contribute to the empowerment of rural communities.
The increase in the world population will mainly occur in the developing countries and therefore food increase needs to occur in those countries. The developed world is supplying food to the developing world. Furthermore, governmental agencies control access to the staple crops that form the major starch, oil and protein sources. It is important to provide a mechanism for sustainable food production where and when needed.
Developing countries contribute significantly to the added value made in agriculture. In this respect it could therefore be beneficial for these to set up a balanced system of intellectual property rights.
There are five major players that contribute to agricultural research: governmental and public institutions, international institutions, non-governmental organisations and industry.
Developing countries should be free to use their land according to their own view. The prejudices and views on industrialised agriculture which colour the "Northern" approach to agricultural produce should not be imposed on those not getting enough to eat.
Developing countries should be helped to have access to biotechnology based on their genetic resources (Convention on Biological Diversity).
All parties to the Convention on Biological Diversity have an obligation "to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries which provide the genetic resources for such research, and where feasible in such Contracting Parties". There will be costs associated with maintaining biodiversity within a centre of origin, which should be borne by the international community.

6 Industry

Industrial development of biotechnology in Europe varies both between different sectors of biotechnology and different areas within Europe. Environmental and food-related issues are more important in northern European countries, whereas production and employment tend to prevail in southern and eastern countries.
The conclusions from public opinion surveys concerning applications of biotechnology are that:
Usefulness is a precondition of support, in no case is a "not useful" application given support.

People will accept some risk if the application is (a) useful and (b) morally acceptable.

Moral concerns act as a veto regardless of views on risk and use.

If risk is less significant than moral acceptability in shaping public perceptions, then public concerns are unlikely to be alleviated by technically based reassurances and other policy initiatives dealing solely with risks.

Employment is in itself an ethical issue where biotechnology in Europe is concerned.

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ORGANIC SALMON PRODUCTION AND CONSUMPTIONS : ETHICS, CONSUMER PERCEPTIONS AND REGULATION

Contract No. :	**FAIR-CT98-3372**	**Coordinator:**
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Starting date:	June 1998	
Duration:	24 months	
EC contribution:	400.000 €	
Website:		

Introduction

This project concludes on the main findings from a programme of research designed to assess issues relating to the production and consumption of organic salmon by using a variety of methodologies (desk research, interest group depth interviews, consumer focus groups and quantitative modelling). Full details of each stage of the research can be found in the relevant reports (Aarset et al., 1999a; 1999b; 2000a; 2000b).

The overall aims of the project were to:

1) evaluate possible definitions of organic salmon as perceived by consumer and producer interests
2) appraise the technical, animal welfare and environmental aspects implicit in organic salmon and
3) explore the critical issues in the regulatory framework at national and EU level

The aim of this project is to 1) identify the salient themes and issues relating to the concept of organic salmon and 2) present policy recommendations based on the key issues identified. The first section of the report provides an overview of the background to the project, in particular, the current system of regulation, the perceived meaning of organic and key issues relating to the concept of organic salmon are discussed. Section 2 summarises the findings from the focus groups and interest groups interviews and section 3 highlights the key technical findings and their implications for organic salmon standards. In the final section, the main findings from the project are discussed and policy recommendations are made.

Consumers are broadly and positively responsive to the concept of organic aquaculture products, but are commonly confused about the meaning of the term “organic” and remain largely unaware of the current system of regulation and implementation. Confusion within the marketplace is varied but in many cases uncertainty is promulgated because of the lack of conformity of organic logos and related signifiers. To only slightly varying degrees, these

observations hold broadly across the European consumers and the regulatory structures reviewed, and so indicate a general theme. This argues for more standardised labelling for organic foods, based on broadly agreed principles and comparable regulation, in a form that consumers can instantly recognise and comprehend.

Various members of the supply chain remain sceptical about the application of organic principles and regulation to farmed salmon, and reservations exist about the impact of applying effectively a dichotomous organic/non-organic system. Though such a division could positively differentiate organic product, it might at the same time intensify any perceptions of inferiority for the much larger proportion of conventionally produced fish. Given the disparate elements in defining organic status, and its perceived importance, an alternative grading scheme, indicating how green / 'organic' the salmon is, may be more appropriate. Such a measure has parallels in other markets and could still be amenable to further brand differentiation.

The research identified quite limited consumer knowledge about fish farming in general, and about specific issues such as the use of chemo-therapeutants and the meaning of sustainability. Knowledge of animal welfare issues as applied to fish was deficient amongst the scientific/technical community, other channel members and consumers. Such deficiencies could lead to consumer disconfirmation. Fish would appear to have been considered only recently compared to other farmed animals and their parallel availability from capture stocks probably contributes to this limited understanding. This knowledge gap is as an important phenomenon, applicable to both capture and cultured fish production systems, and is recommended for further research.

Research and reviews within the study have confirmed that many of the technical measures potentially contributing to organic criteria, such as disease and welfare management, feed supply sources, and more general food/quality standard issues are within the range of current or emerging production technologies. However, there is considerable scope for interpretation as to the methods, degree of application and level of proof, required to satisfy an 'organic'.appelation. Similar imprecision surrounds the concept of sustainability and/or sustainable production as it concerns aquaculture. Here, the definition and use of sustainability indicators, providing graded indices of positive or negative attributes, is likely to have more practical application. In terms of the future development of the salmon and aquaculture sectors, less intensive production systems might offer an option for those who are cautious about the 'purer' organic route but wish to establish a more positive image. This could also be consistent with applying a continuum of green gradation.

Whilst the research programme has focused upon organic salmon, it is considered increasingly important that other species be subject to similar scrutiny as they emerge into more competitive market conditions. This is especially significant given the dual sourcing of fish products from both capture and culture supply points, given the increasing consumer-led pressure for reliable and trusted quality standards and systems of accreditation, and given the need for the European supply sector to be able to define and uphold its product quality standards within a sound commercial context.

Main results

The following results can be extracted from the final report:

Generally, both modern intensive salmon farming methods and organic salmon farming should become increasingly 'sustainable' with time. However, organic methods promote more rigorous efforts to improve water quality and habitat quality particularly through the more efficient use of feed, reductions in the use of chemicals and drugs, and reduced dependence on fossil fuels. Nonetheless, as admitted by the Soil Association (1998) in their guidelines, some compromises have been made in the short term, such as the continued use of fishmeal in feeds, since there are no realistic alternatives at present.

With increased consumer awareness and pressure for less intensively produced food products, it is likely that the appeal and marketability of organic produce will continue to increase, thus creating incentives for more farmers to turn to this type of production. The results from this project suggest that the evolution of organic salmon farming will depend critically upon the producers' ability to identify and develop segments that are willing to pay a premium for organic salmon in the short term, and then to nurture and build from these in future. However it is impossible to determine at what volumes current price premiums will disappear, not least because of the wider determinants of the food consumers' willingness to pay a premium for alternative substitutes and the critical reliance upon the marketing efforts of all within the organic salmon supply chain.

EU/EEA wide legislation for salmon and other aquaculture products are currently seen as a priority to prevent questionable standards being developed and to provide a touchstone, perhaps for other species, in this developing sector. Whilst there are currently critical flaws in the present system of regulation, the advantages of legislative backup at the European level are self-evident and acknowledged by consumers and interest groups alike. As consumer confidence is largely influenced by their perception of the effectiveness of the regulatory system, until regulations are standardised, this can only lead to a lack of consumer trust and confusion over products such as organic salmon and indeed organic foods in general. However, both industry and the regulatory institutions are moving in a pragmatic direction

In terms of the conceptual perception and definition of organic salmon and other aquaculture products the differences in opinion between purists and pragmatists are potentially divisive. The scope for some interest groups or consumers with purist interpretations of organic food and fish to undermine the organic product, and by default conventional production too, must be acknowledged. This is a significant challenge for those responsible for communicating the issues, not least because in many cases the producers, hence promoters, of organic product will be smaller scale and with more limited promotional resources available. The difficulty of the task is perhaps worsened by the added ambiguity of the term 'organic' being applied to livestock compared to the more widely accepted case of crops, fruit and vegetables. However because of the limited scale of organic fish production and the existing, sunk, investment of livestock interests, the prospect of any revision in the use of the term organic for livestock-derived products must be considered highly unlikely.

The plethora of current grading schemes reflect the emergence of the organic phenomena through a variety of disparate organisations, each with their own standards. As attempts have been made to harmonise rules and regulations so has it emerged that there is increasing

potential for the emergence of splinter groups, each seeking to add their own unique claim to differentiation. The net result of such a process is likely to be a return to more widespread consumer confusion and bewilderment wherein everyone is less sure of what each individual label means, and even less so when the consumer moves beyond their common locus of purchase.

The central problem appears to rest upon quite legitimate but varied interpretations of what constitutes 'organic'. Hitherto the envisaged solution to the perceived divisions within the market has been the formulation of a common standard, or at least some movement in that direction. In order to accommodate all existing standards, deemed acceptable, there is inevitably a compromise of the standards concerned. However when the one standard of the lowest common denominator is established, this in itself immediately creates a division which has the capacity to raise suspicions in the mindset of the consumer. This may be seen as analogous to promoting the superior benefits of the certified product but, at the same time, highlighting the inferiority of the remaining product. Arguably this is especially problematic because the imposition of a single standard necessary to communicate the benefits of, what is and is always likely to remain, the minority proportion of production will tend to cast some aspersion upon the greater proportion of output. Clearly it may be argued that this tendency to effectively cannibalise the salmon product is of dubious benefit from a wider strategic perspective.

An alternative approach might therefore adopt a less dichotomous standard to the concept of organic fish. Rather than the current ethos which tends to favour moving towards some common standard with a unifying lowest common green denominator, one option may be to consider formulation of an organic standard which is graded according to the various hues of green that the production process incorporates. In effect this should result in an indicator of green/ organic status in much the same way that consumers are accustomed to with say, the gradation of energy efficiency ratings for domestic appliances. Such a scale might be achievable by assigning each component of the production process with some value according to its degree of green practice; these could then be aggregated to give a total green/ organic score which would locate the product within a range. Such a range might extend from what is deemed to be the lowest acceptable standard (possibly that deemed fit and safe for human consumption) through to a production process which adheres strictly to a combination of the highest of green standards. Necessarily there will be problematic components, such as the trade-off between the use of chemo-therapeutants to prevent disease and animal welfare, but within these balances a more accurate indicator of true organic status may emerge.

Certainly what such a scheme would avoid is the segregation and alienation that the current policy tends to encourage. Moreover such a scheme would perhaps reflect more accurately the real divergence of opinion as to what constitutes green, perceptions that have been clearly evident in the findings of this research. The alternative of a graded standard of green is also potentially far more in line with the type of product differentiation that consumers have grown accustomed to through brands, be they generic or specific to one product range.

Recommendations

- It is recommended that the EC should consider further research into the feasibility of establishing a gradation scheme for farmed salmon as opposed to the dichotomous benchmarking that currently exists.

This project has highlighted the multitude of issues that need to be considered before organic salmon regulations are implemented. There are many unresolved matters relating to the production of organic salmon, such as the very appropriateness of the term organic, animal welfare, chemical inputs and sustainability. At the same time evidence from the interviews highlights the mounting concern with conventional practice and the tendency witnessed towards more intensive production systems. Whilst it has been recognised that the scope for organic salmon may be limited, at least in terms of a willingness to pay the required price premium, and that there are reservations about the application of the term organic, there may yet emerge opportunities for a meso-scale level of operation. A more selective approach to the contemporary technical solutions that have been developed by the industry may well yield further competitive niches for organisations which select neither the pure organic route nor the more intensive alternative. Product from such operations could communicate its market position through the above suggested scheme and this represents a strategic area worthy of further research.

- It is recommended that further research be undertaken into the feasibility of developing meso-scale levels of salmon production, and incorporate assessment of consumer perceptions to such product.

This research project has been focused upon the salmon sector because of the pre-eminent role that species has established in the international arena. However, production trends within a number of other species seem set to mimic this pattern, certainly in direction if not necessarily in scale. Nonetheless as volumes of alternative substitute farmed species expand it might be anticipated that there will be increased attempts at product differentiation. As with salmon, the organic position is an obvious reference point for differentiation and can be expected to emerge within new species launched too.

However as the new farmed species are more likely to have direct (same species) substitutes competing from capture fisheries there might be less certainty as to how consumers and other channel members might perceive the emergent organic products. An extension of the theme of this programme to incorporate the more likely candidates for the next generation of aquaculture products would seem to be timely and warranted.

- It is recommended that further research be undertaken concerning the transfer of the organic fish concept to other candidate species

The final issue to warrant further mention concerns animal welfare. The research project clarified the paucity of understanding in this area, both from the perspective of the scientific community but, arguably more importantly, the consumer. In an era of rapidly heightening green consumerism it was evident that consumer perceptions and understanding of the fish supply chain, in both cultured and captured environments, is woefully incomplete. Given the evident impact of animal welfare concerns in animal husbandry and poultry, it is conceivable that this could be something of a sleeping giant within the fisheries sector. The co-existence

and contemporaneously different characteristics of the supply chains for, in some cases at least, exactly the same species add to the need for a clearer understanding of how these issues are manifest in fish purchase decisions. Failure to import a clearer perspective on fish welfare is likely to impact adversely on future marketing initiatives.

- *It is recommended that further research be undertaken into the area of fish welfare in the dual environments of production and consumption in farmed and captured products.*

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DEVELOPMENT OF CRITERIA TO ESTABLISH HEALTH-BASED OCCUPATIONAL EXPOSURE LIMITS FOR PESTICIDES

Contract No. :	**FAIR-CT98-3663**	**Coordinator:**
Contract type:	Shared-cost	**Prof. Marco Maroni**
Starting date:	1 June 1998	
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EC contribution:	300.000 €	
Website: http://www.cordis.lu/elsa/src/prj-fair.htm		

Introduction

Council Directive 91/414/EEC is harmonising data requirements and procedures for the authorisation of plant protection products (PPPs) on the European market. No authorisation for an active substance (a.s.) or a PPP should be granted if the estimated operator exposure (including mixers, sprayers, re-entry workers and bystanders), according to the proposed conditions of use, exceeds the AOEL (Acceptable Operator Exposure Level), defined as "…the maximum amount of a.s. to which the operator may be exposed without any adverse health effects".

Objectives

The objectives of this project were:

- to propose a methodology for the establishment of health-based occupational exposure limits for pesticide workers, with particular reference to agricultural operators, re-entry workers, professional pesticide applicators, and bystanders;

- to prepare a guidance document (GD) describing general and specific criteria for the establishment of AOELs;

- to develop a reference scientific framework and discuss critical issues related to the establishment of AOELs.

Methodology and materials

Following a comprehensive literature search, extensive discussion within the project group, and a detailed revision process, a *Draft GD* was edited and circulated among a group of about fifty scientists, key experts and stakeholders in the field of pesticides, at the European and non European level. The experts were invited for discussion at a Workshop held in Orta, Italy (March 1-3, 1999), organised by the project team to provide a forum for discussion of

relevant issues involved in the establishment of AOELs, and to obtain comments on the proposed document.

Rationale

The rationale for the new concept of an AOEL was to establish a health-based limit for risk assessment of pesticide exposure within agricultural settings. In the context of pesticide registration, risk is characterised as a ratio between the exposure dose and the AOEL. Acceptable operator exposure levels have become necessary because the legislative framework and working conditions of pesticide operators are different from those of industrial workers. There are a number of differences between AOELs and traditional occupational exposure limits (OELs) used for industrial chemicals: i) pesticides are specifically designed to kill or cause harm; ii) AOELs shall also apply to bystanders (non-occupational population); iii) OELs are typically set for the inhalation route as 8-hour time-weighted average concentrations, based on a working lifetime of 40-hours a week, assumptions that do not reflect typical agricultural working patterns and exposure routes; iv) OELs are set for airborne concentrations, where inhalation is the principal route of exposure, while the main route of exposure for agricultural pesticides is dermal; and v) AOELs take no account of technical and economic feasibility.

While general rules are laid down, harmonised guidance on specific criteria and procedures to establish AOELs for pesticides in the EU has not yet been officially agreed. Historically Member States have adopted different approaches to the setting of occupational exposure limits in the context of pesticides. In 1997 a European Commission Working Document (CEC, 1997) was produced and distributed to Member States as the draft guidance for setting AOELs, but the document does not represent an officially accepted harmonised system.

Main results

Two technical documents were delivered:

- the first 50-page document entitled ***"Recommended method for the establishment of Acceptable Operator Exposure Levels"*** (the so-called **GD)** proposes a methodology for the establishment of AOELs.

- the second background Annex to the GD (100 pages), entitled ***"Criteria to establish health-based occupational exposure limits for pesticides",*** was prepared to develop a reference scientific framework and discuss in more detail critical issues related to the establishment of AOELs raised during the preparation of the GD and during the Workshop.

Contents of the guidance document

Five introductory Chapters were included in the GD: *i)* to place the procedure for the establishment of AOELs in the context of the overall framework of pesticide approvals and explain the rationale for AOEL setting (Chapter 1 and Chapter 2); *ii)* to introduce general aspects of hazard identification and extrapolation for uncertainties (Chapter 3 and Chapter 4); *ii)* to highlight fundamental aspects involved in the interpretation of the AOEL and discuss the scientific opinions raised at the Workshop and during the preparation of the suggested

procedure (Chapters 5 and 6). Some of the comments and criticisms expressed at the Workshop were taken into account and incorporated in the text of the GD, when a majority consensus was expressed. Chapter 7 focuses on a number of key research topics that should be addressed in the future to improve the scientific basis for setting AOELs, and on regulatory issues that might be considered by the European Commission to enhance the present legislation concerning the placing of PPPs on the European market.

Policy-related benefits

The outcome of this project is intended to contribute to the development of a harmonised procedure to establish AOELs for pesticides, in the context of the authorisation of PPPs in the European market. Since an AOEL is required for risk evaluation in authorisation procedures of pesticides, a new European guidance on AOEL setting will support the ECCO peer review groups, and will assist Member State authorities to support appropriate decisions on the inclusion of a.s.' in Annex 1 of Directive 91/414/EEC.

It is possible to conclude that the initial intentions and objectives were met, even though diverging views on the technical procedure to set health-based exposure limits for pesticides were expressed by the project team. In fact, the technical documents written by the project group offer a comprehensive state-of-the-art of present knowledge on the important scientific issues, which have a critical impact on the procedure to set AOELs. These documents also represent a scientific tool that will be of support to applicants in the preparation and submission of scientifically reasoned proposals for AOELs, on the basis of all relevant toxicological information, as required by the Directive 91/414/EEC.

Moreover, the Workshop organised by the project team has represented a unique opportunity to convey pesticide experts from different countries of the world to a joint discussion on AOELs and related issues. The Workshop held in Orta has offered opportunity for discussion to different stakeholders involved in the admission of pesticides on the European market, among them also the pesticide industry and the Trade Unions.

Final comments on the project

There will clearly be some difficulties in developing an agreed uniform approach, because Member States have been operating different systems, reflecting different underlying views. The process of risk assessment and standard setting, by nature requires assumptions and default options, which strictly depend on the availability of data, the understanding of mechanisms of toxicity, and the need for extrapolations. Our effort was to discuss the scientific basis of the process and develop, as far as possible, a scientific framework on the procedure to establish AOELs, so as to make the entire process of AOEL setting more explicit from the scientific point of view, and less dependent on “judgmental” components. As scientific knowledge increases and the degree of uncertainty decreases, more accurate predictions will be possible of which level of exposure may be considered acceptable to prevent undesired effects. It is important that new scientific information be continuously developed and incorporated into the process of limit setting. In the meantime, however, regulatory decisions still have to be taken, and we hope this document will provide support to improve the reliability of risk assessment for registration of pesticides at the European level.

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CONSUMER CONCERNS ABOUT ANIMAL WELFARE AND THE IMPACT ON FOOD CHOICE

Contract No. :	**FAIR-CT98-3678**	**Coordinator:**
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Duration:	39 months	
EC contribution:	700.000 €	
Website: http://www.apd.rdg.ac.uk/AgEcon/research/cefer.htm#anwelf		

Introduction

This project investigates consumer concerns about farm animal welfare and the impact on food choice in the United Kingdom, Ireland, Italy, France and Germany. The project is in response to evidence of growing concerns about animal welfare amongst consumers in the European Union. Such evidence comes from the increasing demand for food products which are perceived by consumers to be more 'animal-friendly', for example free-range eggs, the growth in the number of vegetarians and calls for tougher regulation of welfare in animal production. There have also been a number of consumer surveys which claim that consumers are becoming more concerned about animal welfare in food. Such concerns have implications for the future consumption of products such as meat, eggs, milk and dairy products and the role of these products in nutrient intake. In turn, consumer concerns about animal welfare have important implications for producers and retailers of animal-based food products within the EU.

Although there is a burgeoning literature on the problems of measuring animal welfare from a scientific and philosophical perspective, there are remarkably few published studies of consumer understanding and concerns about animal welfare. Those studies which do exist only address consumer concerns about animal welfare in one or two countries and generally report the results of relatively simple consumer surveys. Consumer concerns about animal welfare have important implications for the future of the animal-based food products industry within the EU. Firstly, as has already been experienced in some member states, the total demand for animal-based food products is sensitive to concerns about animal welfare. Secondly, such concerns may challenge the acceptability of established methods of animal production and transportation. Despite the importance of consumer concerns about animal

welfare for the future of the animal-based food products industry, existing research provides little information on the specific nature of consumer concerns about animal welfare, in particular how such concerns relate to the actual practices used to rear animals, how concerns differ both quantitatively and qualitatively between EU member states, and the potential influence of concerns about animal welfare on the choice of animal-based food products.

The overall objective of the project is to assess the nature and magnitude of consumer concerns about animal welfare within a cross-section of EU member states (United Kingdom, Ireland, Germany, France and Italy), assess the impact on choice of animal-based food products and suggest strategies by which consumer concerns can be addressed.

Objectives

The specific aims of the project are to:

- Identify the nature of consumer concerns about animal welfare within a cross-section of EU member states.
- Assess the differences and similarities in consumer concerns about animal welfare, between consumers both within and across EU member states.
- Identify the relationship between consumer concerns about animal welfare and the methods used to rear animals.
- Assess the knowledge of consumers about the actual practices employed to rear animals.
- Assess the trade-off between animal welfare, price and other product characteristics in choice of animal-based food products.
- Assess the impact of changes in the methods used to rear animals and the potential choice of animal-based food products.
- Find potential strategies through which policymakers, producers of animal-based food products and retailers can address consumer concerns about the welfare of animals produced for human consumption.

Main results

The results of the qualitative and quantitative studies demonstrate that although consumers are concerned about farm animal welfare, this concern is not a priority in food choice. When consumers do express concern, it is evident that this concern is multidimensional. Consumers use animal welfare as an indicator of other, usually more important, product attributes such as food safety, quality and healthiness. Consequently, consumers equate good animal welfare standards with good food standards. The results reveal that consumers are concerned about standards of animal welfare because of the impact on the well being of the animals *and* the impact on food safety, quality and healthiness. These effects are viewed as interdependent.

Consumers define animal welfare in terms of natural lives and humane deaths. In essence, this means that animals should be reared, fed, housed, reproduced and allowed to behaviour as close to natural conditions as possible. Consumers equate natural production methods with

safer food quality. They use the term 'humane' to describe a quick and painless death during slaughter. Consumers claim that they are uninformed about modern animal production and would like more information so that they can make informed choices. However, the issue of information is double-edged. On the one hand, consumers believe they have the right to make informed food choices. On the other hand, consumers engage in voluntary ignorance, in order to abrogate responsibility for animal welfare. Therefore, they may disassociate the product from the animal of origin, or claim that, even though they want more information, they do not trust the government or the food industry as sources of information. Moreover, although consumers claim that they are willing to pay more for improved animal welfare, at point of purchase such claims are not translated into practice. Indeed, although the majority of consumers report high levels of concern about farm animal welfare, such concerns are not translated into behaviour. The vast majority of animal-based food consumed in the EU is produced in intensive systems.

The research identified a series of barriers to purchasing 'animal-friendly' products. The barriers are: lack of information about production methods, lack of availability of products, lack of belief in the ability of individual consumers to make a difference to animal welfare standards, disassociating the product from the animal of origin, and the increased cost of 'animal-friendly' products. When consumers do choose welfare products, invariably they buy free-range eggs. These products are relatively inexpensive and, therefore, the premiums are not so prohibitive.

Recommendations

The fact that high levels of reported concern do not translate into food choice should not be interpreted as consumers not being concerned. The key barriers – lack of information, lack of availability, lack of belief in personal influence, disassociation and cost – prevent consumers from exercising their preference in food choice:

- Information: consumers clearly want more information on how their food is produced so that they can make informed choices. On the other hand, consumers do not want to accept responsibility for animal welfare and, therefore, they also engage in 'voluntary ignorance'. Consumers may also be subject to information overload, especially on labels, and due to experience and/or desire to abrogate responsibility, judge various sources of information such as the Government and food industry as untrustworthy. An EU-based public information campaign to inform consumers about the ways in which animals are produced in the EU, which also addresses food safety and quality issues, should take into account the contradictory nature of consumer demand for information. Animal welfare labels should be subject to EU legal definition. These definitions, and measures for inspection and enforcement, should be a significant part of the public information campaign.

- Availability: the issue of lack of availability of 'animal-friendly' products is related to lack of information, confusion over current labelling, lack of demand and premiums associated with increased animal welfare. While the majority of consumers claim to be concerned about farm animal welfare, the vast majority of animal-based food is intensively produced in the EU. As more consumers become more informed about animal production, demand for more extensively produced food may increase, however, this will be subject to affordable prices and comprehensive labelling.

- Perceived influence: many consumers believe that they are powerless, in terms of their purchasing behaviour, to affect animal welfare standards. This is contradictory to all current marketing strategies, where consumer preferences are viewed as market drivers. This issue may be compounded again by consumer reluctance to accept responsibility for animal welfare, through their demand for animal-based food products. In this way, consumers adopt a fatalistic approach to food choice. Policies to address this should encourage consumers to acknowledge their role in current animal welfare standards and ways in which they can assist in improving standards.

- Disassociation: this is probably the most difficult barrier to address as it underpins the other issues. Increasing urbanisation and separation of food production from consumption has led to pervasive ignorance of modern production methods and separation of the food product from the animal of origin. As consumers become more aware of animal sentience, on the one hand, and continue to demand animal-based food products, on the other, compounded by the industrialisation of animal production, consumers engage in various psychological and behavioural strategies to avoid connecting the product with the animal of origin. Such strategies simultaneously negate their complicity in the killing of animals for food. It is unclear to what extent public policy can address this fundamentally psychodynamic issue. Simply increasing information may lead to further disassociation as consumers are unwilling to acknowledge the slaughter of animals for human consumption. Policy needs to be designed in view of this. Shock tactics will undoubtedly fail. Information needs to be scientifically based, as rational as possible and comprehensible. The realities of modern animal production need to be communicated in a way that takes into account the role of various stakeholders – producers, manufacturers, distributors, retailers, exporters and consumers – and addresses their respective roles in animal welfare standards.

- Cost: although consumers rated this was the least important barrier, it clearly has an important impact on food choice. Indeed, it is well known that consumers would rather attribute food choice to other factors. Consumers state that they are willing to pay more for improved animal welfare, yet such statements rarely translate into practice. At point of purchase, cost is one of the most important factors, as are other direct attributes, such as food safety and quality. Animal welfare is not viewed as having a direct impact on the consumer and is, therefore, not a priority when food purchasing. Where consumers do pay more, such as for ready-made meals or organic food, there are perceived direct benefits, namely convenience and health. The product which consumers do claim to buy, and for which there is a significant market, is free-range eggs. However, the initial cost and, therefore, the relative premium is small compared to other animal-based products. Policies devised to address cost need to take into account that although consumers say they are willing to pay, invariably they do not. The cost of improved animal welfare may need to be viewed as the cost for a public good which, although paid for by the taxpayer, is subsumed under general agricultural financial support rather than differentiated product prices. This requires redefining EU agricultural policy to provide incentives and rewards for farmers to convert to higher standards of animal welfare without passing on direct costs to consumers, which may only serve as barriers to purchase.

- Consumers prefer a combined strategic approach to their concerns which involves impacts on both the supply side and the demand side. In terms of supply, consumers favour

minimum standards and reform of agricultural policy. In terms of demand, consumers favour compulsory labelling and consumer education, which should empower consumers to express their preferences for higher animal welfare standards. On the other hand, the voluntary code of practice scenario is viewed as transitional, only leading towards compulsory measures. The future of animal welfare will undoubtedly be based on a mutual development of legislative and market forces.

- Animal welfare standards in the EU need to be addressed in light of World Trade Organization (WTO) rules. Although the WTO rules do not allow distinctions to be made on the basis of non-product related process and production methods (PPMs), this research demonstrates that consumers do make such distinctions. The results show that consumers are concerned about the impact of production methods on the well being of the animals and/or food safety and quality. However, a series of barriers prevents consumers translating their concerns into food choice, therefore, despite increasing standards of animal welfare in the EU, there remains a large competing market for imported cheaper (lower standard) animal-based food products. The fact that current WTO rules on non-product related PPMs does not allow intensively produced products to be distinguished from extensively produced products has a serious impact on the competitiveness of EU producers. Therefore, animal welfare should be part of the negotiations on agriculture at the Millenium Round of the WTO. The agenda should include discussion of financial support for improved animal welfare, preferential market access for higher welfare products, mandatory labelling, reform of non-product related PPMs and application of Article XX, which currently does not include animal welfare. International standards, perhaps based on a collaborative effort amongst the World Society for the Protection of Animals (WSPA), Office International des Epizooties (OIE) and Codex Alimentarius, may begin to provide a level playing field from which both consumer concerns about animal welfare may be addressed and European livestock production may prosper.

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ASPECTS ETHIQUES, JURIDIQUES ET SOCIAUX DE LA GESTION DE PECHE EN EUROPE (ETHICAL, LEGAL AND SOCIAL ASPECTS OF FISHERIES MANAGEMENT IN EUROPE) – ELSA - PECHE

Contract No. :	**FAIR-CT98-3821**	**Coordinator:**
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Duration:	36	
EC contribution:	399.000 €	
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INTRODUCTION

Started in 1998, "ELSA-pêches" is a three years multidisciplinary programme in social sciences. The object of the programme is the analysis of the Ethical, Legal and Social Aspects of fisheries management in Europe. The objectives of the programme were defined as follows: In the context of the revision of the Common Fisheries Policy (CFP) to come in 2002, ELSA-Pêche is a multidisciplinary research in social sciences having as central objective the ethical, legal and social dimensions of the public policies concerning fisheries management in Europe (main fishing nations in the EU plus Norway and Iceland). For this purpose, it associates researchers of different disciplines of social sciences in order to achieve collectively and at the European level a research focused on the four following objectives:

> **Objective 1** : to identify the grounds for design and implementation of public policies in the field of fisheries management,
>
> **Objective 2** : to identify the new social demands that question the foundations of these policies ; to propose an interpretation of difficulties that they raise; to make the point of foreseeable tracks for reflection from a theoretical point of views and those proposed currently by stakeholders for a recast of public policy.
>
> **Objective 3** : to analyse fishermen perception of present practices and stakes for the future while giving account of determinants of the diversity of these perceptions at the European level.
>
> **Objective 4 :** to make the ELSA-Pêche programme one place of reflection in progress in this various areas while providing an independent basis of reflection in view discussions on the reform of the CFP of 2002."

Among other initiatives, the group has conducted :

- a review of management policies in 12 European countries : Greece, Italy, Spain, Portugal, France, Italy, Ireland, United Kingdom, The Netherlands, Denmark, Norway and Iceland,

- more than 200 interviews of person involved in fisheries management across Europe from the local to the international levels representing all the players of the management systems (fishermen representatives, administration, politicians, scientists, environmental NGOs),

- a survey among European fishing boat owners in the 12 countries; through postal or direct survey, according to the country, 1600 fishermen have responded to the questionnaire over 8000 contacted,

- animation of conferences and discussion panels.

Main results

Fisheries management at a turning point in Europe

The scene of fisheries management in the world is dominated by strong doubts about the future of institutional arrangements that have been designed during the past decade. Bio-ecological sustainability of the resources, economic viability of the exploitation, social durability of both community based and industrial patterns are much questioned. A strong pessimism and a feeling of global failure is counter-balanced by some notes of optimism. Evidence of maintained and robust local institutions is found in some places. Strongly controlled and individual right based systems are said to bare more satisfaction than inconvenient in some countries. While over fisheries managed on the same line collapse. Looking in Europe, we have many management regimes that stand a more or less pessimistic or optimistic evaluation. Within the EU we have the Common Fisheries Policy that regulates fisheries beyond the 12 miles zones and the management of coastal fisheries under state responsibility. The offshore fisheries of the Atlantic, the Channel and the North Sea are managed under a system of TACs and quotas that are only in few cases individual and transferable. The management of fisheries in the Mediterranean enjoys a specific status with the absence of a declared ZEE. Excepted the case of tuna/swordfish fishery, most Mediterranean fisheries are under a national coastal state jurisdiction and look very much like the situation of the Atlantic coastal fisheries. The recent adhesion of Finland and Sweden to the EU as brought a large part of Baltic sea fisheries under the responsibility of the EU. In the EU, regional sea based institutions are more or less advanced, from almost none like in the Bay of Biscay to politically structured initiatives like in the North Sea or the Baltic Sea. Fisheries in North Atlantic involve very complex international relations between Norway, Iceland, the EU and Russia.

Fisheries management in Europe can be characterised as :

- a multilevel system where the management of inshore and offshore fisheries rely on very different and largely disconnected institutional procedures. This is the case of the EU countries under the CPF but also in the Northern Atlantic,

- a politico-scientific process in the case of “international management” where bodies like ICES and meetings of ministers formulate and decide upon the policy while real

economic and social interests have to voice by lobbying to the scientists and the politicians. A game in which national or gear groups are more or less able to voice,

- a social and economic process of direct bargaining in “the inshore fisheries” where local capacities to organise and produce collective action relies more within the fishermen groups and the local administrative bodies. The second, in a more or less paternalistic way, and the first in more of less autocratic or democratic way, directly manage the common lot of daily adjustment and renegotiation of rules to reduce tensions among gear, harbour or national interests.

- a multiple world where some fishermen act in the context of a socially oriented and community based representation of their action with a strong sense of intergenerational transmission of patrimonies, symbolic as well as social and economic; and others who act in pure industrial relation permanently searching for rent opportunities and thus fighting simultaneously to increase constestability of other rights to enlarge their range of action and to protect the rights they gain against contestability.

- an original politico-economic logic of environmental and development NGOs that has recently popped up on the fisheries scene in various ways and that has led to spectacular decisions.

In the EU, it is well recognised that 20 years of CFP has not bared the results awaited from the financial and intellectual resources that the public has put in it. The "official voices" of Northern non-EU countries supports the idea of much more successful realisations in Iceland and Norway, using this as a strong argument against the entry in the EU. The on-going review of the CFP publicly launched with the Bonino survey in preparation of the 2002 review and the publication in 2001 of the "Green Paper on the Common Fisheries Policy after 2002", reveals nothing but a fierce questioning about what should be done to do better at the highest level of the policy-making process.

At the time of the interviews, i.e. the period 1999-2000, marked with the consultation processed launched by the Bonino survey in the EU and the continuing debate about fisheries and EU membership in Scandinavian countries, the dominant issues could be analysed according to the following entries :

(1) A questionable failure of fisheries policies with multiple causes; the very pessimistic view produced by the scientists and the international organisation is often contested and the main causes for failure are numerous : technological progress, lack of effective enforcement will and means, transition from a subsistence and patrimony transmission logic to a return on investment logic, inadequacy of management tool and institutional arrangements

(2) Governance and governability : diversity of objectives and rational in fisheries management, adequacy or inadequacy of the present institutional logic with poor representation of fishermen and excessive role of political arbitrage, opposed views about the lack of adequate scientific knowledge or the excessive role of the technico-scientific expertise, illusion of controllability of fisheries system by identification of mechanical cause-effect relations, inadequacy of control variable chosen and of the means of control, weak values as foundations of the governance schemes proposed by the European institutions

(3) The management tools : alternatives on input/ouput/territorial definition of access rights, on collective/individual allocation, on community/administrative/market

allocation of the rights, pertinence of the criteria and models used to monitor the system, the role of economic incentives like subsidies, the ecosystem protection mean as fisheries management tools

(4) The foundation for a renewed approach to fisheries in Europe for tomorrow : the necessity to promote a polycentric governance where the constitutional levels like EU and States should provide only the legal foundations at the European level to allow a broad range of options in policy formulation and for a multi-level decision-making structure. This should apply to all aspects of public policy including regulating the access to natural resources and other industrial policy ventures. An ethic more oriented toward marine ecosystems, including the human predatory intervention, than toward the stocks/fleets efficiency structure should be promoted beyond the "resource conservation" and "no subsidy" discourses that dominates today. The coastal ecosystem should be given much more specific consideration as well as the articulation of multiple-right based coastal management and offshore fisheries management based on resource use right.

Studying ethics and institutions

Ethics and institutions have been retained as two levels of regulation of human/sea relation to be studied to cover the broad field of "Ethical, Legal and Social Aspects" of fisheries management. Ethics in fisheries are defined as the level of norms that command the sense and representation of rights and obligations in and towards the sea. Institutions for fisheries management are all the rules, constitutional to operational, the organisations and decision-making processes that are set for the purpose of managing fisheries. The evolution of institutions is viewed as the result of a social actor play in which symbolic, political and economic stakes and interests are major driving forces. Fisheries ethics, as well as institutional arrangements, are deeply rooted in the socio-cultural history of social groups and strongly connected to what happens in the over fields of social life.

The "ELSA-pêche" research group has emphasized the ethical entry as an important, and often under-looked, level of "man to man" and "man to nature relation" in the fisheries systems. Institutional research is more popular as fisheries remain one of the main reference cases to illustrate the "dilemma of the commons". Both levels are not independent. Regarding the evolution of practices in fisheries and the evidence of more failures than achievements in world fisheries management, the international evolution of the norms that govern the relation to nature is most likely to play an important role in the future of institutional arrangements in fisheries. Behind the fierce debates that nourish the evaluation of what has been done or that support the inventiveness on how to act in the future, the evolution of alternative definitions of moral duties and rights play a very important role on player perception, voicing, and ultimately the outcome of social transformation.

It is an evidence that the dissemination of new social and nature ethical norms may have a strong influence in areas like fisheries management where realisations are in many cases considered as unsatisfactory. Among emerging ethical norms that may influence the future of fisheries management we may quote :

- precaution, responsibility or rights in and toward ecosystems, functions in ecosystems or animal individuals,

- the need to consider the collective level as such and not as a mechanical outcome of a sum of individual actions, and, in this collective level, to subdue economic or political interest to social preference,

- in forming social preference and consequently, social choice, the need to move from a representative democracy to a participatory democracy.

In all these areas, we can say that the world of action is still far back from the world of ideas in Europe. The past two decades have seen the formation and dissemination of norms that challenges what used to be considered as “right” or “good” in the industrial societies. In a different perspective, one may argue that the emerging “post-modern ethic” of human/nature relation is no more than a second chance given to a “traditional ethic” that can be still found in some fishing communities where the embedness of society to nature is strongly recognised and institutionalised. But the scale of the nature and the scale of social interactions we have to deal with are much larger and complex thus making society/nature system more open. The condition for their governability have then to be invented as an evolutionary process where the "memory" remains or as a rupture where they have been dismissed.

These norms will be more and more used to say what is “acceptable” and what is “not acceptable” in many areas, including fisheries. But the link between the “think”, the ethical debate, and the “do”, the practical translation, is not easy to study empirically. During the last decade, the production of soft law by international organisations, NGOs and even the industry has been a major translation in fisheries. The discourses of the actor, as observed in the course of the interviews or by the survey, also reflects the “ethical” mood (or mode?). The "Code of Conduct for Responsible Fisheries" prepared by FAO in 1995 or the “Green Paper on the Common Fisheries Policy” published in 2001 by the European Commission in preparation for the CFP review debate in 2002, are typical of this discourse production. But how individual and collective action are already or are going to be effectively affected is a much more complex issue. To study empirically how far ethics will command the institutional choices and the process of institutional change in fisheries management is a very challenging task that is beyond the scope of this programme. Therefore, the decision has been made to study rather independently ethical and institutional aspects in this research as a contribution to this ambitious objective.

The results of theoretical thinking and empirical work conducted in the programme provide two levels of analysis and discussion. One is the management system, in its various levels, reduced to the institutional arrangements that frame collective action to regulate access to the sea and its resources. It looks at the perception of the present and future of fisheries management by the actors of the management. A review of the fisheries management institutional framework in the country studied and the interview of key actors of fisheries management provides the basic material for this analysis. The second level consist of "tracking" the values expressed in actor discourses. For this purpose, key actors interviews and the fishermen perception survey provide a unique material in Europe to decrypt the diversity of perception structures among actors of the European fisheries system. When comparing the perception of fishermen a complex scene appears where nationality or scale of individual operator are not the major explanatory variables of the diversity. Clear cuts among opposed views shows that beyond the scene of the institutional game, value systems play an active role in forming opinions and we may assume in regulating individual and collective actions.

Partners

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PUBLIC PERCEPTIONS OF AGRICULTURAL BIOTECHNOLOGIES IN EUROPE

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Introduction

The use of GMOs in agriculture and food has become one of the most controversial topics in contemporary societies, especially in Europe. Promoters of agricultural biotechnologies are concerned that the current public controversy on GMOs in Europe is impeding the development and commercialisation of a new technological field considered to be of strategic economic importance for Europe. At the same time, critics who believe that GMOs involve unacceptable impacts on the environment, health and society, continue to feel that their concerns have not been addressed. The public is somehow caught in the middle. What do people in Europe think about the use of genetically modified organisms in agriculture and food? What expectations and concerns do they have? How do they shape their views when faced with a new issue such as this? How do they perceive this issue within the whole context of modernisation and lifestyle changes?

During the last few years agricultural biotechnologies have been the subject of numerous inquiries, consultation exercises and public debates - and the number continues to grow - yet most protagonists, on both sides, remain dissatisfied. The need to understand public responses to biotechnology has never been more pressing. But understanding the response of policy makers to perceived public concerns is also essential.

A research team from five European countries directed by Prof. Brian Wynne from Lancaster University (UK) was asked by the European Commission to conduct an in-depth study on public attitudes, perceptions and evaluations of biotechnology in agriculture and food.

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Objectives

Three objectives were stated as follows in our research proposal :

1. To explore and describe the factors shaping the diversity of view points about agricultural biotechnologies and related food-products within five different European Member States (UK, France, Italy, Germany, Spain).

2. To compare these factors and their influence on the diverse viewpoints about agricultural biotechnologies between these five Member States

3. To describe the implications of these factors for policy making at national and European levels.

Methodology

In order to get an accurate and comprehensive impression of public understanding of GMOs, the team selected the method of focus groups interviews, an empirical research methods that is particularly adapted to revealing the underlying factors that shape public attitudes. A total of 55 focus groups were organised, between 1998 and 2000, in the five participating countries: United Kingdom, Spain, Italy, France and Germany. In addition to the focus groups, the researchers conducted interviews with the key actors and organised several workshops with stakeholders in the debate.

Main results

The main conclusion from this study is that most stakeholders in the GM debate misunderstand public responses to GMOs, and that this represents one of the key underlying causes for the current impasse in the GM debate. Almost all popular opinions on the alleged misperceptions about the alleged view of “the man and woman on the street” turned out to be simply myths.

Characterisations of public responses to GMOs in decision-making circles are typically framed either in terms of a lack of knowledge - prompting moves to educate the public - or of 'non-scientific' 'ethical' concerns - resulting in the appointment of expert ethical advisers or public consultations about the social acceptability of GMOs. This study shows that these dominant characterisations of the public, and the policies which derive from them, do not capture the full nature of public concerns, nor do they recognise the social, cultural and institutional factors shaping those concerns. The research reported here reveals a more complex picture, in which the distinctions often made between 'real risk' and 'perceived risk', between 'risk' and 'ethical' concerns, or between 'scientific' and 'non-scientific' concerns, are blurred. The PABE study not only highlights the dynamics of societal concerns but also traces them back to the problems inherent in official views of the public and its perceptions of technological risk.

Two types of results about public perceptions of GMOs are presented in the report:

Perceptions of GMOs among ordinary citizens were studied using focus groups held in five EU Member States: France, Germany, Italy, Spain and the United Kingdom (a total of 55 sessions).

Perceptions of public responses to GMOs among stakeholders (actors engaged in the GMO controversy) were studied using interviews, participant observation and document analysis.

The comparison of these two types of results sheds new light on the subject of public perceptions of GMOs. *It reveals the persistence of a number of entrenched views about the public shared by numerous policy actors which are not supported by our analysis of the views of ordinary citizens as expressed in the focus groups.* This has important policy implications, because these mistaken interpretations of public perceptions play an influential role in shaping the communication strategies and policies of decision-makers in government and business, as well as in consumer and environmental NGOs. Thus, policies continue to fail to respond adequately to public demands, and therefore fail to resolve or advance the debate. New policies and strategies - even if they are innovative and sincerely seek to integrate public views - are likely to fail if they continue to be based on these entrenched misrepresentations of the public.
In these circumstances, it seems to us that the most positive contribution from this research on public perceptions of GMOs is to reveal and analyse the gulf found between stakeholder views of the public, and public views as expressed in our focus groups.
The study concludes by identifying as a priority the need for a broad based cultural change in policy thinking about public perceptions of science, technology, and risks. Policy makers should be prepared to consider that the source of the problem is not only to be found in the behaviour of the public but also in the behaviour of institutions responsible for creating and managing innovations and risk. This seems to us the most urgent imperative for the development of a more constructive and satisfactory debate on agricultural biotechnologies in Europe.

Key findings

The complete final report is available in the above-mentioned website. The following key findings have been included and extensively developed in the report:

1. Overwhelming similarity of focus group findings across countries, groups, and time
2. Identification of underlying factors that shape public responses to GMOs
3. Dominant stakeholder views about public responses to GMOs:
4. The focus group results challenged these 10 myths in the following ways:
5. Misconceptions about Trust

Partners

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I. PROJECTS FUNDED UNDER THE 4TH FRAMEWORK PROGRAMME (1994- 1998)

ii) BIOTECHNOLOGY PROGRAMME:

- Ethical, Legal and social aspects (ELSA)

MORAL COMPETITIVENESS OF BIOTECH COMPANIES: BIOETHICS AND COMPANIES

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Duration:	12 months	
EC contribution:	30.000 €	
Website: http://www.stb.tno.nl		

Introduction

In the debate about the ethical aspects of biotechnology, most, if not all attention has been focused on ethical thinking in society - mainly from the perspective of public acceptance of biotechnology and on the role of ethical arguments in this respect. The ethical opinions in general in society - and more specific of consumer groups - on biotechnology and biotechnological products and the differences in national cultures in relation to public acceptation, have been the subject of a number of national and EC studies. This is, however, with respect to the ethical aspects of biotechnology, only one part of the framework, which should be looked at. Especially with respect to the competitive position of European biotech companies, it is necessary to complement these insights and knowledge about ethical thinking in society ('the public'), with new insights and knowledge about how biotech companies think and act in relation to the ethical aspects of biotechnology. The central issue in this project is the so-called 'Moral Agenda' of biotechnology companies..

For that reason a project has been formulated with the goal to gather information about the 'moral agenda' of biotechnology companies, to present this information and, on the basis of this information, to formulate recommendations to the EC about the ethical bottlenecks companies come across and which endanger their (inter)national competitive position.

Objectives

The objective of this project was to get an answer to the following two questions:

which issues are on the moral agenda of biotech companies?

do these issues and their related ethical activities match with what society and the government expect them to do?

The items on the moral agenda relate to subjects that have an ethical aspect. It can be old and settled subjects, but also new and not yet discussed subjects. Some items may have a direct relation to biotechnology activities of the company others may not. Moral agenda must be interpreted in such a way that it includes issues as meeting the requirements of the ethical regulations, the installation of an Ethics Committee inside the company, but also the organisation of lunch session about the ethical aspects of biotechnological research in a company. An important aspect that directly relates to the moral agenda is the moral view of biotech companies, of their employees of a company. Each company has - implicit or explicit - a moral view: this is the opinion of the company about their moral responsibility.

Companies behaviour is more or less determined by their 'external environment', this means by the national and international cultural, economic and social setting in which they operate. For the purpose of this project the most relevant parts of this setting are the public debate in the Member States - the ethical thinking in a country - and the national and international regulations with respect to the ethical aspects of biotechnology.

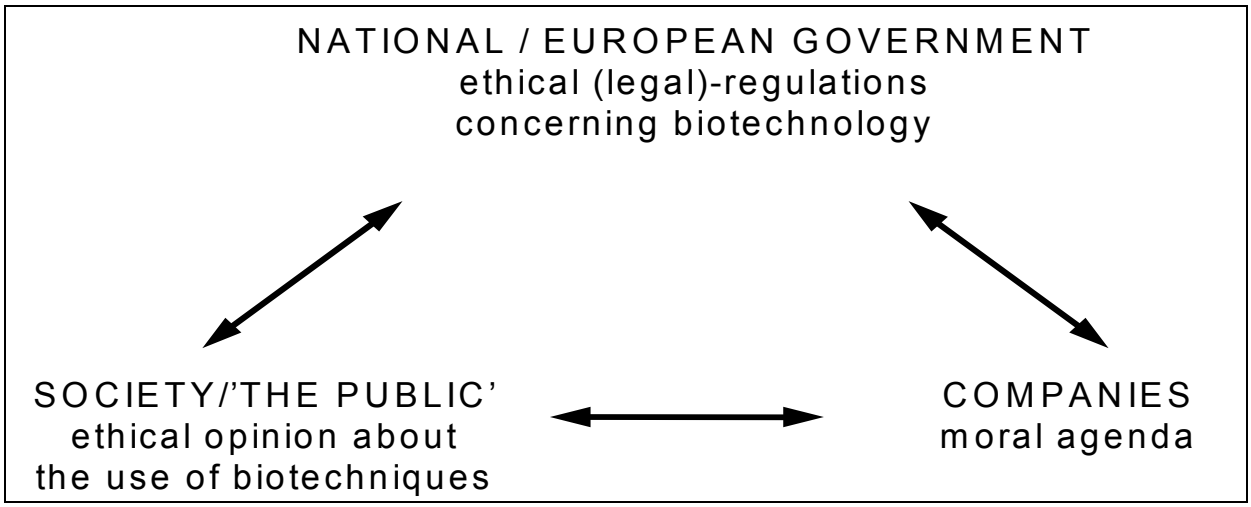
The main goal of this project is to give a first exploring overview of the issues on the moral agenda of biotechnology companies and how these issues relate to the national and international environment of these companies.

Methodology

The methodology was twofold. In order to collect the information to give an overview of the moral agenda of biotech companies, a questionnaire was developed and on the basis of this questionnaire interviews were made with representatives from 10 European biotechnology companies. Second, in order to relate this agenda with the external environment, information was collected from reports, publications in journals and from organisations in the field.

Main results

The ethical activities of companies can be interpreted as belonging to an interactive system. This system contains two other groups of actors that are important for the moral competitiveness of companies: the government in setting the rules in regulatory regimes and the public in having moral views on the use of biotechnology and as consumers of biotechnological goods and services.



The moral agenda of companies is made up in three ways. First, new issues on the Moral Agenda of companies are raised as a direct reaction to the activities of the other two actors. For instance, the company has when it is performing specific biotechnological research to address itself to national or European regulation dealing with the several aspects of the use of biotechnology.

Another case is when activities of social groups directly concern the companies' activities or products (for instance: field releases, the introduction of new products, etc.). The company will formulate an opinion on this and react.

Second, the company's moral agenda contains issues that are raised as an indirect effect of the activities of these two groups. Such effects can be formulating an ethical statement or setting up a professional code.

In the third case, issues are brought forward because the company has the opinion that it has a social responsibility in relation to its processes and products. This responsibility reaches beyond the direct product qualities. It also includes aspects as responsibility with respect to sustainable development (the Body Shop is an example), and even more cultural assets (sponsoring of sports clubs, TV-plays, etc.).

Detailed conclusions have been presented in the final report (see website) as regards:

interaction between the public and companies,
interaction between the government and companies,
interactive system: government – companies – society.

Recommendations

Companies are distrusted as information source all over Europe (Eurobarometer, 1997). This distrust against companies cannot be overcome with more information from the companies. Instead, companies can only improve the way they are viewed upon, through working on their own values and norms. With the primary goal of clarifying them for themselves, i.e. for the people acting in the name of the company. The idea is that clearly defined corporate values and ethical principles would in fact serve as a common guide to decision-making within the company. This, in turn, would enable external stakeholders (the consumers, but also other institutional actors) to better evaluate the company's choices enhancing the understanding of both the scientific, the economic and the moral rationale behind them.

It is therefore recommend that biotechnology companies start to make their own moral codes more explicit, undertaking such a process in a transparent way, and being open to dialogue with concerned stakeholders, such as consumers, citizens and environmental groups, the scientific community, regulatory bodies and the media.

In order to overcome the strict virtue-ethical or deontological judgement of the public, companies could give other actors a role in the communication with the public. This can be done by intermediate organisations. Another possibility is to invite consumer, environmental or other issue-organisations in the company and to start low profile interaction (as practised by Novo Nordisk in Denmark). However, they should keep in mind the virtue-ethical judgement mentioned above. Starting communication is something they cannot do on their own: 'it still takes two to tango'.

The fact that companies do better communicate with governmental bodies for instance in the process of developing regulations, than with the public, suggests that companies make the same mistake as the regulators. This is to say that a mismatch between concerns on risk and safety of companies and the public moral questions may be the cause for the lack of communication between public and companies. Therefore it is recommend that - given the need and explicit wishes of companies to communicate -, further research on the causes for this difference in communication is needed. This research should focus on different conceptions of risk and different conceptions of morals in the companies, in issue-groups and in regulatory bodies.

The attitude towards biotechnology differs strongly over countries. Also the differences in national debate on biotechnology are surmount. Companies' behaviour strongly reflects their social and cultural environment (at least on the point of morals). This means that the differences in moral competitiveness between companies are also (caused by) differences between national cultures and that moral competitiveness of companies is strongly influenced by the national culture. Companies should keep these differences in mind when they try to start communication processes in other countries. This also means that when biotech companies want to implement the EuropaBio principles of dialogue and communication they should adopt it to the characteristics of the national debate on biotechnology.

Partners

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MOSAICC: ELABORATION AND DIFFUSION OF A "CODE OF CONDUCT" FOR THE ACCESS AND SUSTAINABLE USE OF MICROBIAL RESOURCES WITHIN THE FRAMEWORK OF THE CONVENTION OF BIODIVERSITY

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Duration:	18 months	
EC contribution:	200.000 €	
Website: http://www.belspo.be/bccm/mosaicc/docs/summary.pdf		

Introduction

Objectives

The objectives of the MOSAICC-project is to draw up and to promote a consensual Code of Conduct that will serve as a model contract. The MOSAICC Code of Conduct will contain model forms and practical procedures to implement the provisions of the Convention on Biological Diversity for the access to microbial resources, the transfer of technology and the equitable sharing of benefits.

Easy access to and international circulation of microbial resources are crucial to ensure sustainable development in the industrial and developing countries as foreseen in the Convention on Biological Diversity (CBD, Rio de Janeiro, 5 June 1992). The CBD regulates, among other things, in general and in non-operational terms, the access to genetic resources (art. 15), the transfer of technology (art. 16,18 & 19) and the equitable sharing of benefits (art. 15 & 19).

Microbiologists, dealing with microbial genetic resources from all over the world, are obliged to implement these CBD-provisions in their day-to-day activities. Especially culture collections and industries are in need of practical procedures that further enable easy access to and international circulation of those resources. There is a need for a Code of Conduct dealing with these different matters in a pragmatical and operational way, while fully complying with the rules of the CBD and other international conventions (art.22).

The objective of the MOSAICC-project (Micro-Organisms Sustainable use and Access regulation International Code of Conduct) is to draw up and to promote such a Code of Conduct which will represent a consensus obtained between a balanced group of representatives from North and South, coming as well from the non-profit sector (e.g.

government, culture collections, academics, NGOs) as from the commercial sector (e.g. pharmaceutical, chemical and food industry).

The MOSAICC Code of Conduct will serve as a model contract, including model forms of e.g.: Prior Informed Consent-form, Mutually Agreed Terms (MATs), Biological Material Transfer protocol, Biological Material Transfer model-forms, etc. It will provide European culture collections and European industry with the necessary toolbox to deal with the CBD-provisions. First, it would be applied on a voluntary basis by European culture collections and industries. In a second stage this Code of Conduct should be presented at the Conference of Parties (COP) of the CBD with a view to its wider discussion with other countries. MOSAICC will be widely disseminated, both in printed and electronic (Internet) form. Finally, the MOSAICC code of conduct could become some kind of an 'operational standard'.

Main results

The complete report is available at the website. The following elements can be extracted from the report:

MOSAICC stands for «Micro-Organisms Sustainable use and Access regulation International Code of Conduct».

· It is a tool to support the implementation of the CBD at the microbial level, in accordance with other relevant rules of international and national laws. It can serve as a model when dealing with genetic resources other than microbial genetic resources (MGRs).

· It is a voluntary Code of Conduct.

· Its purpose is twofold :
to facilitate access to microbial genetic resources (MGRs) and

to help partners to make appropriate agreements when transferring MGRs.

· It is subject to the relevant rules and provisions stated in :
- the Convention on Biological diversity (Rio de Janeiro, 5 June 1992) especially the terms dealing with :
- Prior informed consent regulating access to resources (Art. 15.1 & 15.2)
- Mutually agreed terms on transfer of Microbial Genetic Resources (Art.15.4 & 15.7)
- the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure (28 April 1977, amended on 26 September 1980 and Regulations);
- other applicable rules of international and national laws.

· It combines :
- the need for easy transfer of MGRs
- and the need to monitor the transfer of MGRs

This is necessary because access to MGRs is a prerequisite for the advancement of microbiology. Furthermore, monitoring the transfer of MGRs is necessary to identify the

individuals or groups that are entitled to be scientifically or financially rewarded for their contribution to the conservation and sustainable use of the MGRs.

- Its operating principles are
  a) identification of the origin :
     – *in situ* origin of the MGRs is identified via initial **Prior Informed Consent** (PIC) procedure providing authorisation for sampling;
     – *in situ* origin of the MGRs is always mentioned when transfer occurs.
  b) monitored transfer of MGRs occurring under **Material Transfer Agreement (MT**A) the terms of which are defined by both recipient and provider.
     Material Transfer Agreement (MTA) is a generic term that can cover either a very short shipment document, a simple standard delivery notice, a standard invoice containing minimal standard requirements or a more detailed specific contract including tailor-made mutually agreed terms. All these documents can be designated as MTA as long as they contain at least :

information about the *in-situ* origin ;

information about provider and recipient ;

mutually agreed terms defined by two main criteria : the **use** of MGRs (test, research, commercial use) and the **distribution** of MGRs. According to the use and intended distribution of the MGRs, mutually agreed terms can be either short or very detailed.

Partners

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SAFETY REGULATION OF TRANSGENIC CROPS: COMPLETING THE INTERNAL MARKET?

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Starting date:	1.10.1997	
Duration:	24 months	
EC contribution:	141.100 €	
Website: http://www-tec.open.ac.uk/cts/bpg.htm **Contact person:** Mary Mc Vay Centre for Technology Strategy The Open University UK - Milton Keynes MK7 6AA Tel.: 44.1908.653672/652103 Email: M.McVay@open.ac.uk		

Introduction

This EU-wide study investigated the safety regulation of genetically modified (transgenic) crops over the period October 1997 to late 1998, in the framework of Directive 90/220, governing the deliberate release and marketing of genetically modified organisms (GMOs). This period coincided with an important new phase for GM technology in Europe, with GM crops being commercially grown for the first time (Bt maize in Spain and France) and GM ingredients beginning to enter the food chain from commodities imported from the United States. Bt maize and soyabean were first imported in late 1996 and early 1997.

Regulators and politicians of EU member states had been working out ways around their initial disagreements over the implementation of Directive 90/220, yet they were suddenly faced with an unprecedented level of mass-media interest and public anxiety. In response, many major food retailers (and subsequently food processors) undertook to exclude GM ingredients from their own-brand products, as a way to maintain consumer trust. These factors lay beyond the regulators' control but affected their decision making.

This study focused on safety regulation, especially on decision-making processes associated with Directive 90/220. For that reason, significant issues such as the role of the media, campaigners, public attitudes and consumer trust are discussed only insofar as they affected the decision-making processes.

Objectives

The study investigated the role of safety regulation in governing the commercial use of GM crops. Its aim was to inform policy debates on the most appropriate form of safety regulation, given the European Commission's aim of harmonising GM regulatory criteria across the European Union so as to complete the internal market. The study took as its objectives the four main objectives of DGXII's biotechnology programme on the ethical, legal and socio-economic aspects (ELSA), namely:

(i) to clarify how ethical, social and legal issues are taken into account in regulatory decisions on GM crops, so that the procedure may be improved;
(ii) to promote an informed dialogue among the key players in public debates on how to regulate GM crops;
(iii) to suggest how risk-assessment research could better inform regulatory decisions; and
(iv) to suggest how regulatory expertise could be appropriately broadened to encompass public and scientific concerns.

The main focus of the study was the safety regulation of GM crops, but the regulation of imported GM food and feed was also investigated as possibly setting precedents for European products in future.

Methodology

The key research issues and a common framework for the research were agreed at a two-day meeting of the research partners held towards the beginning of the study. A second two-day meeting was held mid-way through the study to discuss the main findings and the draft national reports. National reports were based on documentary evidence and interviews. The EU-level legal report drew on the national reports as well as on legal documentation.

In March 1999, towards the end of the project, the coordinators organised a policy workshop in Brussels with key stakeholders and research partners. Participants discussed the practical implications of possible statutory changes to GM regulation in relation to three scenarios: the revision of Directive 90/220, the abolition of the directive, or the imposition of a moratorium. The main aims of this workshop were to contribute to dissemination of the research findings, and to obtain feedback to inform this final version of the EU-level report. This EU-level report draws on the ten national reports and the legal report, as well as on interviews with more than 30 individuals involved in the regulatory procedure at the EU level.

At their first meeting, in October 1997, research partners agreed that four issues were likely to be key to this new phase of GM regulation, namely: commercialisation, precaution and, to a lesser extent, predictability and acceptability. Acceptability in this case denoted the preconditions for a product to be permitted for sale and cultivation at all, rather than consumer willingness to buy it (as studied in market research).

These four issues were linked with the six main aspects of the study outlined in the research proposal (regulatory boundaries, normative judgements, risk-assessment research, labelling practices, a European market, and links to pesticide regulation) to provide a conceptual framework for the study, as shown in the Figure. The relative position of each concept is intended to indicate how closely linked the research team considered the concepts to be, at the outset of the study.

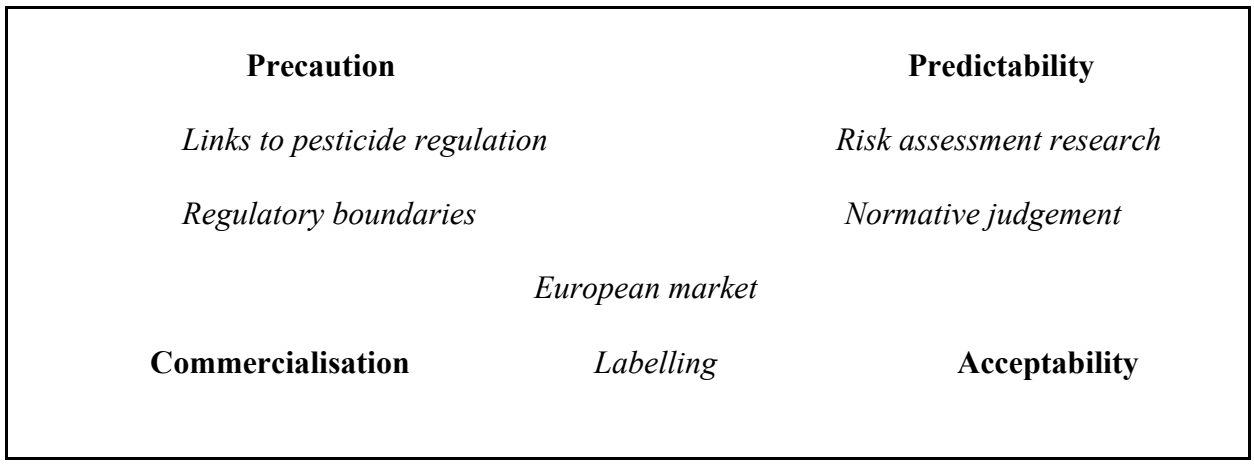

Figure: A conceptual framework for the research

The EU-level and national reports are all structured around the six aspects just mentioned, to aid comparisons.
Each national study was informed by the following set of questions:

- In what ways does commercialisation affect the precautionary approach to GM crops?
- How does each country respond to the commercialisation process?
- How does regulation adapt and respond to commercialisation?
- In what ways does commercialisation open up (or close) issues of predictability and acceptability?
- How do various actors articulate the relationship between predictability and acceptability?
- How are the various organisations and actors anticipating, accommodating or marginalising public concerns?

Main results

The late 1990s were characterised by unprecedented mass-media coverage and public concern about genetically-modified (GM) crops and the food derived from them. Highlights from our research can be summarised as follows:

- By the late 1990s, the European Commission had approved several GM crops for commercial release throughout the EU. Regulators had assessed these crops as safe, judging that any undesirable effects would be no worse than those of conventional products.
- The public protest against GM crops and food that erupted in 1997 challenged the basis of those approval decisions. In response, regulators delayed further commercial approvals and introduced additional precautionary measures.
- Concerns that had previously been raised by a minority of Member States during the EU risk-assessment procedures became more mainstream. Precautions initiated by companies and individual member states became examples for others to follow, some being officially incorporated into the regulatory procedure or into its proposed revision.
- The findings suggest that minority views and independent initiatives should not be viewed simply as deviations from the path towards harmonized regulation, but as important signals and sources of ideas for ganing wider legitimacy for regulatory decisions.
- In effect, GM crops have become a testing ground for several wider issues :

- how to interpret and apply the precautionary principle in practice
- how to devise an EU-wide regulatory approach that accomodates national differences
- how to set environment standards for the sustainable development of European agriculture.

These policy implications can be also extracted from the final report:

As genetically modified products approached the marketing stage in Europe, the uncertainties increased rather than decreased, causing renewed controversy. The idea of a linear progression, with precaution leading to increased predictability, which in turn would make GM crops more widely acceptable and allow them to be marketed just like conventional products, turned out to be inappropriate. Further precautions had to be introduced in response to heightened concern, affecting not only food products but also crops, field trials and the genetic modification process. With the benefit of hindsight, it is possible to see at least three factors that impeded commercialisation. One concerns the outvoting of minority views among regulators and their advisors. Another concerns the narrow range of expertise considered relevant to risk assessment. The third concerns the restricted involvement of stakeholders. These three factors are examined to draw out their implications for future policy.

Minority views

Most of the issues that later caused public controversy, and led some governments to alter their policies at the market stage, were evident earlier as objections raised by a minority of Competent Authorities. Such issues include: labelling, antibiotic resistance, indirect effects, and the impacts of changed agricultural practices. These objections were initially over-ruled or outvoted. The lesson for future policy is that minority views can provide valuable indications of matters that may subsequently be seen as important or that are widely shared by another audience. Even if they are regarded as beyond the remit of regulatory risk assessment, they should be assigned to another arena for further discussion and feedback rather than being over-ruled.

An example that is central to the current public controversy is the appropriate baseline for judging the acceptability of environmental impacts. This is likely to become a more pressing issue as regulations on pesticide use tighten and as international agreements on biodiversity and sustainable development become more relevant to agricultural policy. There is an urgent need to review the baseline for risk-assessment judgements in relation to possible future agricultural strategy.

Appropriate expertise

A related factor concerns the limited range of expertise drawn on by some competent authorities. Involving a limited range of disciplines on advisory panels, for example molecular biologists and geneticists, makes consensus easier to achieve, since these experts share the same language and theoretical models. However, a narrow disciplinary base limits the range of uncertainties that are considered in risk assessment. Difficulties arise when decisions are subsequently challenged by experts from other disciplines who use other models, for example ecologists, or by Competent Authorities who draw on other expertise.
Even when ecologists are consulted, official advisors may take for granted their own baseline for judging what potential effects are acceptable or relevant. This compounds the difficulties when the experts' decision is presented to a wider, public, audience in each member state. Even though this audience may respect the scientists' professional knowledge, it may not share their value judgements about the acceptability of potential effects. To address the controversy about genetically-modified crops, with its contending accounts of the relevant uncertainties, there is a need to ensure all competent authorities consult a similarly wide range of disciplinary and inter-disciplinary expertise.

The Commission has sought to reduce the political aspects of risk-assessment decisions by establishing EU-level scientific committees, less susceptible to the domestic political pressures of individual member states. However, there is a need to acknowledge that such committees can never be completely neutral towards the agricultural context and the public debate. Decisions about genetically-modified crops, while they need to be science-based, are inevitably political.

Involvement of other stakeholders

This leads into the third point, concerning the involvement of other stakeholders. Judgements about the acceptability of potential impacts need to involve a wider constituency than the competent authorities, their scientific advisors and the biotechnology companies. For example, such judgements should incorporate the views of users such as farmers, food processors and retailers, as well as consumers. Some member states have well-established procedures for incorporating the views of other stakeholders. In Denmark, parliament takes up queries raised by the electorate with the regulators.

Elsewhere, other mechanisms are being tested. The UK is establishing an Agriculture and Environment Biotechnology Commission to provide an input to policy from a wider range of stakeholders. In France, non-governmental organizations and seed companies are being given a bigger say, e.g. through inclusion in a Biovigilance Committee to evalute market-stage precautions. While labelling provides end-users with some degree of choice, this is only after all the important decisions have been taken. Costly delays and the rejection of marketed products might be avoided if end-users were involved at a much earlier stage. This would not only help inform companies'strategic decisions about product development but would also lead to better informed users.

When individual member states and companies develop precautions beyond those required by the existing EU-regulations, they provide valuable experience on which the EU-wide system can draw. In this respect, they are a resource, like the minority viewpoints. A democratic Europe can reach legitimate decisions about biotechnology only by acknowledging and

learning from the views of all member states and stakeholders, rather than allowing a partial view to predominate.

Policy workshop

In March 1999, the research team held a policy workshop in Brussels to provide feedback on the results and the preliminary conclusions. Participants included national regulators, biotechnology companies, officials from DGs XI and XII, food processors, and non-governmental organizations. To stimulate discussion about the best way forward in a non-threatening way, participants were invited to consider one of three possible scenarios: a moratorium on production, abandoning the directive, or amending it.

The discussion about amending the directive proved to be the most fruitful, since it allowed participants room for manoeuvre and to express a range of views. The likely consequences of a number of policy options were discussed, including allowing member states to opt out of growing certain crops, making companies strictly liable for their gm products, requiring post-market monitoring, and making the directive less flexible (see diagram).

The other two scenarios, being more extreme, tended to force people to adopt a particular stance for or against the scenario, reproducing polarised positions on the controversy and inhibiting the expression of alternative views. Even so, some valuable points emerged. For example, the initial view was that a moratorium was unlikely since the Commission had already ruled it could have no legal basis. After some discussion it was agreed that, despite this ruling, there were several ways in which a moratorium might come about and a number of forms it could take. Discussion of the impacts led several participants to conclude that in the long run a moratorium might increase public acceptance of gm products rather than halt the technology altogether. Discussion of abandoning the directive led participants to conclude that, despite the difficulties of reaching agreement, member states did share some common ground. If the directive was abandoned, and each member state imposed independent regulations and standards, they would be more susceptible to pressure from the World Trade Organisation. The costs of seeking market approval separately in each country would be prohibitive for smaller companies.

Publications

Full report is available at http://technology.open.ac.uk//cts/srtc/index.html

The Executive Summary, *EU Safety Regulation of GM Crops*, is available in print from the Biotechnology Policy Group, email Technology-BPG@open.ac.uk

Other publications from the project include the following:

Carr, S. and Levidow, L. (1999) 'Negotiated science: the case of agricultural biotechnology regulation in Europe', in U.Collier, G.Orhan, M.Wissenburg, eds, *European Discourses on Environmental Policy*, pp.159-72, Aldershot: Ashgate Publs.

Levidow, L. (1999) 'Regulating Bt maize in the USA and Europe: a scientific-cultural comparison', *Environment* 41(10): 10-22

Levidow, L. and Carr, S., eds (2000) 'Precautionary Regulation: GM Crops in the European Union', special issue of the *Journal of Risk Research* 3(3): 187-285 [includes articles on several member states], http://www.tandf.co.uk/journals/authors/r-authors/jrrspecialissue.html

Levidow, L. and Carr, S. (2000) 'Environmental precaution as learning: GM crops in the UK', in LEARN Group, eds, *Cow Up a Tree: Learning and Knowing for Change in Agriculture: Case Studies from Industrialised Countries*, pp.323-35. Versailles: INRA.

Levidow, L. and Marris, C. (2001) 'Science and Governance in Europe: lessons from the case of agbiotech', *Science and Public Policy* 28(5): 345-60.

Levidow, L. (2001) 'Precautionary uncertainty: regulating GM crops in Europe', *Social Studies of Science* 31(6): 845-78.

Carr, S. (2002) 'Ethical and value-based aspects of the Precautionary Principle', *Journal of Agricultural and Environmental Ethics* 15(1).

Partners

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THE SOCIO-ECONOMIC IMPLICATIONS OF BIO-PESTICIDES

Contract No. :	**BIO4-CT97-2363**	**Coordinator:**
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Starting date:	1.11.1997	
Duration:	12 months	
EC contribution:	50.000 €	
Website:		

Introduction

Objectives

(i) to assess the implications for long term biological efficacy of the current EU regulations and market structures and intellectual property rights for biopesticides;

(ii) to assess whether the EU regulations, markets and legal protection for new biopestides could be restructured so as to enhance the longterm biological efficacy of bio-pesticides, and if so, propose suitable changes;

(iii)to assess the implications of possible alternatives to the current regulations, market structures and property rights for the long term biological efficacy of genetically engineered biopesticides as well as traditional biopesticide methodologies;

(iv)to assess whether a consensus exists regarding regulatory, market and property rights measures that could increase the long term biological efficacy of genetically engineered biopesticides.
The project proposes focusing on Baccillus thuringiensis (Bt) because it is currently the most developed biopesticides, it has a long history of traditional use, it has been bred in many forms and it has also been engineered into a number of field crops. Bt is used in integrated pest management (IPM), integrated crop management (ICM), organic and genetically engineered (GE) approaches to pest management and the GE versions are about to reach the European market. The implications of the detailed study of Bt will be applied to the broad range of biopesticides in existence and in the pipeline.

Methodology

The project reviews the relevant literature in English, French, German and Spanish, interview stake-holders in Sweden, the UK, the USA and Spain and discuss the issues with officials of DGXII, DGXIII, DGVI and DGIII of the European Commission. Stake-holders in France and Germany will be questioned. A European Workshop on Bt has been organised with contributions from all major stake-holders.

Main results

The final report includes an overview of the project, containing the following chapters:

Chapter 1 : introduction, including a reference to regulations

Chapter 2 : History of science presents a chronological history of the scientific discoveries concerning Bt, including the emerging problem of insect resistance.

Chapter 3 : **American Politics** reviews the debates that have been held in the USA regarding the regulation of Bt crops over the past 10 years.

Chapter 4 : European politics reviews the European situation, where only Bt maize has been commercialised to date, mainly in Spain and Portugal but also in France and Germany. The European regulation of Bt crops is weak, incoherent, confused and inadequate by comparison with the policies adopted by the Environmental Protection Agency in Washington. One particular problem in Europe is that the use of Bt sprays is dealt with by one set of administrators working under the terms of the Pesticide Directive, whilst the use of Bt plants is dealt with by an entirely separate set of administrators working under the terms of the Directive on the Release of GMOs (Dir1990/220). The revisions to Dir 90/220 that have now been agreed might improve slightly the ways in which Bt crops are approved and managed in the EU but the revised directive is incapable of managing the sustainable use of biopesticides. It also include **future scenarios** as regards the future and management of Bt crops in Europe.

Chapter 5 covers remaining questions such as intellectual property rights, regulations, market restructuring and the need for a moratorium.

Partners

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THE FUTURE DEVELOPMENT IN FARM ANIMAL BREEDING AND REPRODUCTION AND THEIR ETHICAL, LEGAL AND CONSUMER APPLICATIONS

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Duration:	12 months	
EC contribution:	106.997 €	
Website: **http://www.sefabar.org** **http://www.faip.dk**		

Introduction

Industry is on the threshold of new biotechnological developments in farm animal reproduction and selection. These technologies may raise questions that involve society. This project aims at making new developments in farm animal breeding and reproduction more transparent for both industry and consumers. Farm animal breeding industry and specialists in ethics, legal affairs and consumer affairs will give an overview of the bree-ding developments and their ethical, legal and consumers' implications before the tech-nologies are developed or applied.

The project is a survey based on expert opinions, informed by literature studies and dia-logues with informed key persons.

Representatives of the breeding industry will together with scientists describe the past, present and expected developments for their industry, including the time scale and expec-ted technical and competitive impact of the developments.

Based on these descriptions, the ethical, legal and consumers' specialists will make an overview of the expected advantages, constraints and sensitive areas in their field. Where this is possible, procedures and strategies to handle sensitive issues and legal and politi-cal conditions will be proposed.

The partners will present and discuss their results at a workshop, where industry, scien-tists and extended audiences will be invited: consumer groups, animal welfare and envi-ronmental groups, Europarlemen-tarians and Commission representatives. The results of the project and the workshop will be distributed among industry and science, consumer, welfare, agricultural and political organisations, the European Commission and national governments. The project fulfils a prospective role, anticipating problems and providing early warnings for ethical, social and legal implications of biotechnology in farm animal reproduction and

selection. It may also help breeding industry, consumers and politicians in making well informed decisions and in having well structured discussions for a controlled imple-mentation of these techniques into practical breeding work.

Main results

The issues surrounding developments in farm animal breeding (cattle, sheep, pigs, poultry and fish) are ones in which the public has a real stake: new reproduction and selection technologies like transgenesis and cloning, but also undesirable side effects of high production in farm animals. Furthermore, food production has moved from being supply side driven to consumer driven. Farm animal reproduction and selection, on the outermost begin of the food production chain, has to deal with this new situation in which awareness about the demand of the consumer, and the license to produce of society play a considerable role, at least in Europe. There is a growing need for rational debate among producers, consumers and policy makers and for decision-making based on technological, economical and societal information. This project has worked out a picture of challenges and future scenarios in farm animal breeding and the possible societal merits and constraints.

Breeding and reproduction

The first step in the breeding of farm animals involves the definition of a breeding goal: what kind of cattle, pigs, poultry or fish is desired? The following steps in the process are the selection of those animals that describe best this goal as future parents and the reproduction of the animals. Breeding companies and cooperations do this work for the farmers. Further globalisation of breeding, increase of the size of farms, improved computing facilities, (bio)technological developments, sustainable product-ion and biodiversity will influence the structure and content of breeding. Three future scenarios – conventional, alternative and low cost – are represented. Each with consequences for production costs, uniformity of breeding goals and balanced breeding, and with possibilities for or likeliness that certain (bio)technologies will be applied. For example, heat induction may be an ideal instument to guide reproduction in low input areas, but does it reflect the ideas of the customers of organic agriculture products?

Ethics

Society – both consumers and producers – has an ethical responsibility towards breeding and reproduction. What is it that people are concerned about? On the one hand there are concerns towards animals, humans, the environment or biotechnology itself: unintended negative side effects of breeding and (bio)technologies can be in conflict with animal welfare and animal integrity. Humans are concerned about the possible effects of new developments on their own health and welfare, on genetic diversity and the environment. Furthermore, they question biotechnology itself. On the other hand the positive applications represent an obligation not to dismiss these options. Methods to weigh the concerns and the possibilities are outlined to help working towards acceptable solutions.

Law

Developments in farm animal breeding and biotechnology have legal consequences. The impact of the new patent law on production methods, marker assisted selection, the patentability of animals and of animal genes has been analysed. The potential problems associated with patents are outlined: the risk of competition between patent holder and breeder, the research exemption, effects of broad claims or patents on biotechnological processes, the impact of the farmer's privilege and the traceability of genetically modified

animals. Furthermore, animal welfare legislations will influence breeding (developments) more and more. Case-by-case assessment seems to be a workable option.

Consumer
Breeding farm animals seems far away from the consumer. However, consumers have clear opinions about the genetic modification (GM) of animals. Animal welfare is a concern, but so is the price and quality of the product. Benefits should be evident to consumers before novelties get accepted. GM of animals, at least for food production, is expected to raise a lot of opposition. However, even if animal breeders will not GM or clone their animals, they may expect to meet negative publicity of GM/cloned animals for medical purposes: the general public will not make the distinction. Awareness about consumers is important, even if their behaviour is not very predictable at large. Contacts with animal welfare organisations are important. The concerns of society deserve serious consideration.

Workshop
The framework of possibilities and concerns was represented and discussed before an audience of industry, scientists and representatives from society at 3 June 1999 in Utrecht, The Netherlands (http://www.faip.dk/breesoc.htm). The workshop was opened by Sally Keeble UK MP, who put the role of farm animals in society in perspective. The vice-chairman of the Farm Animal Welfare Council added economical considerations on welfare to the picture. A lively discussion on all these presentations and project results took place. The scene has been set. Breeding industry learns about the concerns and wishes in society, and brings its questions and possibilities to the public. Developments continue. The dialogue, necessary to build understanding and to finetune the activities of both consumers and breeders, should continue. More detailed information about the exact wishes of society, the cultural differences within society and between North/South Europe, the possibilities of breeding industry and research to address society demand, the legal, economical and global framework and the involvement of animal welfare representatives will help the realisation of a further, informed dialogue.

Conclusions
The information of the project is disseminated to scientists and industry managers as well as to politicians and societal groups (a.o. consumer, animal welfare and farmers organisations) in order to make farm animal breeding and reproduction more transparent. The report of the project is used to educated students in animal breeding. Furthermore, a brochure on the project explaining animal farm breeding and the main ethical, legal and consumer items, in 12 European languages has been disseminated within the animal and food sector and among policy makers. Clearly, it is important to continue the discussion on societal aspects of farm animal breeding and reproduction. The opinion in society and the (potential) possibilities in farm animal breeding and reproduction are changing continously. Also, there is a need for clear, economically sound and society accepted farm animal breeding prospects in Europe, based on mutual discussion. However, more ethical and animal friendly breeding alternatives need to be worked out into detail because of the unknown economic aspects and the social risks of these pathways. **See follow-up project SEBABAR under 5th FP.**

Partners

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PLANT INTELLECTUAL PROPERTY

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Starting date:	1.10.1998	
Duration:	24 months	
EC contribution:	356.500 €	
Website: The results of the project, together with the proceedings of the International Conference on Plant Intellectual Property within the European and Global Context held in 2001, have or will be published: a) **on the project website** http://www.shef.ac.uk/uni/projects/pip and b) by Hart Publishing Ltd 2002 **Website:** http://www.shef.ac.uk/~pip/		

Introduction

The project sought to identify the views of the European plant breeding industry, (SMEs and multi-nationals) with regard to attitudes towards: a) existing EU plant intellectual property protection; b) the potential impact of the Directive on the Legal Protection of Biotechnological Inventions c) the proposed Review of Article 27(3)(b) TRIPs in 1999 (the optional exclusion of plant varieties from patent law) and d) the results of the Review of Article 27(3)(b) post 1999. The findings are that whilst the majority of plant breeders support the current plant variety rights system (with caveats relating to primarily essentially derived varieties, the research exemption and the cost of acquiring and enforcing the rights), the majority (most of whom fall within the Commission's definition of a Small to Medium Sized Enterprise) have little experience of the patent system making it difficult to assess the practical impact of the recent legislative changes. It is also relevant to note that the availability of effective and appropriate plant intellectual property rights in countries outside the EU affects the marketing decisions of many of the companies which responded. At the legislative level, whilst there has been concerted action to harmonise protection at the pan-European level, the national laws of most member states remain disparate. Very few have implemented the Directive on the Legal Protection of Biotechnological Inventions and less than half (6) have brought their plant variety rights legislation in line with UPOV 91. One member state, Greece, is not a member of UPOV.

Objectives

The project had three main general objectives:

- Objective 1 was to assess attitudes towards plant intellectual property protection from within the European plant breeding industry.

- Objective 2 was to examine whether existing European plant intellectual property provision provides a coherent and consistent framework of protection which is both effective and appropriate.

- Objective 3 was to look at European policy and practice, both at the EU and national levels, in the context of the review of Article 27(3)(b) of the Agreement on Trade Related Aspects of Intellectual Property Rights, which is ongoing at the World Trade Organisation .

Methodology

The central strength of the project was the interaction between the Partnership based on the diversity of backgrounds and expertise. These different fields of expertise provided a comprehensive framework against which the research was set. This inter-dependent involvement was seen by the Partnership, as the key to the success of the project for it helped ensure that there was coherence to the work. The focus, detail, objectives and outcomes of the Work Packages was determined by the Partnership and was implemented by the Researcher Co-ordinator based in Sheffield.

The focus of the project was the determination of the views of those using or affected by plant intellectual property. In order to ascertain these views a number of different methodological approaches were employed. The most important of these approaches was the literature/paper reviews of existing/proposed EU-wide and national legislation and, where possible, documented opinions/views on this legal provision. (This was necessary in order to provide a comprehensive background against which the views of the plant breeders could be placed)., Questionnaires which elicited these views; and analysis of these views in anticipation of future legislative developments were also part of the approach. The project sought to encompass both descriptive work and analysis. This was seen by the Partnership as a central strength of the project, as without one, the other would have been rendered effectively redundant.

Because the project spanned the whole of the EU, it encountered potentially diverse national laws, policies and practices. In order to provide the necessary perspective and experience the preliminary research work into national practices was undertaken on behalf of the Partnership by sub-contractors based in a number of EU member states. Each of these worked under the close direction of the Research Co-ordinator. The sub-contractors were Dr Geertrui van Overwalle of the University of Leuven (responsible for Belgium, the Netherlands and Luxembourg). Dr van Overwalle also served as general consultant to the project; Alexander Krefft of the MPI (responsible for Germany, Austria and Greece); Martin Ekvard, a Swedish intellectual property lawyer specialising in plant variety protection based in Stockholm (responsible for Sweden, Denmark and Finland); and Rosa Manjon Serrano, a Spanish intellectual property lawyer specialising in intellectual property law and biotechnology (responsible for Spain, Italy and Portugal). Information relating to the UK and Ireland was collected and analysed by the Research Co-ordinator, Dr Mike Adcock.

The work was carried out using two parallel research models:

The first was an empirical study of attitudes towards plant intellectual property protection within the EU plant breeding industry in all fifteen member states. The function of this study was to collect information relating to previous and current use of plant intellectual property

rights and to assess what changes, if any, the industry would like to see made to this provision. The methods used for collecting this information were two questionnaires, a Workshop, held in January 2000 and an International Conference (PIPWEG 2001), which was held in January 2001. Full details of the project findings, the Workshop and the Conference can be found on the project website: http://www.shef.ac.uk/uni/projects/pip

The second was an assessment of

i) the existing provision of EU plant variety protection at both the EU and national level;

ii) proposed/future European plant intellectual protection provisions (e.g. the draft EU Directive on the Legal Protection of Biotechnological Inventions, the proposed introduction of a Council Regulation creating an EU Patent and the proposed revision of the European Patent Convention); and

iii) the revision of Article 27(3)(b) which is taking place under the auspices of the World Trade Organisation. This was conducted via a paper/literature review.

The Questionnaire

The objective of the two questionnaires was to obtain information in respect of the following general areas:

the intellectual property needs of the plant breeding industry in light of the confluence of old and new plant breeding technologies and assessment of whether the existing provision meets these needs;

the practical impact and application on both the plant breeding (small scale, SME and multi-national) and farming communities, of new provisions in plant variety protection following the revision of the UPOV convention in the 1991 and the introduction of the Community Plant Variety Right regulations (EC 2100/94). These include: the extension of protection to essentially derived plant varieties and the revised farmers' privilege;

the actual or perceived impact of these practices on research and development within the plant breeding industry, on trade in plant material both at the national, EU and international level and on the farming community;

attitudes towards the review of Article 27(3)(b) and views as to the form that review should take.

In identifying those to whom the questionnaires were sent the Partnership was again uniquely placed. Through the involvement of SICASOV, which is part of the International Association of Plant Breeders, (ASSINSEL), it was possible to have direct access to national plant breeders unions in all member states of the European Union. Also, due to the close working relationship between the plant breeders unions and the farming community, access to farming unions was made possible. The Partnership also drew on its considerable number of contacts within the industrial and academic sectors in order to identify other individuals or organisations which could potentially be involved.

Main results

Approximately 2600 questionnaires (2100 first questionnaires, 460 second questionnaires) were distributed on the basis of the extensive database of names and addresses compiled by the sub-contractors. There was a 21% response rate for the first questionnaire and a 26% response rate for the second. The comparatively high response rate vindicates the time and attention which was paid to the substance and form of the questionnaire. The only country from which there were no replies was Portugal. Of the breeders who responded the majority from each country fell into the category of Small to Medium Sized Enterprise and, with the exception of the Netherlands, the main breeding activity is agricultural plant breeding. In the Netherlands, the responses from the agricultural plant breeding sector were second to the ornamentals and floriculture sector.

The views expressed were, for the most part, uniform across all countries. The most commonly used plant intellectual property right is the plant variety right and there is general satisfaction with both the right itself and with the administration of the right by granting office. Unsurprisingly the largest number of complaints with the system were directed at the cost of acquisition, although these must be tempered by the views of the majority of breeders that the cost was commensurate with the rights granted and was therefore acceptable. In terms of the type of right the majority of breeders still use the national systems, but there are clear signs that the Community Rights system is beginning to be preferred. The reasons for this are not clear but it could be due the scope of the right afforded in addition to the pan-European nature of the right once granted. Where there were concerns over plant variety rights these invariably related to the new provisions adopted as a result of the introduction of the UPOV Convention 1991 and in particular the 'essentially derived' and 'farm saved seed' provisions. These issues were discussed at length at both the Workshop and Conference and it appears that a general resolution will result via an ongoing dialogue between the breeders and the granting offices. In general the breeders were satisfied with the right at the EU and national level, but were concerned over protection at the international level and would like to see greater coherence in protection possibly via the establishment of a global plant variety rights office.

It is less easy to state the views of the breeders with regard to patent protection. In nearly all countries, the Netherlands being the exception, the majority of plant breeders had little or no experience of the patent system. In terms of sectoral experience the multi-nationals indicated experience of the rights although not necessarily in terms of the protection of plant material. This meant that in the majority of instances responses to the patent questions fell into the 'Don't Know' category. It was therefore not possible to draw a final conclusion other than that the developments in European patent law, together with the increase in patent applications involving all aspects of genetic material, means that it is likely that plant breeders will be exposed to patents either as rights holders or as affected third parties. The apparent lack of knowledge about the system or awareness of the possible consequences of third party rights over research programmes means that there is likely to be an issue about the need for more information to be made available. Also. In addition it may be necessary for concerted EU action to support those breeders financially unable to acquire rights or licence in the right to use other parties intellectual property, yet which are responsible for the development of key new varieties. This is a critical issue given the fact that the majority of EU plant breeders fall within the SME category, a sector which traditionally under uses intellectual property

protection and which equally could be regarded as less able to undertake litigation. The exception to the general responses was the Netherlands where a number of breeders responding had experience of patent protection and generally were satisfied with the protection acquired. These responses however, are not consistent with the experiences of the Dutch plant breeders union, Plantum NL which has identified via discussions with its members problems with the scope of rights and in particular with the potential impact of the patent concept on research use which is considerably more restrictive on third parties than that available under plant variety rights.

One view which was common to all countries and sectors is that the bar on the patenting of plant varieties should remain at the national, EU and international levels. In addition the majority of breeders stated that if the bar were removed they would choose plant variety rights over patents because the nature of the right was more appropriate for their needs.

Of legislative concern is the fact that whilst there has been concerted activity to harmonise European practice via the adoption of the Directive both by the European Pariliament and the EPO (the latter for the purposes of supplementary interpretation)and the introduction of a Community Plant Variety Rights Regulation which is in line with the UPOV Convention 1991, the national laws of member states remains disparate. Whilst all are member states of the EPC, only five countries have implemented the Directive and six have brought their laws into line with the UPOV Convention 1991. If a coherent system of protection is thought desirable then there is a need for coherence at the national **and** EU levels.

It is clear from the results of the project that the full impact of the developments in plant intellectual property rights has yet to be felt in the European plant breeding industry.

Recommendation

The recommendation from the project is that whilst plant breeders are currently satisfied with the provision of plant variety rights there are concerns over the impact of patents on the ability to undertake research and development. The situation should be monitored with a view to a similar survey being undertaken in the period 2006-2010 to assess the actual impact of the recent developments on the plant breeding industry. This would be in line with the review mechanisms set down in Article 16 of the Directive on the Legal Protection of Biotechnological Inventions. The short time-frame is recommended to ensure that any adverse affects of patents, for example impeding research and competition, are halted at the earliest opportunity. We would also recommend that the national divergences in plant intellectual property provision are assessed to see if they provide a barrier to research and development.

For further details See Accompanying measure QLG6-2001-30131, under 5FP.

Partners

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ASSESSING DEBATE AND PARTICIPATIVE TECHNOLOGY ASSESSMENT

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Starting date:	1.11.1998	
Duration:	24 months	
EC contribution:	392.573 €	
Website: http://www.inra.fr/Internet/Directions/SED/science-gouvernance/pub/ADAPTA		

Introduction

The overall objective of the proposed project is to further the understanding of the development of public debate and participatory technology assessment by systematically analysing and comparing several (15) experiences carried out in the field of biotechnology and other technologies in the following European countries: Denmark, France, Germany, The Netherlands, United Kingdom.

This will be done by investigating and comparing case studies on four dimensions:
- the emergence of public debate,
- the social shaping of the debated problem,
- the institutional structuring of the forum,
- the way to consider the impacts and results.

The aim of the project is to facilitate the promotion of public debate on science and technology policy at regional and national levels in Europe.

The objectives of the proposed project fits with the following ELSA objectives:1)-Understanding and answering public attitudes and diversity of viewpoints, as well as the social shaping of public attitudes; 2) Fulfilling a prospective role, anticipating the problems and providing early warnings for new ethical, social and legal issues.

The general approach of the proposed project comprises basically the following stages:

1. A general **overview** of participative technology assessment and public debate experiences in European countries will be given (task 1);

2. In depth **analysis** of participative technology assessment and public debate concrete cases in the field of biotechnology and other technologies (tasks 2, 3, 4);

3. International **comparison** of the in depth analyses covering several different dimensions will be made: according to some levels such as: technology (biotechnology versus other technologies), country, institutional structuring, impacts (tasks 6);

4. **Finalisation** of the project (task 8);

5. Two important **discussion steps** structure the research process:

- a first international workshop for the presentation and reflection on the in depth analyses of national experiences (task 5),
- a second international workshop, policy focused, for the presentation and discussion of the European comparative analysis and policy recommendations to the European Commission (task 7).

Main results

The ADAPTA project aims at providing a better understanding of the role of structured participatory processes (such as pTA) in the area of biotechnology in Europe. The research does not focus on such structured processes *per s*e, but it gives a comprehensive analysis of the interactions between such events and wider public debate in various institutional and political contexts. The research also analyses the interactions between these various forms of public participation (formal and informal) and the policy process in the area of biotechnology. Six countries have been studied by national teams: Denmark, France, Germany, Portugal, The Netherlands, and the United Kingdom. Three fields of observation have been chosen: urban transport, genetically modified organisms in food and agriculture and genetic testing. In total, 17 case studies have been carried out to assess those interactions. The urban transport debate cases have been used to test the field research methodology. The report is focused on the analysis and comparison of 12 cases on the use of GMOs in agriculture and food on the one hand and on the use of genetic testing for human health on the other hand. An International Workshop has been held in October 2000 1 , as part of the ADAPTA project dissemination process. This Users' Workshop was designed as the final step of the research process. Our objective was double: to see if participants' experience and researchers' findings fitted together and to provoke a discussion on some key questions in order to improve the final report. For the purpose of this publiaction, the summary and results of the **GMO Food Case studies** comparative analysis (chapter 4 of the final report) has been extracted from the report, as follows:

The report presents the transversal analysis of six case studies on the interactions between public debate, pTA and policy process on the GM Food issue. The characterisation of public debate on GM Food shows that sharp differences between countries exist in terms of the temporal evolution of the public debate as well as in terms of framing and space of mobilisation. We suggest that one of the main factor explaining differences in the dynamics of public debate lays on the degree of openness of the policy process. However, different factors favour an international dissemination of the public debate and tend to erase national

differences in the recent period: (i) the transnational dimension of the GM food issue, because of agricultural trade, EU and international regulations and also actors (Companies as well as some NGOs) who have global strategies; (ii) the very low degree of openness of the GM socio-technical network . In this context, beyond their diversity, pTA exercises have common effects. They foster trans-arena interactions and help to articulate different "visions of the world" in the process of technology assessment. However, it is very difficult to assess their effects since they occur in a period of major changes in the relations between science, policy making and the public. Therefore, it is very difficult – and even not relevant- to sort out the effects of pTA from the effects of other forms of Public Debate – like direct actions, trials in court,….For sure, Public Debate has played a major role in the evolution of the policy process. The intensity of trans-arena work which took place in various European countries was probably necessary to re-open the policy process and the GM technological trajectory. In such a context, it is very much difficult to assess the impact of "one-off" events as pTA. However, they may play a very important –and complementary- role since in the context of a rather polarised debate, they show how important and fruitful it is to take into account lay people worldviews in the innovation/assessment processes. This analysis shows that, if pTA exercises are designed as isolated initiatives, they may appear as window-dressing devices and have low credibility and effects. In order to have an effective impact, they have to be a part of an overall effort towards openness of innovation and policy process.

The complete version of the cases and national reports as well as the complete results are available in the website.

Partners

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MAMMALIAN CLONING IN EUROPE: PROSPECTS AND PUBLIC POLICY

Contract No. :	**BIO4-CT98-0367**	**Coordinator:**
Contract type:	Shared-cost	**Dr. Jacqueline Senker**
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Duration:	25 months	
EC contribution:	50.000 €	
Website: **http://www.sussex.ac.uk/spru/biotechnology/Themes.html#Mammalian_cloning_in_Europe**		

Introduction

This study is designed to provide an assessment of mammalian cloning technology, its possible risks and benefits, and how public policy might help steer its development in amanner which is both socially acceptable and economically useful.

The creation of the first cloned mammal, 'Dolly' the sheep, has been seen as a landmark, demonstrating both the power of science and the scale of public fears surrounding genetic engineering. This technical achievement has provoked controversy and stimulated major public policy debates in many countries, with the emphasis on the ethics of cloning humans. However, fear of human cloning has overshadowed the longer-term significance of this research, as it is in the field of animal biotechnology and in the development of new medical technologies that cloning could provide major benefits.

Public policy makers are therefore faced with a dilemma in balancing the need to maintain public confidence in biotechnology, by guaranteeing that research on cloning is ethical and socially acceptable, whilst at the same time ensuring that regulation will not inhibit its industrial exploitation.

The objectives of the study are therefore to:

1. Assess the scientific significance of the cloning of mammals and identify both short and long-term potential applications of the technique;

2. Make a comparative analysis of the public perception of mammalian cloning, the ethical problems raised, and the public policy response to these issues, in the UK and the Netherlands;

3. Analyse the relative success of different national approaches to mammalian cloning and suggest how public policy might be best used to socially manage the technology in Europe.

To meet these objectives the work programme was composed of the following activities:
• A detailed literature review of research on mammalian cloning
• Interviews with leading scientists and companies working on mammalian cloning.
• A short survey of European biotechnology firms working in fields related to cloning
• Detailed case studies of the public debate and regulation of cloning in the UK and the Netherlands.

Main results

The complete report of the project is available at the website. The following conclusions can be extracted from the report:

1. The development of cloning and nuclear transfer technology

In order for the development of technologies based on cloning and nuclear transfer to be realised a number of factors will be required to enable the construction of stable sociotechnical networks around particular technological options. These will include technical progress in realising the applications and proof that the associated risks are limited, broad social acceptability, significant commercial interest and a permissive regulatory environment. Each of these factors for the main applications of cloning is summarised below in Table 7.3.

As can be seen, very few of the options currently under development are technically well advanced, have few risks, command broad public support, have a good level of industrial interest and are permitted by regulatory authorities in both the UK and the Netherlands. Judged by these criteria, the options that seem most likely to be further developed appear to be:

- The production of therapeutic proteins in the milk of transgenic animals
- The creation of transgenic animals for research purposes
- The preservation of endangered species
- Human stem cell therapies

However, none of these options is without either technical or ethical problems and it must be stressed that it is too early to make a final judgement about which technologies will ultimately be widely adopted. Furthermore, whilst research into several of these options is currently allowed in the UK, it is prohibited in the Netherlands. In contrast, xenotransplantation and the production of nutraceuticals using transgenic animals have only limited public support, a lower level of commercial interest and are still associated with significant risks. Uncertainty also surrounds the future development of cloned or transgenic livestock due to both animal welfare concerns and the strong possibility of consumer resistance. Finally, it is clear that the real prospects for the development of human reproductive cloning in Europe are very limited when judged by any of the criteria used here.

Table 7.3: Summary of the main factors influencing the selection of different options for the application of cloning and nuclear transfer

Application	Level of technical progress/ risks	Level of social acceptability	Level of commercial interest	Regulatory status in the NL	Regulatory status in the UK
Production of pharmaceutical proteins in the milk of transgenic mammals	Good progress/ few major risks	No major ethical issues and a level of social acceptability	Significant number of biotechnology firms. Investment by major companies	Research using nuclear transfer is currently prohibited	No major restrictions on research
Production of neutraceuticals in the milk of transgenic mammals	Limited progress/ unknown risks	Only a limited level of social acceptability at present	Low level of commercial interest	Research using nuclear transfer is currently prohibited	No major restrictions on research
Xenotransplantation	Limited progress/ major potential risks	Only a limited level of social acceptability at present	A small number of biotech firms interested, but little investment from major companies	Research is currently allowed on animals. First human trial approved	Research is currently allowed on animals. No human trial has been approved
Transgenic animals for research	Good technical progress/ risks to health of animal	Unknown level of social acceptability	A small number of firms involved	Research using nuclear transfer is currently prohibited	No major restrictions on research
Cloning in livestock breeding	Some technical progress/ risks to health of animal	Unknown level of social acceptability	A small number of firms involved	Research using nuclear transfer is currently prohibited	No major restrictions on research

Application	Level of technical progress/ risks	Level of social acceptability	Level of commercial interest	Regulatory status in the NL	Regulatory status in the UK
Transgenic livestock	Some technical progress/ risks to health of animal	Unknown level of social acceptability	A small number of firms involved	Research using nuclear transfer is currently prohibited	No major restrictions on research
Preservation of rare species	Some technical progress	Unknown level of social acceptability	No commercial interest	Research using nuclear transfer is currently prohibited	No major restrictions on research
Cloning of pets	Some technical progress/ risks to health of animal	Limited social acceptability	Limited commercial interest	Research using nuclear transfer is currently prohibited	No major restrictions on research
Human stem cell therapies	Some technical progress	Some opposition to embryo research	Large number of biotechnology firms involved. Investment from large companies	Research on pre-implantation embryos allowed	Policy still being formulated
Human reproductive cloning	Very little direct research/ major health risks	Socially unacceptable	No commercial interest	Prohibited	Prohibited

2. The regulation of cloning

It is clear from the two case studies that the way in which emerging technologies are regulated can have an important impact on the actual development of the technology. In this sense it is useful to think of innovation as involving the mutual shaping of technological options, industries, public attitudes and regulatory regimes.

This project has attempted to use the idea of the 'social management of emerging technologies' to judge the success of different approaches to public policy in dealing with the challenges posed by cloning. Whilst it is clear that governments and other policy makers can only have a limited impact on how technologies develop, their actions are important. In particular, the official sanctioning of a new technology can play a key role in building public trust for its use. Equally, stringent regulatory policies can inhibit innovation or even prohibit the development of particular technological options.

It might therefore be suggested that public policy should be used to help steer the development of emerging biotechnologies in such a manner that public confidence is maintained and risks are minimised, whilst at the same time enabling the industrial exploitation of research to proceed in a socially acceptable manner. To achieve this it is clear from the case studies that policy makers need to maintain some level of control of the policy agenda and, at the same time, keep in touch with public opinion and concerns. If key issues are not anticipated then public confidence may be lost and policy will be created under adverse political circumstances. However, if the policy making process loses touch with popular feeling there is a danger that decisions will be made which lack broad support. This may ultimately lead to a loss of trust and problems such as those that have surrounded GM food in the UK.

Following on from this point, the way in which policy is made and the types of regulatory instruments used are critical. Some level of lay or public involvement in decision making is important to ensure that the regulatory process is kept in touch with public opinion. The monopoly of decision making by scientists and technical experts, which has historically dominated the approach in the UK and several other European countries, puts regulatory systems at risk of missing important changes in popular sentiment and being perceived as only serving particular interest groups. The findings of the Wellcome Trust's research on this topic are of great importance in this respect. In contrast, the Dutch policy making tradition, with its emphasis on open public discussion, consensus-building and widespread consultation, is a good model for ensuring that decisions are broadly supported and might be seen as a model of good practice.

Another key issue highlighted in the case studies is the issue of anticipation and it may be that more formalised mechanisms should be introduced for identifying emerging technical developments which might cause public concern. This might be seen as a form of ethical horizon scanning and could be used by regulatory agencies to plan their work so that they are better able to rapidly respond to new challenges. To some extent the UK system of expert advisory groups has, in part, played this function and might be thought of as a model.

Finally, the regulatory system needs to be flexible, whilst at the same time operating with a strong mandate from government. The dilemma caused in the UK by the HFE Act well illustrates the fine line which policy has to tread. On the one hand strong statutory measures were essential for ensuring political and public support for embryo research. However, the tight drafting of the legislation has caused unintended consequences with respect to cloning research. This demonstrates just how difficult it is for regulators to anticipate the future.

In conclusion, nuclear transfer and cloning techniques offer a number of potential benefits whilst at the same time raising important social and ethical issues and posing new challenges to regulatory agencies. Government can have an important role is steering the development of cloning technology so that its benefits can be realised whilst maintaining public support and trust. This will require the careful development of policy-making processes which try to anticipate future possibilities, involve the public and encourage debate.

Partners

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BENCHMARKING THE MORAL DECISION-MAKING STRENGTH OF EUROPEAN BIOTECHNOLOGY COMPANIES

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Starting date:	1.09.1998	
Duration:	12 months	
EC contribution:	60.000 €	
Website: http://www.stb.tno.nl		

Introduction

The debate in society about the ethical and social aspects of biotechnology has forced companies to react on the social and ethical pressures they feel around them. Companies adopt different procedures to react on these pressures in their surroundings. The form and structure of these procedures differs strongly per company and relate to a number of internal and external factors. From the perspective of biotech companies, it is necessary to get more insight in the procedures companies could develop in dealing with the ethical aspects of biotechnology put forward by their stakeholder inside and outside the company. Benchmarking these procedures can be a useful instrument in the learning processes of the companies involved. It enhances the companies' ability to interact in the public debate and to develop expertise in dealing with ethical questions. For the EU these insights can be used to find out if specific stimuli are needed to strengthen the competitive advantage of European biotechnology companies in this respect.

Objectives

The objectives of this project are:

- to make an inventory of the procedures - including decision making procedures - of European biotechnology companies that try to adopt to the new moral pressure put to them,

and

- to advice the European Commission and industry on the basis of this benchmarking research in order to improve the interaction between companies and their stakeholders in ethical issues related to biotechnology.

In order to reach these objectives, a central question was formulated: *How do European biotech companies integrate the social discussion about the ethical aspects of biotechnology, in their ethical decision making processes on biotechnology?*

This central question has been operationalised in three questions dealing with the following aspects:

1. Which are the (decision making) procedures and other activities companies undertake in reaction to ethical responses from their stakeholders, outside - but also inside -the company?

2. What are the ethical models practised by these companies in undertaking their specific sets of procedures/activities?

3. What are the consequences of these procedures/activities for the biotechnological activities of the company?

Methodology

In order to get an overall European picture of the procedures and other activities companies undertake in reaction to ethical responses from their stakeholders, of the ethical models practised by these companies and of the consequences of these procedures/activities for the biotechnological activities of the company a literature survey was made which formed the basis for two questionnaires.

- a long questionnaire that had to be used in in-depth interviews with a restricted, but representative number of European Biotechnology companies

- a short questionnaire that had to be sent by post to a more extensive, but still representative group of European companies.

A representative number of European biotechnology companies were selected; representative for country, sector and size. Hundred and twenty companies were sent a short questionnaire focussing on the tools for ethics management; 24 replied. Thirty companies were invited for a more in-depth interview with the long questionnaire; 12 responded. The results of the postal questionnaire and of the in-depth interviews were processed and presented in anonymous way in this report.

Main results

There seems to be a rather high degree of ethical awareness in the companies when we consider the roundtables and discussion circles, internal as well as with external experts, consultants, issue groups and interested public. These activities occur both as an example of an institutionalised tool for managing ethical issues as well as an informal way of dealing with moral questions within companies. The same is true for integrating ethical criteria into assessment processes, application interviews and the regular interviews with employees throughout the year.

The findings on the basis of the long questionnaire – which of course has a data basis that is much too small in order to be able to come to general representative conclusions - do not support the outcome of recent studies stating that compared to the developments in the United States of America, European companies are still "ages behind" as far as the use of ethic management tools is concerned. However, only two companies use these tools as an integral part of an encompassing ethics management program. These included internal ethics audits, review processes, an ethics committee and an ethics officer who is responsible for supervising the implementation of the code, for ensuring its realisation by additional measures such as ethics training, as well as reviewing and actualising its contents regularly on the basis of measures that involve the whole company.

Against the background of the criteria formulated in the study, it is likely to assume that the moral decision making strength of the responding companies can be qualified as being rather high. This would correspond to the evaluation of the respondents themselves with regard to the position of their top-management: all companies claim to include ethical reflection into their decision-making processes. However, in the case of five companies this is done only as a reaction to the demands from external stakeholders, whereas only three of the respondents consider ethical reflection to be the underlying basis of strategic thinking and decision making in their company – all of them using institutionalised forms (ethics programs) of managing ethical issues. Besides, there is a significant lack of regular ethics training being an integral part of Human Resource Development, which would support the ability of company members to deal appropriately and supremely well with ethically relevant situations of decision making. This is especially remarkable against the background of the outcome that in most companies the employees themselves are considered to be morally responsible.

A well developed moral culture has to use both genuinely opening tools and measures of managing ethical issues (such as roundtables and discussion circles) and genuinely closing measures (such as fixing rules and norms by codes of conduct or guidelines as well as checking the implementation of these rules and norms by internal audits, external revisions and evaluation processes). Improving the moral integrity and decision making strength of companies requires both kinds of measures in an outweighed, complementary form. Most of the responding companies are sharing this estimation: a code of conduct, guidelines for decision making, an ethics committee, internal and external ethical/ social audits were named by the respondents as being most appropriate in order to deal properly with ethical issues in the field of biotechnology. However, there is a significant gap between these insights of the respondents, i.e. between considering tools of this kind as helpful instruments especially with regards to moral decision making processes, and the real use of them in their own companies. Therefore it is doubtful whether the decision-making strength of the interviewed companies is as high as the respondents themselves expect it to be. But there is no doubt that it could (and should) be improved by additional initiatives respectively by realising the plans some of the respondents have already announced for the near future.

Recommendations to the EU

The answers of the twelve responding companies and their orientation towards an integrity approach confirm the impression of a general tendency among European companies which is that they are fed up with external regulations and restrictions. Only one (German) company explicitly committed itself to the principle of legality and compliance with the rules as its leading corporate ethical orientation.

However, to set up rules and laws for all kind of morally relevant actions, situations and decisions is neither possible nor efficient. On a global market, supporting a culture of self-initiative, corporate responsibility and proactive ways of managing entrepreneurial challenges is gaining much more importance, e.g. by a self-imposed commitment to specific (social, ethical, ecological) standards also in countries or regions where the national law is not as well developed as in European countries. Against this background, a major task of the EU could and should be to further encourage and support proactive forms of dealing with ethical issues. This could be done, for instance, by recommending to companies working with biotechnology (or on any other morally relevant field) to develop and implement properly – i.e. within the framework of encompassing ethics programs - codes of ethics and/ or guidelines which are based both on European or international rules and standards as well as on ethical values and principles. The advantages of this form of proceeding are on the one hand that existing regulations and norms will be better accepted and complied to if they are embedded in some sort of an ethics program containing measures and tools to strengthen the moral awareness and integrity of all company members in order to create an ethical value oriented corporate culture in general. Also, the underlying sense of regulations and the necessity to stick to them can be recognised more easily when they are communicated within the context of an ethical orientation and a corresponding understanding of the moral/ social responsibility of companies. It is possible to do justice also to culture specific differences in this way.

In addition to that – being perhaps even more important - the self-imposed ethical orientation of companies has an important function to balance and compensate potential gaps or insufficiencies of existing regulations occurring in day-to-day business. Therefore, the national state authorities as well as the EU should keep in a vital dialogue with biotech companies as the user of their regulations – on the one hand in order to check the relevance and appropriateness of the existing rules, on the other hand in order to help companies to deal properly also with the moral implications of their biotech activities. For organising or institutionalising this dialogue, some of the management tools that are in the focus of this research project could be very helpful, for instance establishing an ethics hot-line respectively a centralised call - or "compliance"- centre connected with an ethics committee of experts (either on a national or European level) whose members help to solve acute problems or answer questions on the respective field. This offer might be especially relevant for smaller companies, which cannot afford to have their own ethics committee.

Partners

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I. PROJECTS FUNDED UNDER THE 4TH FRAMEWORK PROGRAMME (1994- 1998)

ii) BIOTECHNOLOGY PROGRAMME:

- Public perception/socio-economic impact of biotechnology

BIOTECHNOLOGY AND THE EUROPEAN PUBLIC

Contract No. :	**BIO4-CT95-0043**	**Coordinator:**
Contract type:	Concerted action	**Prof. John Durant** National Museum of Science and Industry Present contact: **Prof. George Gaskell**, Methodology Institute, London School of Economics and Political Science, London WC2A 2AE. **Email:** g.gaskell@lse.ac.uk
Starting date:	1 December 1995	
Duration:	36 months	
EC contribution:	400.000 Ecu	
Website:		

Introduction

This proposal has been formulated to address two of the tasks outlined in the Biotechnology Work Programme 1994-98:

a) "support will be given to a concerted action involving biotechnology, social sciences and communication sciences, analysing public perceptions in European countries and in a world-wide international context"
and
b) "a concerted action based on national expertise will be supported in order to improve the next Eurobarometer (planned for 1996) and the evaluation of its results.

As a major contribution to furthering our understanding of public opinion and its impact on the continued growth and development of biotechnology in Europe, we have coordinated a major research initiative (see (a) above). This initiative brought together independently funded national studies and an international comparative analysis of public discourse on biotechnology in policy making, media coverage and public perception. The initiative was supported by the European Federation of Biotechnology Task Group on Public Perceptions, and it involved as collaborators Member States of the European Union and two non-EU European countries (Poland and Switzerland). In addition, laboratories in Canada and the USA conducted parallel studies leading to comparisons between Europe and the broader international context.

The concerted action comprisee three work packages: first, the design and development of the Eurobarometer survey; second, the statistical analysis of the Eurobarometer 1996 survey data; and third, the evaluation and interpretation of the Eurobarometer results in light of public debate in the participating countries, as evidenced by the national studies of biotechnology policy and media discourse. A knowledge of how public policy, public debate and public attitudes are evolving in different European countries is a prerequisite for the drawing of practical policy implications from the data.

The concerted action led to the following measurable deliverables:

(1) A technical report on the design and development of the biotechnology survey 1996;

(2) A public report presenting the statistical analyses of the Eurobarometer 1996 data, including comparisons with 1991 and 1993;

(3) A public report in which partner laboratories interpret the Eurobarometer data in the light of their analysis of media coverage and policy developments ;

(4) A public report analysing the significance of national trends in Public perceptions of biotechnology for European policy deliberators;

(5) A public report comparing media coverage, policy developments and Public perceptions in Europe and N. America, focusing on the implications for the competitive development of biotechnology in Europe.

Main results

- Re-design of the Eurobarometer 46.1. in 1996, followed by full national statistical analysis (AT, DK, FI, FR, DE, GR, I, NO, NL, CH, SE, UK) plus international comparative analyses and analysis of time series questions from 1991 and 1993 Eurobarometers ;

- A major publication was produced in 1998, with contributions from all BEP participants detailing analyses from all three research modules (policy analysis, media analysis and Eurobarometer/public perceptions analysis) ;

- As a result of the 3-year programme of research, key topics emerged which were significant in the development of public perceptions and together provide a landscape against which new trajectories are emerging. Topics analysed are as follows : (I) public perceptions of Dolly the sheep ; (ii) introduction of GM in foods : the case of RR soya ; (iii) traditionalist and post modernist attitudes to biotechnology : the Blue-green split ; (iv) attitudes or non-attitudes to biotechnology ? (v) evolution of public debates and their relation to European policy making on biotechnology- a 25 year analysis ; (vi) an analysis of international media coverage of biotechnology ; (vii) European and American attitudes to biotechnology ; (viii) images of biotechnology in public minds ; (ix) regional analysis of attitudes to biotechnology in Europe ; (x) the institutionalisation of ethics ; (xi) the relationship between knowledge and attitudes.

- Securing a contract from Cambridge University Press to publish results of these analyses. Length 120 000 words. Estimated publication dated end of 2000.

- In the US a parallel Eurobarometer was conducted by Prof. Jon Miller at the University of Chicago (using 80% of the same questions).

- Members of the BEP research network have presented research findings at a number of national and international conferences and seminars.

European added value

- Full interpretative discussion and analysis could only be achieved with the genuine collaboration of the different national groups. Knowledge about national social and political contexts and up to date information on current events of national significance were essential inputs to the research.

- For information on the research and publications and external reviewing, a large number of international contacts were made with stakeholders in industry. NGO groups, policy makers, people involved in national public consultation initiatives, academics researchers, etc. These contacts provide a useful resource.

Partners

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EUROPEAN FEDERATION OF BIOTECHNOLOGY TASK GROUP ON PUBLIC PERCEPTIONS OF BIOTECHNOLOGY (2 CONTRACTS)

Contracts No. :	**A) BIO4-CT95-0135** **B) BIO4-CT98-0529**	**Coordinator:**
Contract types:	Concerted Actions	**Prof. John Durant** National Museum of Science and Industry London And since 1999 **Dr. David Bennett** University of Delft Oude Delft 60 NL-2611 CD Delft Tel: +31.15.212.7800 Fax: +31.15.212.7111 **Email:** **David.Bennett@efbpublic.org**
Starting dates:	A) 01.12.1995 B) 01.12.1998	
Duration:	60 months (36+24)	
EC contribution:	A) 600.000 Ecu B) 460.000 Ecu	
Website: www.efbpublic.org		

Introduction

The task group on public perceptions of biotechnology consists of 50 members from European countries, from research, industry, consumers and environmental organisations and the media.

It is funded mainly by the European Commission and works towards the following goals:

- to increase public awareness and understanding of biotechnology and the life sciences throughout Europe, to advance the public debate about their applications and to facilitate dialogue between interested parties.
- to maintain an independent position between science, industry, government, public interest groups and the media.
- to communicate primarily to opinion leaders and decision makers, and through them to the general public.
- to monitor developments in policy, legislation, research and commercialisation with particular emphasis on public perception aspects to forecast needs and focus on relevant activities

Main results

The Task Group was actively involved over the period with the following:

- **Publications** to facilitate general public access to balanced information about biotechnology in clear, non-technical language in the form of concise, authoritative briefing papers on a variety of key topics in the main European languages; handbooks of information sources: *"Biotechnology for non-specialists"; "Public Opinion about Biotechnology: a Survey of Surveys";* reports of workshops, conferences, etc, all available on our Web-site.

- **Conference, workshop and seminar organisation** involving the science, industry, public interest groups, government and media to inform and advance public debate about key issues in biotechnology: e.g. in 2001 *"Advanced Workshop on Embryo Research",* Brussels, *"Stakeholder Dialogue on Environmental Risks and Safety of GM Plants", Leiden NL a*nd *"Available Options for Animal Feed in Europe",* Brussels; providing support for other similar national and international events.

- **Support and collaboration** with scientists (e.g. European Molecular Biology Organisation), industrialists (e.g. EuropaBio), policy makers (e.g. European Parliament), educationalists (e.g. European Initiative for Biotechnology Education), journalists and public interest groups (e.g. Genetic Interest Group) in activities.

- **Education and training** in communication techniques and strategies in courses run by the Task Group and other organisations: e.g. *"EU Advanced Workshop on Biotechnology Ethics and Public Perceptions of Biotechnology",* Oxford, 1997, 1999, 2001 & 2002.

- **Press and media relations** organised for key conferences to promote coverage by journalists and the public's understanding of biotechnology: e.g. *"8th European Congress on Biotechnology"*, Budapest, 1997; *"European Biotechnology Forum: Public Perceptions and Public Policy",* Brussels, 1998; *"Biotechnology in Public"*, Vienna, 1998, *"1st Polish Biotechnology Congress",* Wroclaw, 1999,

- **Informatics** data collection and integration in the above activities of public information and educational materials on biotechnology; maintenance of the Task Group web-site (www.efbpublic.org) with publications downloadable free of charge and *"Ask the Scientist"* email enquiry service.

Dissemination, implementation and evaluation of educational materials on biotechnology (2 contracts)

Contracts No. :	**A) BIO4-CT96-0016** **B) BIO4-CT98-0304**	**Coordinator:**
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Starting dates:	01.01.1996 01.11.1998	
Duration:	48 months (24+24)	
EC contribution:	A) 600.000 Ecu B) 400.000 Ecu	
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Introduction

The European Initiative for Biotechnology Education (E.I.B.E.) had been working from 1991 to March 2001 to promote public understanding of biotechnology through raising awareness and understanding among younger members of the public, e.g. future citizens of school age. EIBE has become an active European multidisciplinary network of some 30 experts in biotechnology education drawn from 28 centres in 17 EU countries.

The project **BIO4-CT96-00016** was centred around the development of E.I.B.E. units for in-service teacher training (INSET) and initial teacher training using scientific and technological subjects in association with relevant economic and societal issues, and a range of teaching media and materials. The project **BIO4-CT98-0304** focused on the dissemination of these E.I.B.E. materials via different media (e.g. the World Wide Web, CD-ROM), on the implementation of the E.I.B.E. units into the classroom, including the adaptation of the units to humanities, and on the evaluation of the dissemination and the implementation.

E.I.B.E. operates through development and provision of teaching materials and strategies, and expertise to science and non-science teachers in schools and colleges across the EU. Its inter-disciplinary membership consists of educationalists and educators in science and technology and in societal and ethical issues. Among the points established through its work is a variation and unevenness in biotechnology teaching through the EU which is strongly influenced by national and regional differences in organisation, tradition and culture. The ideas and programmes of work hitherto independently developed by E.I.B.E. members on a local basis have been raised in value by the benefits of transnational activities, and adapted to the educational system of different European countries.

Main results

EIBE Units

The main focus of attention has been the development of units for supporting teachers through in-service training and initial teacher training. Meanwhile 20 units have been completed in English and different versions of other languages. Each unit is under the responsibility of a co-ordinator supported by a development group. The central services provision has responsibility for the production of all final versions. All completed units have been revised following trailing and evaluation in national or international workshops. Adaptation to the educational and cultural needs of particular countries has been carried out. EIBE produced a CD-ROM with all material developed. These teaching materials are also posted on the World Wide Web (http://www.eibe.info). Language version of units have been made in Bulgarian, Czech, Danish, Dutch, Estonia, French, German, Italian, Polish, Spanish and Swedish. A range of teaching media and materials has been developed and disseminated, including DNA and ELISA kits, a DNA model, and cartoons to aid explanations of complex concepts.

Analysis and Evaluation

Transnational analysis was done by EIBE members in several related areas including: (i) concepts, interests and attitudes of 15-18 year old students about genetechnology; (ii) conceptions of students about micro-organisms and related concepts; (iii) teachers' perspectives on the nature of science and biotechnology. An evaluation procedure for EIBE units was developed and refined during teacher workshops, in Belgium, Germany, Ireland, Luxembourg, Spain and Sweden, and in classroom situations. A model is being developed for evaluation of implementation in the classroom with a view to future use in adaptation of units to local educational and cultural contexts. The outcomes of analysis and unit evaluation were made available during unit development to enhance the effectiveness of units and several papers were published in national and international journals.

Publicity, Dissemination and Networking

A publicity flyer and a biannual EIBE Newsletter, one of the most important tools for the dissemination of E.I.B.E. materials, has been produced in 6 languages (i.e. Dutch, English, French, German, Italian, Spanish). Distribution to appropriate recipients is the responsibility of an EIBE partner in their respective country. A www EIBE home page was designed and maintained and its use monitored. It continues to be visited continuously and increasingly. A large proportion of the visits is from domains located throughout the world including a broad range of European countries. The success was such that maintenance of the web site has been transferred to IPN so that it remains accessible after the completion of the E.I.B.E. project.

A CD-ROM containing all E.I.B.E. materials including information on good microbiological practice and problem solving in ethical, social, economic and further context was developed. An ELISA-Kit of IPN/Steffens was supplied with a handbook in both German and English. Together with Eppendorf a PCR-Kit was developed by IPN for educational proposes. It serves as a supplement to Unit 2 "DNA fingerprint".

Partners have had several papers on the work of EIBE published in journals and in newsletters of national educational organizations. Many have made contributions to conferences world-wide, e.g. Austria, Belgium, Bulgaria, China, France, Germany, Italy, United Kingdom, United States. Active contacts including some joint activities have been made with the European Communities Biologists Association (ECBA), the EFB Working

Party on Education, the EFB Task Group on Public Perception of Biotechnology, the Education and Learning in Europe Project (EULE) and the International Network for Chemical Studies (INCS) of UNESCO.

The partners are drawn from a wide geographical range across the EU and representation has been broadened over time. For example during the second project membership was enlarged with the University of Patras (Greece) – as a partner of the European Union – as well as the University of Sofia (Bulgaria), the Pedagogical Centre Prague (Czech Republic), the University of Tartu (Estonia) and the University of Gdansk (Poland) as Eastern European representatives members of E.I.B.E. In addition the ETH Zuerich, Switzerland, joined E.I.B.E. For the dissemination and implementation several workshops with teachers were carried out and in addition E.I.B.E. members participated in various national and international conferences.

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EDUCATING BIOTECH CONSUMERS

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Duration:	27 months	
EC contribution:	268.000 €	
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Introduction

Objectives

Biotechnology is having a progressively significant influence on the economies of nations rich and poor, and on the lives of their citizens. Concerned primarily with the major areas of active public interest (genetics and molecular biology as applied broadly to healthcare, crops and food), this project explores how citizens of the EU are currently being helped to understand the technical, economic and ethical facts and significance of biotechnology as they may impact both their own personal lives and the local, national and wider communities in which they reside. This study provides a comparative overview of the range of opportunities for education in biotechnology open to citizens in the various Member States of the EU — opportunities organised by governments and their agencies, by educational establishments, by a wide variety of organisations and institutions variously interested in informing/influencing public attitudes and of course by the media in its many forms. Switzerland was included because of its experience of a referendum on genetics and biotechnology as well as the United States where it all started.

Main results

• Each country was reviewed by broad category of activity: government, formal education, scientific societies and similar organisations, industry, consumer organisations, environmental and other special interest groups, the press, broadcasting, and museums and exhibitions; from some countries there were additional headings.

• Biotechnology is generally recognised as having important multidimensional societal impacts; there are countless examples of both public and private sector attempts to inform the public of the latest developments. Many good ideas and initiatives have come to light, some on a large scale funded by governments, industry or other major organisations, others run on a

shoe string by interested individuals, often school teachers. A recurring theme is that educational resources for biotechnology were often difficult to come by, offered only for short-term initiatives and frequently leave the problem of how to continue after the start-up phase.

• Not surprisingly, the two most critically important sources of biotechnology education are government and the media. In some countries, government pronouncements are accepted as being sound advice: in others they were treated with scepticism exactly because they come from government.

• Education policies also varied widely form one country to the next. Many are attempting to incorporate biotechnology into school curricula but are finding the multidimensional nature of the topic difficult to fit easily into curricula of compartmentalised subject-by-subject learning.

• The influence of academia and other national bodies also varied widely. A recurring theme was the lack of research scientists who could effectively communicate their findings and their implications to the public at large.

• The survey finds that appropriate media coverage is probably the single most important route for information to the public, at least in the short to medium term.

Suggestions and recommendations

• Biotechnology education is a long-term issue requiring a long-term view; it should not be constrained by short-term funding. Within this context, the updating and marketing of EU-sponsored educational material needs to be undertaken on an ongoing basis.

• Governments must encourage biotechnology education to be treated as a multidisciplinary subject with teachers specifically encouraged to offer lessons relating biotechnology to economics, ethics and social issues. They should take steps to ensure that scientists communicate clearly with society by rewarding scientists for communication activities and motivating them to cultivate networks of relationships with journalists.

• There is a need in some countries for respected public bodies and agencies sufficiently prestigious and divorced from the political process that the public can have confidence in the views they express. Such bodies might be European or international bodies.

• While acknowledging their commercial imperatives, the survey suggests that the media everywhere recognise clearly the public importance and interest in scientific matters, and provide for their readers, listeners and viewers accordingly.

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EUROPEAN TRAVELLING EXHIBITION INITIATIVE

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Introduction

This unique initiative utilised the skills of twenty major European institutions to enable a European tour of two biotechnology exhibitions, developed in Germany and the United Kingdom. The German exhibition toured to Greece and Portugal, while the UK exhibition went tour to France and Portugal. Each exhibition traveled for one year, reaching approximately 1.5 million visitors. These complementary exhibitions were conceived to inform the non-specialist public about contemporary practice in biotechnology, especially genetics. The UK exhibition looked at the science behind genetically modified food, the German exhibition looks at the basic principles of genetics and the methods of genetic engineering. Both exhibitions examine at contemporary issues in these fields and discussed what the future might hold.

All the texts and interactive displays in the exhibitions were be translated into the language of the countries to be visited. Each of the twenty European partners contributed to the project by giving advice and assistance from their own specialist areas. The partners have a wide range of expertise in biotechnology, exhibition development and touring exhibitions.

Not only was this venture expected to play a key role in the advancement of the European public's understanding of biotechnology, but also to help to develop the skills and expertise of all the partners. Through this European collaboration, a wealth of experience and knowledge was obtained, which will prove invaluable in developing the touring biotechnology exhibitions of the future.

Main results

The Science Museum and the Deutsches Hygiene-Museum have both been actively involved in the translation and adaptation of their exhibitions to the host venues. The Science Museum acquired first hand knowledge of the cultural differences in the attitudes towards food in Britain and France when translating the exhibition text. Not only was it necessary to translate the text itself, but also to modify the way food issues were presented in the exhibition. According to Eurobarometer 46.1, the French are more positive towards the application of

biotechnology in medicine and animals than other Europeans, yet they are more sceptical about the application to food. Attitudes, examples and pictures had to be adapted to fit in with the French notion of food and food traditions. The end product was extremely well adapted to the conditions in France. The two museums were directly involved with the translation into French, Portuguese, Spanish and Greek, and they had the final word in correcting and accepting all textual presentation. There has been a high level of collaboration across the borders, and the museums involved have established professional working contacts on the European museological scene.

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EUROPEAN DEBATES IN BIOTECHNOLOGY: DIMENSIONS OF PUBLIC CONCERN

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Introduction

The key objectives of the Concerted Action were as follows:

- to explore in detail how the European public think about the moral and risk related dimensions of different applications of biotechnology;
- to understand the bases of trust and confidence in regulatory bodies;
- to monitor the press coverage and developments in policy initiatives in biotechnology for the period 1996-1999, as an extension of the existing harmonized international database (1973-1995);

Main Results

Exploring public concerns

A series of fifty in-depth and group interviews with respondents in seven countries was conducted. The interviews were fully transcribed and systematically analysed with aid of the Atlas Ti software package. The topic guide, analysis and interpretation involved active participation of researchers from each country.

Ambivalence in everyday talk

A number of shared themes emerged that help to explain the survey findings of Eurobarometer 46.1 and clearly show that the ambivalence found in the survey is a feature of everyday talk about biotechnology. On the whole, and notwithstanding some risks, medical and pharmaceutical applications are seen as the outcome of good genetics and in the hands of trusted doctors. By contrast, the cloning of animals and the production of GM foods are examples of bad genetics and raise a number of concerns, not the least of which is that they

are seen to be unnecessary. Why, people wonder, should any risks be taken when there are no apparent benefits?

Nature's revenge

Expressions such as tampering, meddling, fiddling and interfering with Nature are commonplace. Nature evokes two types of argument: it is the human duty to venerate God's creation, and alternatively to intervene in the complexity of nature is to run the risk unknown and even unknowable consequences. These ideas are at the root of the moral objections expressed in the Eurobarometer survey 46.1.

Delayed effects and the runaway train

People worry about the possibility of 'delayed effects', dangers lurking in the future caused by what is done today. More broadly, biotechnology is likened to a "runaway train", a high speed and unstoppable journey to an unknown destination, fuelled by industrial science, without brakes and ignoring the warning signals of public opinion.

Regulation: yes but is it possible?

Regulation of both industry and scientists is seen to be essential but people worry if this is possible because of the speed of scientific and technological developments, the need for international regulation and cooperation and the relative powerlessness of democratic institutions when compared to multinational companies.

Policy issues 1996-1999

The analysis of the policy arena extended previous research which had charted the development of policy debates and regulations from 1973 to 1996. The contours of the policy arena were mapped under three headings: policy events, trigger events and policy outcomes. Data came from a variety of sources included governmental policy documents, reports from regulatory bodies and public interest groups.

Harmonisation of debates

The national debates became increasingly internationalised following the two key events of the watershed years. Controversies in Europe, particularly over GM foods have had a visible impact on the USA and Canada.

Shifting distinctions

Dolly the sheep led to a swift and unanimous condemnation of the use of cloning techniques for the purposes of human reproduction. However, the apparent consensus on moral standards was eroded as new distinctions, such as therapeutic versus reproductive cloning, entered the debate.

Institutionalising ethics

Various ways of addressing public concerns were attempted. The institutionalisation of ethics, in the creation of ethics committees, broadened the debate beyond considerations of scientific risk. On the one hand, this represented an acknowledgement that the issues go beyond risk and include fundamental values. But, ethics committees raised other questions:

what is the basis of their democratic legitimacy and should expert deliberation replace political debate?

Limits to harmonisation

The controversies over green biotechnology highlighted the difficulties of framing policies at the European level. Horizontal regulation in form of directives during the early nineties (c.f. dir. 90/220) did not lead to the expected harmonisation. Risk assessment procedures showed that the technicalities of the issue could be handled, but not the underlying assumptions, risk philosophies and values.

Media coverage of biotechnology

A systematic media analysis comprising the dimensions of intensity and content was conducted. Using keywords such as genetic*, biotech*, etc., online media databases were accessed to determine the absolute number (intensity) of articles published in each year in selected opinion-leader newspapers. This corpus of media material was used to establish a representative sample of articles for each year in each country. The selected articles were analysed using classical content analysis in the form of a coding frame comprising 26 variables including actors, themes, frames, risks and benefits. The design of the coding frame allowed for cross-national coverage of the content of print-media coverage.

International synchronisation

Up to 1996 media coverage was rather low key and concentrated on national concerns. The arrival of GM soya into Europe, and 'Dolly the Sheep' led to an explosion of media coverage and to the synchronisation of news content across Europe, if not globally.

Diversifying frames

During this period the image of the new technology became more ambivalent. The dominant idea of the early 1990s, that genetic engineering is ‘progress’ lost ground to issues of ‘public accountability’. Stories about the benefits of biotechnology also gave way to discussions of risk and uncertainty.

Red and green distinctions

Within this shift of framing, red or bio-medical and green or agri-food applications become increasingly differentiated in the press. Red is associated with independent scientists researching at the frontiers of knowledge in the quest for progress and medical innovations; green is the domain where business, interests groups and international regulators struggle over economic prospects and public accountability in the management of risks. The reporting of controversies is centred on green issues, shielding red developments from similar public scrutiny.

National differences

Across the participating countries we observe five types of media coverage:

Poland, Italy, German, Canada and the USA: prospects with few concerns over either red or green biotechnologies

France, the Netherlands and Finland: both prospects and concerns over both red and green biotechnologies.

UK, Greece, Sweden, Switzerland and Austria: rejection of green biotechnologies and caution towards red biotechnologies

Portugal: a newcomer to the debate, rejects green and supports red biotechnology.

Denmark: a long standing debate in which both red and green biotechnologies are viewed with caution.

It is of note that types of media coverage are generally well aligned with the styles of national policy making and with the direction of public opinion.

Case studies

Dolly the sheep

In tracing the evolution of this narrative, we show, via a systematic content analysis of print media in Europe and North America, that the chief storyline emerging was one of human, not animal cloning. Dolly the sheep became the motivated symbol for humans as clones. In this story, the initial consensus was one of moral outrage and condemnation. Why did Dolly hit the headlines worldwide? It was not the scientific event as such that explained the story's popularity, but the fact that the Dolly issue had profound cultural resonances. That it occurred *across* national imaginations revealed a social construction process of a large-scale mosaic.

Media representations

Journalists across Europe and North America drew on similar metaphorical images; they highlighted the same key events and actors; they tried to 'balance' their accounts of those who denounced and those who exalted the breakthrough, though the former were clearly in the ascendant. In terms of media practices, it is interesting that the account of Dolly was treated as a unique event, an enormous surprise, a 'technological leap', despite the fact that the idea behind her creation had been around for more than half a century.

Modernity and runaway science

The struggle to define the more enduring representation of a technological advance is at the heart of the story of Dolly. It is a story that illustrates a fleeting moment of moral consensus on this particular scientific endeavour. At the same time, it richly encapsulates the continuing ambivalence about the project of modernity and its notion of 'Progress'. It encompasses concerns about the increasing chasm between a run-away science and the rest of society, and involves the projection of society's worst fears about the unbridled power of scientists. It incorporates the continuing ambivalence about science and embodies deep fears about threats to human identity. Through the allusions to the crossing of boundaries between the 'natural' and the 'artificial', it has brought out in sharp relief the deepening anxieties about the usurpation of Divine power.

The reception of 'Roundup Ready' soya in Europe

In the autumn of 1996, ships carrying the annual harvest of soybeans for the EU market were sailing from US harbours. This soya was intended partly for the European food industry that uses soya as a raw material in the production of additives, food products, and livestock-feed. But, for the first time, the ships' holds contained more than traditionally bred soya. These shipments were mixtures of which about two per cent comprised a genetically manipulated strain of soya. The new strain was called 'Round-up Ready'.

This case study utilised data from official documents and news media sources in a cross-national study of the responses by governments, media and the public to the arrival in Europe of genetically modified soya. Four countries were compared: UK, Italy, Denmark and Sweden. Researchers from each of these four countries contributed to the design, data collection, analysis and interpretation process.

Variation across Europe

At one end of the spectrum, the soya issue became a 'hot' issue in countries such as Denmark and Austria, where public attention as well as political awareness is intense. At the other end of the spectrum were countries like Greece and Italy, in which neither the public nor the political system paid the issue more than the most perfunctory attention during these months. In between these extremes were countries like Sweden and the UK, with a moderate degree of attention directed at the soya issue.

National 'discursive environments'

With the possible exception of Italy, 'Round up Ready' served to bring biotechnology back onto the public agenda. Yet it played different roles in the disparate discursive environments of the four countries studied. Whereas its effect in Denmark and the UK was largely to re-open dormant debates on biotechnology and cause qualitative developments within these discussions, the impact in Sweden and Italy was more profound, with the controversy introducing new discourses. In Sweden, a new and critical discourse concerning GM foods emerged from both the soya and the maize issues, where the dominant biotechnology related discourses had previously been medical, ethical and regulatory. In Italy, the pattern is somewhat different, because the soya issue itself was of only minor consequence. However, combined with the maize issue, it has had a more or less similar effect to that in Sweden. In addition to this, there are subtle traces of a change in the Italian EU discourse, from a rather positive attitude towards a more critical position triggered by the GM maize and soya controversies.

Critiques of the way Monsanto was handling the soya issue were developed in all four countries. But this was not so much a question of EU/US relations, as it was a critique of the way in which multinational companies attempt to dictate politics and bypass fundamental consumer rights, i.e. the freedom of choice. This was, in other words, a moral statement, and not a rejection of Monsanto's right to sell products on the European market per se.

II - PROJECTS FUNDED UNDER THE 5TH FRAMEWORK PROGRAMME (1998- 2002)

INTRODUCTION

Ethical and Socio-economic research in the QoL Programme (1998-2002)

Progress in Life sciences and Biotechnology offers many prospects for our personal wellbeing and for our social and economic welfare. At the same time the development of new technologies and their applications raises a number of important questions about impact on people, society and markets. In the frame of RTD programmes, the Commission is invited by the Council to sponsor activities aimed at studying those impacts. In particular such activities require expertise on the ethical and socio-economic dimension and public understanding of new technologies, thus contributing to the debate that is presently taking place in society. The Fifth Framework Programme (FP5), particularly the QoL Workprogramme, confirms the importance of such activities and stresses that they should be in the centre of all key actions, with a view to harmonising scientific progress and social expectation. Action lines 12 and 13 under Generic Activities stress the launching of specific research and analytical studies in this respect. These 2 lines are articulated as follows:

Action line 12- BIOETHICS

Research in bioethics has the following main objectives (i) to develop an ethical framework for research and to clarify the responsibilities of researchers, policy makers and economic actors; (ii) to contribute to a balanced dialogue between the public and the actors in the field, and an increased public awareness and consultation on ethical issues taking into account different socio-cultural contexts; (iii) to help inform decision makers and citizens with regard to appropriate policy options, and to anticipate and address questions raised by scientific and technological developments, including those arising from this programme; (iv) to create and support pan-European networks of ethical expertise. Priorities are:

12.1. Ethical aspects of scientific and technological developments, notably: (i) the human genome, genetic testing and screening, testing for predisposition, and human genetic diversity; (ii) germline gene modification; (iii) the use of human stem cells; (iv) in utero therapy; (v) xenotransplantation; (vi) ***the use of modern technologies and methods in plant and animal breeding;*** (vii) the use of information technology in medicine.

12.2. Ethical framework for life sciences, notably: (i) the involvement of human beings in research, in particular children, vulnerable groups and people in developing countries; (ii) the use of human cell tissues (including foetal tissues); (iii) ***the use of animals in research, in particular non-human primates***; (iv) ethical conduct of research and issues linked with the dissemination of results.

12.3. Public policies, law, human rights and bioethics, notably: (i) ***bioethics in education systems and professional training; (ii) ethical aspects of consumer, environment, animal welfare and agriculture policies, including issues related to the Biodiversity Convention;*** (iii) ***research on links between bioethics and legislation (Community legislation, international treaties and declarations on bioethics, intellectual property rights,***

development of patent law and practice in the field of biotechnology and its impact on the protection of human rights, consequences of citizens' ethical concerns for international trade relations); (iv) protection of privacy and personal data, including genetic data.

12.4. Bioethics infrastructures and methodologies, notably: (i) comparative analysis of competencies and methodologies used by national, local and international ethics committees; (ii) networking of information infrastructures on legal and ethical data and associated methodologies; (iii) concepts of European and universal ethical standards and their relation with national and regional ethical values; (iv) bioethics and multiculturism; (v) bioethics and the media.

Action line 13- SOCIO-ECONOMIC ASPECTS OF LIFE SCIENCES AND TECHNOLOGIES

This generic activity aims to encourage (i) the socio-economic evaluation of life sciences and technologies within the perspective of sustainable development, and (ii) the socio-economic evaluation of health care technologies. This activity aims to provide useful information to policy makers both in the Member States and at Community level, and also to promote public debate. Highly focused, timely studies concentrating on topical issues are also welcome. Priorities are:

13.1 Development of indicators and knowledge bases relevant to public policy making, covering: RTD strategies/Technology forecasting/Perceptions of new technologies;

13.2 Managing technology in society: impact of genetic information/Health technology from a societal viewpoint/Implications of new technologies for policies;

13.3 Analysis of social and economic driving forces and of new opportunities in the bioindustries, including: impacts of life sciences and technologies on industrial and economic growth/Competitiveness and job creation/Innovation systems/Intellectual Property Rights/Availability of investment capital and human resources/Regulations.

- Key data

Action 12- BIOETHICS

Overall a total of 190 proposals (included accompanying measures such as support for meetings, workshops, training courses, etc.) have been submitted under the QoL programme during the period 98-2002 for generic activity 12 (6 calls for proposals, and 16 deadlines). Around 20% of the proposals were focused on non-medical bioethics issues, notably on food and animal biotechnology, research with animals, environment and biodiversity, etc. **6 projects have been selected and are presently running (1 under negotiation).** These 6 projects, including 3 accompanying measures, are presented in the following pages.

Out of a total budget of over 15 million Euros allocated for different calls for proposals on Bio-ethics (including accompanying measures), the projects presented in this publication represent over 3 million (i.e. 20% of the budget). The remaining 80% of the budget reserved for Bioethics is mainly devoted to health and medicine related projects.

Action 13: SOCIO-ECONOMIC ASPECTS OF LIFE SCIENCES AND TECHNOLOGIES

Overall a total of 60 proposals (accompanying measures excluded) for socio-economic studies have been submitted under action line 13 of the QoL Programme (6 deadlines). Roughly 20% of the projects submitted deal with agricultural, agro-food and food biotechnology related issues. A total of 10 Socio-economic studies (11 million Euros) have been launched under Action line 13. Two Agro-food related projects (SEFABAR and PEG, 1.5 million Euros) are presented in some detail in the following pages.

- Conclusions

In both bio-ethics and socio-economics the response to the calls in the field of agriculture, food, biodiversity and food related topics represents at best one fifth [6] of both the number of proposals and the budget requested. This should be put into the general context of the limited overall response to the calls, in particular for socioeconomics, if compared with other key actions or activities under QoL programme. It is also linked to the fact that the total budget allocated to both bioethics and socioeconomics activities is limited (less than 30 million Euros), compared with other activities of the programmes.

There are other reasons for this mitigated response.

As regard **socioeconomics**, in addition to the socio-economic activity (area 13) there was the possibility to submit proposals directly to the Key Action "Improving the Socio-economic knowledge base" of the Improving Human Potential Programme (in particular under the thematic area: "Technology, Society and Employment"). Furthermore studies oriented towards socio-economic analysis but focused on public health would find a more appropriate fitting under action line 10 (Public Health and Health Services Research). This multiplicity of entry points represent, in our view, an intrinsic quality of the programme and is well reflected, for instance, by the Agricultural, Fisheries and Food biotechnology R&D contracts "with high socio-economic dimension" which are listed on page 122. Most of these projects appear to be based on the balanced integration of pure and applied research activities.

As regards **bioethics and related issues (**e.g. public perceptions, consumers trust in food, food risk assesment and management, risk communication, etc) we can observe a number of projects with additional ethical dimension funded under Key action 1 (food, nutrition and health). Some examples are: Consensus–workshops[7] (QLAM-2001-00067), Consumer-focus [8] (QLAM-2000-00157), Trustinfood (QLRT-2001-00291), Pro-children (Promoting and sustaining health through increased vegetable and fruit consumption among European schoolchildren-QLRT-2001-00547). In the field of farm animal welfare[9] (key action 5) there

[6] This figure is rather optimistic and should be interpreted with caution since the categorisation of proposals is not always easy

[7] http://www.consensusworkshops.org

[8] http// www.spi.pt/consumerfocus

[9] http://europa.eu.int/comm/research/quality-of-life/animal-welfare/seminars/pdf/animal-welfare_en.pdf

are also projects including ethical and social considerations. In addition, we suspect that the **Social and ethical science community** in the life sciences field is not yet used to working across EU borders and has not been encouraged to do so since till now; traditionally, the customers were mainly national bodies. If this is true it is obvious that the interest of researchers in the wider EU context is bound to improve in the future. Without underestimating the efforts made under the ELSA approach and other programmes to promote multidisciplinary projects trying to build bridges between two cultures of humanities /social sciences and natural sciences, the gap between these communities is still very large.

To speed up this process, but also to help hard core scientists to find partners with the appropriate expertise to assemble projects coherently tuned with socio-economic expectations as well as ethical concerns we have implemented in February 2000 a Biosociety web site (http://Biosociety.cordis.lu). The users are informed on socio-economic and ethical topics linked to the new technologies in the field of Life sciences and can access various services including:

- a directory of almost 400 socio-economic experts involved with the impact of new technologies;
- catalogues of funded projects (FP4 and FP5);
- the most recent E.U. legislation on biotechnologies;
- a Bio-glossary of more than 800 technical-scientific biotechnology related terms;
- information to proposers to help them to fully cover socio-economic aspects in R&D proposals;
- a bioforum to stimulate public debates;
- an automatic mailing service for the latest news.

The site is now developing to cover more effectively these aspects. We expect the site to grow into a reference information source for both social and ethical researchers, but also open to hard core researchers in Life Sciences and interested citizens.

AGRICULTURAL, FISHERIES AND FOOD BIOTECHNOLOGY R&D CONTRACT "WITH HIGH SOCIO-ECONOMIC DIMENSION"

Key action 1: Food, Nutrition and Health

Number	Title
QLK1-CT-2000-00040	DISSEMINATING THE RESULTS OF EU FOOD RESEARCH PROGRAMMES TO SMALL AND MEDIUM SIZED FOOD INDUSTRIES, HEALTH PROFESSIONALS AND CONSUMER GROUPS THROUGH A 24-COUNTRY INTERACTIVE NETWORK SYSTEM
QLK1- CT-2000-00100	DIETARY HABITS PROFILE IN EUROPEAN COMMUNITES WITH DIFFERENT RISK OF MYOCARDIAL INFARCTION: THE IMPACT OF MIGRATION AS A MODEL OF GENE/ENVIRONMENT INTERACTION
QLK1- CT-2000-00266	THE ROLE OF DIETARY PHYTOESTROGENS IN THE PREVENTION OF BREAST AND PROSTATE CANCER
QLK1- CT-2000-00431	THE PREVENTION OF OSTEOPOROSIS BY NUTRITIONAL PHYTOESTROGENS
QLK1- CT-1999-00765	NEW METHODOLOGIES FOR ASSESSING THE POTENTIAL OF UNINTENDED EFFECTS IN GENETICALLY MODIFIED FOOD CROPS
QLK1- CT-1999-00752	OPTIMAL NUTRITION TOWARDS OSTEOPOROSIS PREVENTION: IMPACT OF DIET AND GENE-NUTRIENT INTERACTIONS ON CALCIUM AND BONE METABOLISM
QLK1- CT-1999-00651	NEW METHODS FOR THE SAFETY TESTING OF TRANSGENIC FOOD
QLK1- CT-1999-00156	FOOD SAFETY IN EUROPE
QLK1- CT-1999-00916	THE ROLE OF SOCIAL, GENETIC AND ENVIRONMENTAL FACTORS IN HEALTHY EATING: A MULTICENTRE ANALYSIS OF EATING DISORDERS AND OBESITY
QLK1- CT-1999-01182	EUROPEAN NETWORKS ON SAFETY OF GENETICALLY MODIFIED FOOD
QLK1- CT-1999-00010	HEALTHY AGEING: HOW CHANGES IN SENSORY PHYSIOLOGY, SENSORY PSYCHOLOGY AND SOCIO-COGNITIVE FACTORS INFLUENCE FOOD CHOICE

Key action 3: The cell factory

Number	Title
QLK3- CT-2000-00103	OPTIMISING NUTRITIONAL QUALITY OF CROPS
QLK3- CT-1999-00004	ENHANCED, INTELLIGENT PROCESSING OF FOOD AND RELATED WASTES USING THERMOPHILIC POPULATIONS
QLK3- CT-1999-00729	DESIGNING AND IMPROVING HEALTH AND FOOD RELATED PRODUCTION PROCESSES USING FILAMENTOUS FUNGAL CELL FACTORIES

Key action 5: Sustainable agriculture, Fisheries and Forestry, and integrated development of Rural areas including Mountain areas

Number	Title
QLK5- CT-2001-02461	SUSTAINABLE CONSERVATION OF ANIMAL GENETIC RESOURCES IN MARGINAL RURAL AREAS: INTEGRATING MOLECULAR GENETICS, SOCIO-ECONOMICS AND GEOSTATISTICAL APPROACHES
QLK5- CT-2001-01608	RURAL EMPLOYMENT AND AGRICULTURAL PERSPECTIVE IN THE BALKAN APPLICANT COUNTRIES
QLK5- CT-2001-01923	THE ROLE OF SMALL AND MEDIUM-SIZED TOWNS IN RURAL DEVELOPMENT
QLK5- CT-2000-00094	URBAN PRESSURE ON RURAL AREAS: MUTATIONS AND DYNAMICS OF PERI-URBAN RURAL PROCESSES
QLK5- CT-2000-00407	OPPORTUNITIES FOR AND BARRIERS TO TOURISM LED INTEGRATED RURAL DEVELOPMENT IN RURAL REGIONS OF SELECTED MEMBER STATES
QLK5- CT-2000-00559	THE AGRICULTURAL, ECOLOGICAL AND SOCIO-ECONOMIC IMPORTANCE OF FREE-RANGING LIVESTOCK REARING IN EUROPE
QLK5- CT-2000-00593	DEVELOPMENT OF ORIGIN LABBELLED PRODUCTS: HUMANITY, INNOVATION AND SUSTAINIBILITY
QLK5- CT-2000-01031	MEDMONT - TOOLS FOR EVALUATING INVESTMENT IN MEDITERRANEAN MOUNTAIN AREAS - AN INTEGRATED FRAMEWORK FOR SUSTAINABLE DEVELOPMENT
QLK5- CT-1999-30783	A SPATIAL PERIPHERALITY, INNOVATION AND THE RURAL ECONOMY
QLK5- CT-1999-31211	SUPPORTING AND PROMOTING INTEGRATED TOURISM IN EUROPE'S LAGGING RURAL REGIONS
QLK5- CT-1999-01296	EUROPEAN LIVESTOCK POLICY EVALUATION NETWORK: DEVELOPMENT OF A LIVESTOCK POLICY DECISION SUPPORT SYSTEM
QLK5- CT-1999-01510	AN ASSESSMENT OF THE PRACTICALITIES AND ACCEPTABILITY OF A BOND SCHEME AS PART OF COMMON AGRICULTURAL POLICY REFORM
QLK5- CT-1999-01526	STRATEGY FOR INTEGRATED DEVELOPMENT OF AGRICULTURE AND RURAL AREAS IN CEE COUNTRIES
QLK5- CT-1999-01611	SUSTAINABLE AGRICULTURE IN CENTRAL AND EASTERN EUROPEAN COUNTRIES

II. PROJECTS FUNDED UNDER THE 5TH FRAMEWORK PROGRAMME (1998- 2002)

iii) Quality of life Programme

- Bioethics

STRATEGIC INITIATIVES TO DEVELOP AN INTERDISCIPLINARY ORGANIZATION THAT CONTRIBUTES RESEARCH AND PROVIDES EDUCATION IN ETHICAL ASPECTS OF BIOTECHNOLOGY

Contract No. :	**QLAM-2001-0107**	**Coordinator:**
Contract type:	Accompanying measure	**Prof. Franco Celada** c/o Advanced Biotechnology Centre Largo Rosanna Benzi, 1016132 Genoa (Italy) Phone: +39 010 5737303 Fax: +39 010 5737304 **E-mail:** celada@cba.unige.it
Starting date:	02.05.2002	
Duration:	36 months	
EC contribution:	745.228 €	
Website		

Introduction

This strategic initiative is launched to correct the insufficient disciplinarian and theoretical characterisation of the branch of Ethics concerned with Biotechnology, and the virtual lack of BioT-Ethics teaching, particularly at the level of the doctorate student. Thirteen of the foremost authorities in the field, from eleven different European countries, will meet twice a year to delineate and focus upon those aspects at the biology-industry interface where ethical dilemmas arise, to consult with "witnesses"(ranging from industry to Research Institutes and to NGO's), to organise co-operative studies in ice-breaking areas, and to discuss means and methods that can be translated into training programmes.

Objectives

- To improve and advance ethical thinking through research in the area of Ethics, drawing a cultural profile of the discipline's branch that tackles problems arising from the impact of life sciences with industry and to contribute to the generation of new solutions and new standards from the contrast between general principles and the evolving reality;

- To sort out those aspects of ethics that are borne out of the very scientific / industrial progress and therefore are efficacious for the education of graduate students in biological / technological disciplines – who should be trained in thinking responsibly and in communicating with citizens on matters which raise ethical questions;

- To perform field tests of teaching and of alternative ways of education, in cooperation with European doctoral training sites in biotechnology.

Expected results

The expected results are among others a course of BioT-Ethics delivered to European doctoral students of Biotechnology and the opening of a BioT-Ethics European conference.

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FLAD/NSF INTERNATIONAL BIOETHICS INSTITUTE, WORKSHOP FOR BIOETHICAL TRAINING OF LIFE SCIENCES FACULTY, EDITION III

Contract No. :	**QLAM-2001-0222 (III Edition)**	**Coordinator:**
Contract type:	Accompanying measure	**Humberto DELGADO ROSA** Centro de Biología Ambiental Facultade de Ciências da Universidade de Lisboa Rua Laura Alves, 157 , 5° E Murtal Tef: 351.21.4531969 Fax: 351.21.4521061 **E-mail:** hr.lg@mail.telepac.pt
Starting date:	01.04.2002	
Duration:	9 months	
EC contribution:	33.800 €	
Website: Http://www.flad.pt Http://www.biotech@state.edu Http://snaefell.tamu.edu/~gary		

Introduction

FLAD/NSF INTERNATIONAL BIOETHICS INSTITUTE has been funded by the European Commission in the I edition (QLG6-1999-30050) and III edition (QLAM-2001-00222). The partners submitted a proposal for a funding of the second edition but it was not successful. Anyway, the results of the three editions are included hereafter.

The FLAD/NSF INTERNATIONAL BIOETHICS INSTITUTE (FNIBI) aims at helping biological science faculty members of Europe and the United States of America to integrate ethics into their courses and laboratories, teaching them how to discuss ethics with their students. All three annual editions of FNIBI took place in June/July (in 2000, 2001 and 2002), mainly at the premises of the Luso-American Development Foundation (FLAD, *Fundação Luso-Americana para o Desenvolvimento*) in Lisbon.

FNIBI was supported by major grants of **FLAD**, the **National Science Foundation** (NSF, USA), and of the European Commission, D.G. Research, Programme "*Quality of Life and Management of Living Resources*" (for the first and third editions). The first and second editions also received grants from the Foundation for Science and Technology (***Fundação para a Ciência e a Tecnologia***, FCT) / Ministry of Science and Technology, Portugal, with the support of the "*Fundo de Apoio à Comunidade Científica*" and "*Programa Operacional Ciência, Tecnologia, Inovação do Quadro Comunitário de Apoio II*", while the second edition has received complementary funding from the Institute for International Scientific and Technological Cooperation (***Instituto para a Cooperação Científica e Tecnológica Internacional***, ICCTI) / Ministry of Science and Technology, Portugal.

FNIBI has the involvement of **Iowa State University** through its Bioethics Programme, Office of Biotechnology, and Plant Sciences Institute; and of the University of Lisbon (UL) through two of its research units, the Centre of Philosophy (***Centro de Filosofia***, Faculdade de Letras, UL) and the Centre of Environmental Biology (***Centro de Biologia Ambiental***, Faculdade de Ciências, UL). FNIBI was also supported by the Orient Foundation / ***Fundação Oriente***, Portugal, and by the **European Society for Agriculture and Food Ethics**.

FNIBI aimed at the following general results:
- training of >30 life science faculty per edition;
- creation of pedagogical resources;
- induction of the revision of course syllabi;
- promotion of international collaborative teams;
- enhancement of web resources on teaching strategies in bioethics.

Each FNIBI edition had the following main milestones:
- "kick off" event (colloquium) to announce FNIBI to the scientific community;
- application and selection process;
- one week summer workshop.

Main results

Report of Activities

Launching events

In order to bring attention to FNIBI and its call for applications, a launching event was organized each year, in the from of a conference or colloquium on a relevant ethical issue. These launching events were the following:
27 March 2000: conference on "**Ethics and genetically modified foods**", by Gary Comstock, FNIBI's course director, University of Lisbon / Faculty of Sciences;
8-9 March 2001: colloquium on "***Environmental Ethics, an Ethics for the Future***", Centre of Philosophy at the Faculty of Humanities, Univ. of Lisbon; opening conference by G. Comstock ("*Vexing Nature? Environmental Ethics and Agricultural Biotechnology"*); conferences by Humberto Rosa, FNIBI's onsite coordinator ("*Animals, environment and ethics: alliance or contradiction?"*), and by Cristina Beckert, FNIBI's onsite faculty member (*"Animal ethics. a contradiction in itself?"*);
22-23 March 2002: colloquium on "**Environmental Ethics and Sustainable Development**", Superior Institute of Applied Psychology, Lisbon; conferences by Gary Varner, FNIBI's onsite faculty member (*Environmental Ethics and Sustainable Development*"), H. Rosa ("*The Biodiversity Crisis and Sustainability*"), and C. Beckert ("*The Main Currents of Environmental Ethics*").

Follow-up meetings

The launching events of the second and third editions provided the occasion for FNIBI's "*follow-up meetings*". These meetings are open to all past participants, especially those from the host country, and aim at renewing acquaintances and interests established at the summer workshop, reporting on individual progress in introducing bioethical discussions into science

classrooms, and discussing emerging moral issues in the life sciences. FNIBI's graduates were offered free participation at the colloquia, and were invited for a meeting with FNIBI's organizers. Each meeting gathered around 5-7 participants and 2-3 of FNIBI's organizers. A report on both meetings in enclosed as **annex II**.

Diffusion of FNIBI

FNIBI was promoted and diffused both through specific leaflets and through the Internet. The leaflet was used largely in Portugal, where it was distributed among departments and universities of all kinds of life sciences (biology, biochemistry, agronomy, veterinary medicine, medicine, environmental engineering, marine sciences, etc.), and also next to other institutions and individuals somehow related to bioethics or life science teaching. The leaflet of the third edition was also distributed by mail next to several European universities, picked as samples of relevant Universities per each eligible country. E-mail was the main diffusion tool for the remainder of Europe and for the US. A call for applications was widely distributed next to all sorts of entities, especially Universities, but including individuals, specialized discussion lists, etc., related to FNIBI's scope. For the third edition, the e-mails of relevant contacts of a large proportion of each country's Universities (biological departments, international affairs offices, deans, etc.) were picked in the web, through the links available at www.braintrack.com, and a request for diffusion of FNIBI's call for application was sent. The web pages of FLAD (http://www.flad.pt) and of the Bioethics Programme of Iowa State University (http://www.biotech.iastate.edu) were duly prepared to inform on FNIBI, and to give access to the application forms.

Reactions and applications

The diffusion of FNIBI resulted into expressions of interest from a wide variety of people and geographical areas, passing well beyond Europe and the USA. Requests of information appeared from such varied parts of the world such as:

Argentina (Faculty of Medical Sciences, Univ. Nacional de Rosario)
Australia (Dept. Veterinary Sciences, Univ. Sidney)
Brasil (Univ. Estadual de Londrina, Paraná; Univ. Federal Fluminense; Univ. Federal de Santa Catarina)
Canada (Animal Welfare Centre, Atlantic Veterinary College, Charlottetown)
Chile (Univ. de Concepción)
Cuba (Centro de Ingeniería Genética y Biotecnología)
Ecuador (Univ. San Francisco, Quito)
Eritrea (Univ. of Asmara)
French Guyane (Centre IRD, Cayenne)
Ghana (Univ. of Science and Technology, Kumasi)
Guatemala (Univ. del Valle de Guatemala)
India (Indira Gandhi Agricultural Univ., Raipur; Sardar Patel Univ., Gujarat)
Israel (Tel Aviv Univ., Univ. of Haifa)
Jordan (Univ. of Jordan)
Kyrgyz Republic (Kyrgyz Agrarian Academy)
Mexico (Univ. de las Americas, Puebla; Faculty Veterinary Medicine, Univ. Nacional de Mexico)

Russia (Biological Faculty, Moscow State Univ.)
South Africa (Univ. of Cape Town)
Sudan (Univ. of Karthoum)
Thailand (Nat. Center for Genetic Engineering and Biotechnology, Bangkok)
Turkey (Bahcesehir Univ.)
Uruguay (Faculty of Agronomy, Montevideo)

From this sample it can be concluded that the diffusion of FNIBI probably reached life scientists universities from all over the world, and that FNIBI is attractive for a wide range of profiles and nationalities.

Other requests of information or applications came from the **USA** and **Europe**, and namely from **Austria, Bulgaria, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Spain, Sweden, Switzerland, United Kingdom**.

The diversity of candidates was considerable, either in geographical origin or specific areas within the life sciences These included **agriculture, agronomy, animal welfare, anthropology, biochemistry, biomedicine, biophysics, biotechnology, botany, cell biology, developmental biology, ecology, endocrinology, environmental education, environmental sciences, ethology, food science, genetics, human nutrition, laboratory animal science, limnology, marine biology, microbiology, natural sciences didactics, neurobiology, nursing, pharmacology, physiology, plant biology, psychology, veterinary medicine, zoology,** etc. FNIBI was attractive for non life science faculty too, including areas such as **economy, education, history of science, languages, law, philosophy, political science** and **sociology**.

The selection procedure followed the pre-established competitive procedure among the candidates. The number of eligible candidates has grown steadily from edition to edition: 37 in 2000, 74 in 2001, 93 in 2002. Observership participation was offered to some applicants that did not match the selection criteria (non life science faculty members), but with a profile/activity considered especially interesting.

Advance preparation

Some few weeks before each summer workshop, all participants received a copy of the textbook "*The Elements of Moral Philosophy*", by James Rachel (2.nd edition), and of FNIBI's handbook. This volume included case studies, articles, bibliographies and other classroom resources, together with the full program of the institute, texts by the invited speakers, evaluation sheets, contacts of former participants of FNIBI and of Bioethics Institutes in the USA, etc.. Participants were asked and expected to read the textbook as advance preparation for the summer institute, and to read the pertinent parts of the handbook in advance of each corresponding session of the institute.

Workshop program overviews

The final program overviews of each of the summer workshops are included as annexes.

Public conferences

During each of the summer workshops, public conferences on animal ethics issues were held by one of the prominent invited speakers. These conferences were the following:
"*Humans and Animals: the next ethical revolution*?", by Prof. Gary Varner (A&M University, Texas)
"*Animal Rights, Human Wrongs*", by Prof. Tom Regan (North Carolina State University)
"*Ethics and animal biotechnology*", by Prof. Peter Sandoe (Royal Veterinary & Agricultural University, Copenhagen)

Visit: Oceanarium

To help participants know each other, and to raise interest on marine bioethics issues, an early visit to the Oceanarium of Lisbon took place. The group was received and conducted by one of the biologists of the Oceanarium, Dr. Miguel Oliveira or Dr. João Pedro Correia, who kept lively discussions with the participants.

Field trip: Natural Park of Arrábida

As a courtesy of the Orient Foundation / Fundação Oriente, in 2001 and 2002 the program included a visit and full day in a magnificent monastery of the XV century, the Convento da Arrábida, located at the heart of the Natural Park of Arrábida, and right next to the Marine Park of Arrábida. The day started by a lecture on marine issues, and proceeded into the normal working sessions at the premises of the Orient Foundation.

Special topics: agricultural biotechnology

The first edition of FNIBI introduced marine ethics as a special issue within the program. The second and third editions were planned to give special emphasis to what is probably the specific ethical issue on the non-biomedical life sciences more involved in public international controversy: agricultural biotechnology and the development of genetically modified organisms, crops and foods. A leading expert on the topic, Prof. Peter Sandøe (Centre for Bioethics and Risk Assessment, Royal Veterinary & Agricultural University, Copenhagen), who is also the chairman of EURSAFE, the European Society for Agriculture and Food Ethics, conducted major sessions on the topic. Furthermore, examples and case studies on agricultural biotechnology were used throughout the workshop (v.g., the "golden rice" case study on the session on active learning).

Pedagogical strategies and case study development

FNIBI is conceived as an active learning endeavour, devoted to enable participants with strategies and techniques to stimulate and attract their students to bioethics discussions and learning. All speakers were asked previously to consider a special attention to interaction with participants, to the use of case studies, role-play or write-and-pass exercises, or other active learning tools. Such was the case for the generality of the sessions. Adding to that, the workshop program included several sessions for case study construction and presentation. Participants were organised into groups previously to the summer workshop, according to their origin and affinities. This resulted in the development of the following case studies:

FNIBI 2000 - Case studies: examples of case studies are the following:

 # 1 – "Pfiesteria hysteria: a case history"
 # 2 – "S*onar technology and echolocation in whales"*
 # 3 – "The o*rphan embryos"*
 # 4 – "*Hidrotermal vents – an ethical case study in the marine sciences"*
 # 5 – "*Liver xenotransplantation from a transgenically modified pig"*
 # 6 – "*Animal rights and pig production"*

FNIBI 2001 - Case studies: examples of case studies are the following:

 # 1 – "*Don't Goose Me!*"
 # 2 – "*Wild or Life*"
 # 3 – "*Genetically Modified Conservation*"
 # 4 – "The case of the blind laying hens – assessing animal welfare"
 # 5 – "*Lost in the Maize*"
 # 6 – "*Publish or Perish: an editor's dilemma*"
 # 7 – "*Atlantic Salmon in Western Ireland*"

FNIBI 2002 - Case studies: examples of case studies are the following:

 # 1 – To Bt or Not to Bt? - A Case Study of Genetically Modified Corn
 # 2 – Bt and Intellectual Property Issues
 # 3 – The Estonian Moose Dilemma
 # 4 – Governmental Intervention for the Promotion of Organic Agriculture
 # 5 – Farmer Bloggs' Decision
 # 6 – Transgenic Salmon: Towards a superfish?
 # 7 – Who Owns My Genes?

Evaluation by participants

Participants were asked to fill evaluation forms covering the whole of the summer institute in general, and each session and speaker in particular. Using as example the FNIBI 2001 evaluation results, the following summary analysis emerged:
32/33 considered that FNIBI fully achieved its goals (1/33 partially);
active learning techniques, together with case studies and ethical theory, were among the aspects considered most useful;

no clear pattern emerged for the least useful aspects;
as an overall grade (from A to F), FNIBI deserved an average **A** (excellent);
most topics and speakers were, in general, very appreciated.
For FNIBI 2002, a pre- and post-workshop evaluation form was used. The respective results and analysis are not yet available.

Global evaluation

Taking into full account its three editions, it can be objectively said that FNIBI was not less than a great success. Its goals were fully achieved, as reflected by the level of highly positive evaluation of participants. There is no doubt that all and each of the faculty members that attended the institute had their perception and capacities on bioethics permanently changed, and that this will result in life science students discussing bioethics in their classes. In addition, active learning is likely to become a new paradigm for several of the participants. FNIBI was for several of the participants a sort of life-changing experience, as can be sensed from the comments received from participants. According to their own information, some few months after the summer workshop, several participants have engaged into bioethical activities of different kinds.

Textbook and future of FNIBI

A textbook on life science ethics, arising from the US Bioethics Institute and from FNIBI, edited by director Gary Comstock, is on the point of being published by Iowa State University Press.

As future research and development needs, the Bioethics Institute project should now develop into a further international tool to help assist on the introduction of bioethics into life science studies in Europe. Competent and motivated human resources are not all that is needed for a successful integration of ethics into the biological curricula. Further than that, there is the need to develop written and on-line materials in several languages, adapted to the cultural and social contexts of different countries, in order to assist in reaching science students and on-line students outside Europe's university campuses. An **Advanced Bioethics Institute** would serve to 1) deepen the knowledge of participants in practical ethics applied to the life sciences; 2) support basic research in life science ethics pedagogy; 3) enrich participants' classrooms and research with diverse international perspectives; 4) assist participants in adapting and translating the Bioethics Institute's textbook, "Life Science Ethics", and 5) prepare participants to teach the Bioethics Institute's on-line course, "Life Science Ethics".

Annex I

FNIBI 2000 – Summer Workshop Overview
Saturday, July 8

10:30-11:00 Institutional Welcome:
Charles Buchanan, FLAD and Prof. ***Barata Moura***, Rector, U. Lisbon

11:00-13:00 Humans and animals: the next ethical revolution? (public lecture)
Gary Varner, Texas A&M University, USA

15:00-17:30 Introduction to the Institute: ***Gary Comstock***, Iowa State Univ., USA
Helping Science Students to Become More Active Learners: **Comstock**

18:00-19:30 *Porto de Honra* (reception)

Sunday, July 9

9:00-13:00 Field Trip: Oceanarium of Lisbon

14:00-18:00 What is Ethics?: ***Cristina Beckert***, University of Lisbon
Insignificant contributions and partial compliance:
Paula Casal, Univ. Keele, UK

Monday, July 10

9:00-13:00 Ethics and the Marine Sciences: ***Kenneth Tenore,*** Univ. Maryland, USA

14:00-18:00 Environmental Ethics: ***Cristina Beckert***
Ethics and Genetic Engineering:
Peter Sandoe, Royal Veterinary & Agricultural University, Denmark

Tuesday, July 11

9:00-13:00 **Writing Case Studies to Incorporate Ethics into Science Classes:**
Gary Comstock

14:00-18:00 Ethics and Animals: ***Gary Varner***, Texas A& M University
Ethics and Biodiversity: ***Humberto Rosa***, University of Lisbon

Wednesday, July 12

9:00-13:00 **How I Introduced Ethics into Science Courses After the Institute:**
*Jorge Marques da Silva***, Univ. Lisbon**
Ethics and Human Medicine: ***Alexandre Quintanilha***, Univ. Porto

14:00-18:00 Ethics and Science: ***Gary Comstock***
Ethics and Religion: ***Gary Comstock***

Thursday, July 13 **Complete work on case studies**

Friday, July 14 Presentations of case studies

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Annex I (continued)
FNIBI 2001 – Summer Workshop Overview

Saturday 30 June at Fac. Sciences Univ. Lisbon (FCUL)

10:00–13:00 ***Welcome,*** Prof. Pinto Paixão, Dean of FCUL
Introduction to the Bioethics Institute**,** Gary Comstock, Iowa State University
15 – 18 Visit: ***Oceanarium***

Sunday 1 July Field trip: ***Arrábida Natural Park,*** at Convento da Arrábida

8 Departure
10.30 – 11:30 ***Arrabida Marine Park***, Emanuel Goncalves, Institute of Applied Psychology and Miguel Henriques, Institute of Nature Conservation, Portugal
12 – 13 Guided walking tour to Convento da Arrabida
14:30 – 18:00 ***What is ethics?*** Cristina Beckert, Univ. Lisbon
Teaching life science ethics using active learner techniques**,** Gary Comstock, ISU

Monday 2 July at FLAD

9.30 – 13.30 ***Welcome,*** Charles Buchanan, FLAD
Ethical theory, Gary Varner, Texas A&M Univ.
Ethics, agriculture, and biotechnology, Part I, Peter Sandoe, Royal Vet.&Agric. Univ.
14.30 – 18.30 ***Ethics, agriculture and biotechnology, Part II,*** Peter Sandoe, Royal Vet.&Agric. Univ.
Ethics and the marine sciences, Emanuel Gonçalves, Inst. Applied Psychology, Lisbon

Tuesday 3 July

9.30 – 13.30 ***Helping science students be more active learners: golden rice case***, Gary Comstock
How to write case studies to incorporate ethics into life science classes, G. Comstock
14.30 – 18.30 ***How to analyze ethical arguments***, Gary Varner, Texas A&M University
Environmental ethics, Gary Varner

Wednesday 4 July

9.30 – 13.30 ***How I introduced bioethics in my veterinary medicine courses***, L. Lopes da Costa, Vet. Med., Technical Univ. Lisbon
Ethics and biodiversity, Humberto Rosa, Univ. Lisbon
14.30 – 18.30 ***Open: sharing session***
Groups: write case studies

20:00 Optional dinner (at a ***Fado house***)

Thursday 5 July

9.30 – 13.30 ***Animal ethics,*** Tom Regan, North Carolina State Univ.
14.30 – 18.30 ***Present case studies***

Friday 6 July

9.30 – 16 ***Present case studies***
17 – 19 *Public lecture*: ***Animal Rights, Human Wrongs***, **Prof. Tom Regan**, North Carolina State Univ.
20 – 21 Farewell cocktail

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Annex I (continued)

1.1. FNIBI 2002 – Summer Workshop Overview

Thursday 27 June

9:30–13:00 ***Welcome,*** Charles Buchanan, FLAD
Addressing the ethical dimension of the EU funded research - future perspectives**,** speaker to be confirmed, D.G. Research, European Commission
Introduction to the Bioethics Institute**,** Gary Comstock, Iowa State University
What is ethics? Cristina Beckert, University of Lisbon
14:30 – 16:00 ***Teaching ethics using active learner techniques*****,** Gary Comstock
17:00 Public lecture: ***Ethics and animal biotechnology,*** Peter Sandoe, Royal Vet.& Agric. Univ., Copenhagen

Friday 28
9.30 – 13.30 ***Ethical theory,*** Gary Varner, Texas A&M Univ.
14.30 – 18.30 ***Ethics, agriculture, and biotechnology,*** Peter Sandoe

Saturday 29 at the Faculty of Sciences, University of Lisbon (FCUL)
10:00–13:00 ***Welcome,*** Prof. Augusto Barroso, Dean of FCUL
Environmental ethics, Gary Varner
15 – 18 Field trip: ***Oceanarium***

Sunday 30
8:00 Depart for ***Arrábida Marine Park***, and guided tour of Convento da Arrábida
Ethics and oceans, Karin Pittman, Univ. Bergen, Norway
Helping science students be more active learners: Golden rice case, Gary Comstock

Monday 1 July

9.30 – 13.30 ***How I introduced bioethics into my science courses***, Karin Pittman
Golden rice case (concluded), Gary Comstock
14.30 – 18.30 ***How to write case studies to incorporate ethics into life science classes,*** G. Comstock
Groups: Write case studies

1.2. Tuesday 2 July

9.30 – 13.30 ***How to analyze ethical arguments***, Gary Varner, Texas A&M University
Ethics and biodiversity, Humberto Rosa, Univ. Lisbon
14.30 ***Sharing session: Participants discuss how they are presenting ethics to students***
Rest of afternoon free
20:00 Optional dinner (at a ***Fado house***)

1.3. Wednesday 3 July

9.30 – 13.30 ***Ethical theory: Utilitarianism and rights,*** Tom Regan, North Carolina State U.
Animal ethics, Tom Regan
14.30 16.00 ***Groups: write case studies***

1.4. Thursday 4 July

9.30 – 13.30 ***Present case studies***
14.30 – 16.00 ***Sharing session: evaluation of the Institute***
16.00 – 17.00 ***Farewell cocktail***

Partners

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EUROPEAN INFORMATION NETWORK ETHICS IN MEDICINE AND BIOTECHNOLOGY

Contract No. :	**QLRT-2001-0057**	**Coordinator:**
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Starting date:	1.01.2002	
Duration:	36 months	
EC contribution:	1.121.600 €	
Website: www.eureth.net (will be accessible from November 2002)		

Introduction

The Thematic Network will develop an information network and knowledge base in the field of ethics in medicine and biotechnology. The network is designed as a virtual unit of different databases constructed along common database structures and a core thesaurus that allow for cross-searching and comparative information research. It will make relevant sources and value-added information on the field of ethics in biomedicine and biotechnology and related legal sources available to academics, researchers, Bioethical professionals, decision-makers and consumers. The network will also ensure compatibility with other international databases in Europe or beyond European borders. The knowledge base can be accessed through a common Internet portal. It shall provide exhaustive, valid and reproducible Bioethical information thus enabling individuals and societies to better evaluate their options, pursue a balanced dialogue, reach qualified decisions and adopt sustainable policies.

Objectives

The proposed network aims to :

- Improve the research and knowledge infrastructure in the area of ethics in medicine and biotechnology ;
- Pool information resources and provide support for the construction and operation of databases and other information tools ;

- Supply user groups (researchers, bioethical professionals, decision makers, consumers and the public) with structured and reviewed material from medical, ethical and related legal sources ;

- Provide access to institutions working in the field of biomedical ethics ;

- Promote the harmonisation of existing database initiatives in the field of bioethics, and thus

- Foster an informed and educated dialogue between researchers, policy-makers and the public on both a national and European level.

Expected results

Milestones and expected results of the proposal will be the development of common documentary standards and a multilingual hierarchical core thesaurus, the establishment of an internet portal on bioethics including the integrated European Literature Database EuroBELIT and the European Communication and Information system EuroBECIS, the development of value-added information products, and the creation and expansion of the two thematic database networks EUROETHICS and ENDEBIT.

Partners

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ALTERNATIVE METHODS IN ANIMAL EXPERIMENTATION – EVALUATING SCIENTIFIC, ETHICAL AND SOCIAL ISSUES IN THE "3RS" CONTEXT

Contract No. :	**QLRT-2001-0028**	**Coordinator:**
Contract type:	Shared cost	**Dr. Flavia ZUCCO** Istituto di Neurobiologia e Medicina MolecolareConsiglio Nazionale delle Ricerche V.le Marx 15 I – 00131 Roma Tel.: +39.06.86090245 Fax: +39.06.86090370 Email: f.zucco@in.rm.cnr.it **Appointed researcher:** **Dr. Caterina Botti** **Email: catbot@libero.it** **External collaborator:** **Dr. A. Stammati** **Email: stammati@iss.it**
Starting date:	1.01.2002	
Duration:	36 months	
EC contribution:	399.492 €	
Website: **Anim. Al. See** **(It is planned as one of the final activities of the project)**		

Introduction

The issue of the use of animals as experimental model in biomedical research is still of major ethical, scientific and economic importance, and could be better managed not as a yes/no issue. In this context the alternative methods are often considered a panacea, as if it would exist a universal alternative. For this reason, it can be very useful to assess the impact of the recent development of alternative methods to animal experiments on the current concepts, related to this issue. Thus, our intention is to explore, in the more comprehensive possible way, the interplay between the scientific, ethical and socio-economic aspects and their respective influence in specific areas of application.

On this respect, the project will take into account two main relevant features.

The first one is that the evaluation of alternative methods in animal experimentation must be the result of the balance and interactions of different aspects, whose relative weights change from case to case: scientific validity; welfare of the animals involved; normative and regulatory aspects; social aspects (such as public perception) and ethical acceptability. For this reason the project will be interdisciplinary and see the participation of researchers coming from different field, such as biology, philosophy and social studies.

The second important feature to be taken into account is that alternatives in animal experimentation is not a new concept. An important point of the project is in fact the focus on the "3Rs" model elaborated by Russel and Burch in 1959, based on three concepts:

"Refinement", "Reduction" and "Replacement", a model that is recognised to be pivotal to the issue of alternatives in experimentation. The European Commission strongly supports "3Rs" development, validation and implementation, as laid down in some of the articles of the Council Directive 86/609.

The project is aimed at offering specific conceptual and operational definitions in order to give a new, more up-dated and more comprehensive interpretation of the model, to improve the implementation of alternative methods This operation, as a matter of fact, appears to be needed since from the time of the original elaboration of the model many things have changed in the field of animal experimentation. For example, two aspects such as scientific validity or public perception have changed their characterisation in the last years.

Objectives

The final objective of the project is to define up-dated conceptual landmarks relevant to the issue of alternatives in animal experimentation in the "3Rs" context. Such landmarks will have both theoretical and practical value. On a theoretical point of view, we intend to better clarify the responsibilities of the different actors involved in the issue of alternatives in biomedical experimentation, and to increase the awareness of the general public on the complexity of this issue. Our theoretical effort will be then also reflected in the practical side of the project, where we will define conceptual landmarks, under the form of guidelines and recommendations, to be helpful for bioethical committees and decision makers when it comes to suggestions aimed at improving the existing European normative related to animal experimentation.

Therefore, in particular, the conceptual landmarks will be useful in:

(1) defining and clarifying the weight of the different conceptual component involved in evaluating possible alternatives in animal experimentation;

(2) identifying the different roles and interactions of the different subjects involved and their responsibilities;

(3) helping to increase the awareness of scientific community, general public, regulators, on the complexity of the interactions between the different responsibilities;

(4) helping bio-ethical committees to evaluate and decide on possible alternatives in the use of animals as experimental model in particular research projects;

(5) helping decision makers to improve the existing normative.

Methodology

The project will develop in three phases.

In the first phase of the project, the leader group will co-ordinate the conceptual analysis aimed at elaborating questionnaires to be sent out to a platform of experts involved at different levels in the evaluation and use of alternatives in animal experimentation, to survey the general understanding of the « 3Rs » model. This will be done in order to assess the actual consensus on the concept of alternatives. The elaboration of the questionnaire and its

diffusion is an important part of the first phase of the project, and will be carried on as follow: 1) Development of the questionnaire by the identification of the relevant questions; 2) Development of a sampling strategy, to ensure a good representation of persons involved in research, industries, public institutions, both at national and international levels. The sample will be represented on one hand by subjects from international organisations, with different professional and cultural backgrounds, related to scientific, commercial and regulatory role; on the other hand, by subjects coming from U.K., The Netherlands and Italy. Two main reasons support such choice. The first consists in the need for the researchers participating in the project to "test" their use of the notions involved in the field of alternatives with the results of the questionnaire coming from their own socio-cultural background. The second one lies in the fact that the three countries are representative of very different cultural and social contexts: in the U.K. the public opinion and the cultural milieu have led to a particularly advanced approach to animal housing and use; The Netherlands are known to be a very pluralistic society open to social reforms; Italy seems to have a more conservative approach, due to the influence of catholic culture and the political influence of the Church. Then the participants to the project, on the basis of the personal knowledge and experience in their particular field, will analyse the results of the questionnaires. The aim is to create operational definition related to different aspects mentioned above, with a special focus on possible conceptual and practical difficulties in integrating different European countries.

In the second Phase, three different multidisciplinary groups, will apply and try out the results of the first phase to case studies relevant to the «3Rs » model. One group will work at the concept of « Refinement », and two related case studies: experimental protocols involving non-human primates; housing of non-human primates. The second group will focus on the concept of « Reduction » and two related cases: up and down and single doses approaches. The third group will work at the concept of « Replacement » focused in particular on topical toxicity, mainly concerning the in vitro cosmetic testing. Each group will organise a workshop to discuss and present its results. The results of the different groups will be collected in a second preliminary report.

In the third phase, conceptual landmarks useful for workers involved at different levels in the issues of alternatives in animal experimentation will be worked out. In particular, the final aim is to obtain a more up-dated interpretation of the «3Rs » model. In a final conference a report will be presented to the expert platform, and final guidelines and recommendations, with a special focus in finding common standards at a European level , will be elaborated.

Main results

The present project is at the moment in the first year of activity, corresponding to the first phase and the beginning of the second.

It is our opinion that the successful implementation of alternative methods in animal experimentation will not depend only on the scientific and technological progress, but it will also rely on the evolution on the entire conceptual framework that we outline in the present project.

- An important innovative aspect is indeed the interdisciplinary nature of the project, integrating philosophical and scientific expertise specialised in the field of alternatives in animal research. This methodology is the most suitable to reach the objective of this project,

that is, to work on a new conceptualisation of alternatives in animal research at an European level.

- Another innovative aspect of our approach is to challenge the existing conceptual framework against practical cases. This process will allow to assess the level of integration between the practical experience in alternatives and the appropriateness of the actual theoretical background.

- The results of the analysis will be reflected in the formulation of recommendations and guidelines for the evaluation of alternatives in animal experimentation. These recommendations and guidelines will represent the operational innovative aspect of the present project, representing the practical side of the theoretical effort, aimed at defining operative standards and practices in this field, based on a more updated and more comprehensive agreements between different European cultures.

- The outcome of the present project will also represent an important theoretical tool to approach the issue of the increasing gap between science and humanities, which is one of the crucial points of the epistemological debate. As a matter of fact, in the field of bio-medical research concerning human subjects such gap has been narrowed by the practical effects of the theoretical debate in bioethics among medical professionals and researchers of various disciplines. It is then reasonable to expect that the same approach in the field of animal experimentation could help closing the gap that seems to persists between protectionists, scientists and regulators.

In particular the expected results are:

First phase: preparation and distribution of a questionnaire to assess the actual framework concerning the concept of alternative; elaboration of outcomes (in progress);

Second phase: identification of consensus criteria to be tested in case studies relevant to the « 3Rs » model.

Third phase: integration of the results of the previous phase in the elaboration of conceptual landmarks as a basis for guidelines and recommendation.

5. Partners

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THE DEVELOPMENT OF ETHICAL BIO-TECHNOLOGY ASSESSMENT TOOLS FOR AGRICULTURE AND FOOD PRODUCTION

Contract No. :	**QLRT-2001-2594**	**Coordinator:**
Contract type:	Shared-cost	**Dr.Volkert BEEKMAN** Agricultural Economics Research Institute Centre for Methodical Ethics and Technology Assessment PO Box 29703 NL - 2502 LS The Hague Tel: +31-70-3358147 Fax:+31-70-3615624 Email: **v.beekman@lei.wag-ur.nl**
Starting date:	Under negotiation	
Duration:	36 months	
EC contribution:	813.123 €	
Website:		

INTRODUCTION

The general objective of ETHICAL BIO-TA TOOLS is to develop and improve tools for the ethical assessment of new technologies in agriculture and food production in general and modern biotechnologies in particular. The project thus responds to the plurality of consumer concerns that increasingly informs the European public debate on agriculture and food production. This general objective is divided in four sub-objectives:

1) the development and improvement of ethical decision-making frameworks to facilitate regulatory decision-making about modern biotechnologies;
2) the development and improvement of consensus conferences to facilitate public opinion-formation about ethical aspects of modern biotechnologies;
3) the development and improvement of ethical benchmarking to facilitate decision-making by economic actors in the food chain; and
4) the establishment of a network for comparative discussions about ethical (bio)technology assessment tools for agriculture and food production.

Scientific approach

The ETHICAL BIO-TA TOOLS workplan is broken down in three substantial workpackages (WPs):

- WP1 (Ethical decision-making frameworks) aims at the development of a practical decision-making framework to assist public and private decision-makers map and consider the ethical dimensions of animal and plant biotechnologies. It will build on earlier, only partially succesful, work which focused on the development of a framework known as the 'ethical matrix'. This approach will be critically analysed and compared with other emerging methods, such as those based on multi-criteria mapping.

(6) WP2 (Consensus conferences) aims at the development and improvement of consensus conferences to facilitate public opinion-formation about the ethical aspects of modern biotechnologies in animal and plant breeding. It, therefore, includes an assessment of existing participatory tools, i.e. consensus conferences, in different European regions. A checklist will be developed of what should be done and considered to achieve the established goals of particular consensus conferences.

(7) WP3 (Benchmarking) aims at the development of ethical benchmarking as a tool to facilitate communication between economic actors in the food chain and consumers in order to gain trustworthiness. It includes conceptual analysis and translation of the ethical notions of trust, responsibility and care from medical and political fields of application to agriculture and food production, and will develop a framework for communication between the respective experts in food chain management and agricultural and food ethics.

Expected results

The primary achievement of the project will be the availability of three ethical (bio)technology assessment tools to facilitate opinion – formation and decision-making in agriculture and food production. Foreseen milestones are the publication of the interim reports “description”, “evaluation” and “development” in months 11, 19 and 27 respectively, and the publication of the final report as well as the practical guidelines and instructions for the application of the developed tools in month 35.

Partners

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PLANT INTELLECTUAL PROPERTY WITHIN THE EUROPEAN AND GLOBAL CONTEXT (PIPWEG)

Contract No. :	**QLG6-2001-30131**	**Coordinator:**
Contract type:	Accompanying measure	**Dr Margaret Llewelyn** SIBLE – Sheffield Institute of Biotechnology Law and Ethics, University of Sheffield, Crookesmoor Building, Conduit Road, Sheffield, S10 IFL UK Tel +44 (0) 114 2226829, fax + 44 (0) 114 2226832 **Email:m.llewelyn@sheffield.ac.uk**
Starting date:	01.02.2001	
Duration:	8 months	
EC contribution:	68.725 €	
Website: **i)** ***Proceedings of PIPWEG 2001: Conference on Plant Intellectual Property within Europe and the Wider Global Community*. Sheffield Academic Press 2002,** **ISBN 1 84127 326 0** **ii)** PIP website: **http://www.shef.ac.uk/uni/projects/pip** Forthcoming: *European Plant Intellectual Property:* Hart Publishing Ltd 2002		

Introduction

The Accompanying Measure facilitated the hosting of an International Conference on *Plant Intellectual Property within the European and Global Context* in Angers on 9/10/11 January 2001, the dissemination of the conference proceedings through publication by Sheffield Academic Press and wider dissemination of the results of project BIO4-CT98-0190 by Hart Publishing Ltd in 2002. The Conference provide a platform for dissemination of the initial results of the EU-wide survey of the attitudes of the European plant breeding industry and enabled these results to be placed in both a European and international context.

Background

From September 1998 until the end of January 2001 the Sheffield Institute of Biotechnology Law and Ethics co-ordinated the project.

SIBLE was well-placed to carry out research of this nature and to undertake the measure contracted for under QLG6-2001-30131. It is an internationally recognised research centre specialising in all aspects of biotechnology. In particular it is renown for its work in intellectual property law and work carried out within the institute already has an international reputation which ensures that it is disseminated at the highest policy levels. The project met with approval from within both the plant breeding and legal communities. Indeed the extent to which plant breeders from all sectors of plant breeding, from agricultural crop production to

medicinal plant production, actively participated within the project demonstrates the extent to which the issue of how to effectively and appropriately protect the commercially valuable products of plant research and development is critical to the ongoing viability of the European plant breeding industry. The results of the project clearly show that without effective and appropriate protection the industry is concerned about its future particular in light of the lack of an open debate on the impact of intellectual property rights on their ability to carry out research and development. From the beginning the project has been consistently held up as a mechanism by which these views can actively fed into the legislative and policy decision making process. As such the project is regarded by the industry as an important addition to the discussions.

This approval, together with considerable interest in equivalent follow-up projects, has been forthcoming not merely from within the EU but from around the world. This interest has not been confined to countries within the developed world but, almost more importantly, it has come from developing countries which are looking to Europe as a potential model of how they should respond to the obligation entered into as a result of membership of the TRIPs Agreement to provide either patents or an effective *sui generis* system of protection for plant varieties (Article 27(3)(b). In addition developing countries are looking at how they can balance the rights granted under a patent with those granted under a plant variety right. The extent of the interest from within the EU and outside was been such that the project came under considerable pressure to disseminate the results to the widest possible audience and not confine its findings to the European environment.

The impact of the views made at the conference, together with those obtained through the project BIO4-CT98-0190, is likely to be considerable at both the EU, national and international levels. Given the considerable economic importance attached to agriculture, with much of this value coming from the ability of plant breeders to produce improved plant products, it is vital that the rights which are provided to protect these products are appropriate to the needs of the plant breeder, many of whom fall within the EU definition of a Small to Medium Sized Enterprise.

Objectives

The objectives of the Accompanying Measure were :

a) the hosting of an international conference as part of the international debate on plant intellectual property provision;

and

b) to disseminate the proceedings of the conference to the widest possible audience through dual publications of the proceedings and the results from project BIO4-CT98-0190, via the Sheffield Academic Press and Hart Publishing Ltd respectively.

Methodology

The work comprised:

a) transcribing and translating the conference proceedings, checking the evolving international legal environment for developments affecting the contributions, assisting the contributors with producing the final publishable works and editing the proceedings, and

b) replacing the previous publishers, Butterworths, with two other publishers, Hart Publishing Ltd and Sheffield Academic Press and finalising the report under BIO4-CT98-0190 for publication in 2002.

Main results

The Conference

The conference, which concluded the BIO4-CT98-0190 project, developed its focus from being mainly Euro-centric to international. This meant that interested parties from around the world would have access to the project results, engage in a debate as to how the European experience is impacting on the European plant breeding industry and, in global terms more critically, to draw on the European experience in order to develop their own plant intellectual property provision.

The level of interest which the event attracted can be seen by the calibre of those who agreed to be involved in the event. At the behest of the Community Plant Variety Rights Office, based in Angers, the event was held in Angers. This showed support for the project and its objectives. Speakers (both from within the EU and outside) were drawn from a variety of diverse backgrounds and cultures. They included representatives from the plant breeding industry, the farming community, non-governmental organisations, eminent professors of law from Europe and the United States of America, and organisations such as the UN, WIPO, Organisation of African Unity and the Andean Pact. It was the first time that speakers from such disparate backgrounds and interests have been brought together and its importance in respect of the global access to plant genetic material cannot be underestimated.

There were parallel internal European and external international reasons why this conference was timely and warranted support

Internally the European Patent Union, which oversees the European Patent Convention, began a revision of the Convention, one of the issues under consideration was the protection of basic genetic material. The start of this process took place at the same time as the European Commission introduced its proposals for an EU patent which is intended to take account of technological developments in a manner to date not apparent within existing European patent law. In respect of the plant breeding industry it is critical that their views as to the extent to which plant material should form the basis of an intellectual property right were heard and taken into account in both debates. As this industry is critical to the continuing economic viability of the EU it is crucial that the views of those engaged in the use of plant material

should be heard. One of the intentions behind the conference was to provide a platform for the industry from which their views as to whether the rights serve their needs could be presented.

The reason why the conference was timely from the international perspective was because the World Trade Organisation extended its review of the implementation of Article 27(3)(b) from 2000 to the end of 2001 (in the first instance). Many developing countries remain unconvinced of either the need or desirability of introducing private property protection for genetic resources. It is also possible that the WTO will look again at whether or not Article 27(3)(b) should form part of the TRIPs Agreement. In respect of the former, it is in the interests of the bioscience industry as a whole to ensure that there is uniformity of protection at the global level. Europe is in a very strong position to present its policy and practice as a model of how this protection should be formulated. The involvement of representatives from developing countries in the conference served to help to underline the European position and reinforce the premise that all rights introduced should be based on balancing the needs of industry against those of society. In respect of the latter, the conference provided a non-contentious forum within which the debate over the future of plant intellectual property was conducted.

Because of this interest the project team was compelled to enlarge the focus of, and participation in, the conference. The resulting Accompanying Measures award, which was not intended to fund the conference itself, enabled the project team to employ the requisite support team to administer the conference appropriately and disseminate the resulting documentation in a manner commensurate with the level of interest and importance which it has to date attracted.

The conference took the form of a two day meeting held at the Centre de Congres in Angers, France on the 10th and 11th of January 2001.

The conference covered such key matters as the policy and practice of the Community Plant Variety Rights and European Patent Offices, the nature of new concepts in plant intellectual property (for example the notion of essentially derived varieties) and allowed speakers from outside Europe to describe their plant intellectual property experience enabling the European position to be placed in a global context..The conference provided a forum for discussion of some of the areas of concern in plant intellectual property provision identified through project BIO4-CT98-0190. Whilst it would not be possible to state that the problems were resolved or fears allayed, the discussion at the conference did indicate that, particularly in the case of plant variety rights and issues such as essentially derived varieties, resolution could be possible via an ongoing dialogue between breeders and granting offices. The conference also enabled the project findings to be compared with the experience of plant breeders organisations such as FIS/Assinsel. These additional perspectives proved invaluable for the purposes of evaluating the findings under project BIO4-CT98-0190.

The speakers were (in alphabetical order):

Dr M. Adcock (SIBLE, UK), Dr. A. Alexandra (CAPPE, Australia), Professor J. Barton (Stanford University, USA), Dr S. Bragdon (IPGRI, Italy), Dr. B. le Buanec (FIS/ASSINSEL, Switzerland), Dr B. Charlwood (Brazil), Dr B. Claes, (EPO, Germany), Dr J. Elena (CPVO, France), Professor C. Franz (IAB, Austra), B. Greengrass (formerly UPOV, Switzerland), Dr J. Guiard, (GEVES, France), Dr. D. Klein (COPA & COGECA, Germany), Dr M. Koller (Bundessortenamt, Germany) Dr M. Llewelyn (SIBLE, UK), F. Moran (Plant Technology Ltd, Eire), T. Roberts (CIPA & Roberts & Co, UK), R. Royon (CIOPORA, France), Dr G. Sage (formerly Monsanto, UK) A. de la Soujeole (SICASOV, France), L. Svensater (Sweden) and A. Tesselaar (Australia).

108 delegates attended from around the world.

II. PROJECTS FUNDED UNDER THE 5TH FRAMEWORK PROGRAMME (1998- 2002)

iii) Quality of life Programme

- Socio-economics

PRECAUTIONARY EXPERTISE FOR GM CROPS

Contract No. :	**QLG7-2001-00034**	**Coordinator:**
Contract type:	Shared-cost	**Dr. David Wield** Center for Technology Strategy Open University Walton Hall UK - Milton Keynes MK7 6AA Tel : +44 1908 653759 Fax : +44 1908 652175 **Email:** D.V.Wield@open.ac.uk also: **Dr. Les Levidow** **Email:** L.Levidow@open.ac.uk **Dr. Susan Carr** **Email:** S.Carr@open.ac.uk
Starting date:	01.01.2002	
Duration:	30 months	
EC contribution:	549.000 €	
Website: Website: http://www-tec.open.ac.uk/cts/bpg.htm **Contact person:** Mary McVay Centre for Technology Strategy The Open University UK - Milton Keynes MK7 6AA Tel.: +44 1908 653672 Email: M.McVay@open.ac.uk		

Introduction

In response to regulatory and trade conflicts, the European Commission has adopted guidelines for the precautionary principle. The guidelines emphasize risk-management measures as a precautionary response to predictive uncertainty, while requiring efforts to obtain more scientific information. They imply that more research could straightforwardly reduce the uncertainty. In the case of GM crops, however, more scientific information has intensified scientific controversy about risks and the appropriate methods for researching them.

Official expertise plays a central role in judgements on scientific uncertainty. Expert bodies are being expected to resolve scientific disagreements from an 'independent' standpoint. According to the Nice Council in 2000, the experts responsible for scientific risk assessment should be kept functionally separate from those responsible for risk management, which entails a political appraisal of the desired level of protection. Yet expert advice on risk assessment is often seen as politically biased.

To enhance the public accountability of public-funded research, the European Commission has proposed 'the development of new and sustained forms of dialogue between researchers and other social operators', i.e. not simply government and industry. Given that regulatory decisions involve normative considerations, 'Many of these issues call for various forms of participatory processes within which stakeholder involvement is important both for the formulation of concepts and questions as well as for the implementation', according to a report from a October 2000 conference on 'Science and Governance'.

Three key processes increase the complexity surrounding the use of the precautionary principle:

- Regulatory measures operate within conflicting accounts of uncertainty in risk assessment and scientific knowledge.

- Regulatory authorities claim that their decisions are 'science-based', yet their expert advice incorporates value frameworks, often rooted in particular models of agricultural futures.

- Stakeholder groups lack clear access to those frameworks, e.g. through public involvement in evaluating them, or through clear standards for evidence which innovators must provide.

Social-science perspectives can help to illuminate those processes.

Objectives

For dealing with conflicts over GM crops and their food uses, the precautionary principle has been widely accepted, but its meaning is contentious. For that case study, this project analyses how current European practices compare with different accounts of the precautionary principle. As contributory objectives, it analyses the following features of procedures for regulating GM crops:

- how regulatory measures draw practical links between risk research, assessment and management;

- how expert bodies mediate between regulatory science and public-scientific controversy, e.g. through judgements on scientific uncertainty; and

- how stakeholder groups (e.g. innovators and NGOs) attempt to influence regulatory processes, within or beyond formal procedures.

Using the analytical results, the project will suggest the following:

- how to clarify EU guidelines, so that they better reflect national regulatory measures, and so that decision-making procedures can be publicly accountable and scientifically defensible;

- how expert bodies could better accommodate public-scientific controversy within their judgements, and how national practices could contribute to an EU-level precautionary expertise;

how to enhance policy learning about these issues among users of the research findings.

Methodology

For GM crops in Europe, this project analyses how current practices – regulatory measures, expert judgements and stakeholder roles – compare to different accounts of the precautionary principle. These practices are being studied at EU level and in 7 member states (see Table). The project will build upon and integrate earlier studies of public attitudes, risk regulation, precaution and deliberation.

Table: Three Institutional Practices

	i) Regulatory measures	**ii) Expert judgements**	**iii) Stakeholder roles**
Objective to analyse	How risk research, assessment and management are linked in practice	How expert advisory bodies mediate between regulatory science and public-scientific controversy	How stakeholder groups attempt to influence regulatory measures, within or beyond formal procedures
Subsidiary questions	How such links are drawn by innovators, research institutes and regulators How priorities are set for the cause-effect uncertainties to be tested and managed	How such bodies are broadened or supplemented; How they set criteria for evidence, environmental norms; How these criteria relate to wider concerns	How they participate in deliberative procedures; How they promote accounts of evidence, uncertainty, precaution and sustainable agriculture
Analytical perspectives	Precaution as epistemic humility about science; Socio-cognitive framing of uncertainty	Expertise becomes more important politically but less credibly neutral or independent	Deliberation of value-frameworks and problem-definitions
Data sources	Documents and interviews	Documents and interviews	Documents, interviews, advisory panel, workshops

Users of the research are involved through a Brussels-based advisory panel, which has already met in March and September 2002. Users will be involved also through a scenario-analysis workshop, which will consider several plausible scenarios for future developments.

Expected results

Dissemination: Shortly after each workshop, a draft report will be circulated to participants for comment; the final version will be made publicly available. At the end of the project, the overall final report will include an Executive Summary, to be produced for widespread distribution, as well as separate reports from the EU and national studies.

Policy relevance: The results will illuminate how precautionary expertise could address the policy problems which the EU faces.

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SUSTAINABLE EUROPEAN FARM ANIMAL REPRODUCTION AND SELECTION (SEFABAR)

Contract No. :	**QLG7-2000-01368**	**Coordinator:**
Contract type:	Thematic network	**Anne-Marie Neeteson** and **Anna-Elisa Liinamo** Farm Animal Industrial Platform (FAIP) Benedendorpsweg 98 NL - 6862 WL Oosterbeek Tel:+31 26 339 15 38 Fax: +31 26 339 15 39 e-mail: **Neeteson@iaf.nl** and **anna-elisa.liinamo@alg.vf.wag-ur.nl**
Starting date:	01.12.2000	
Duration:	36 months	
EC contribution:	908.000 €	
Website: http://www.sefabar.org Project related websources: Patenting biotechnological inventions in the farm animal area (available from www.faip.dk/985proce.htm) List of Questions and Answers on patenting (available from www.faip.dk/patent.htm) Report on farm animal genomics in Europe, to be found at www.faip.dk/genome.zip		

Introduction

SEFABAR is organized under the responsibility of the Farm Animal Industrial Platform *(FAIP)*, and guided by a Management Group that includes representatives of the European Association for Animal Production (EAAP), the European Aquaculture Society (EAS), the World's Poultry Science Association (WPSA). SEFABAR will develop a network to facilitate and stimulate economically sound, society acceptable sustainable strategies of farm animal breeding and reproduction. Scientists and industry managers will explore sustainable breeding strategies for cattle, pigs, poultry and fish. Results of case studies on socio-economic aspects with regard to farm animal breeding and reproduction will be integrated into this process. The case studies consist of the visualization of the cultural differences within Europe and between Europe, USA and Asia (Wageningen University - Rural Sociology), the study of ethically and animal welfare regulatory aspects (Royal Veterinary and Agricultural University - Centre for Bioethics and Risk Management and Akademie fuer Tierschutz), a study on the role of public opinion (INRA - Laboratoire de la Recherche sur la Consommation) and a study on the economic situation and world trade aspects (University of Exeter - Agricultural Economics Unit). Society and policy makers will be informed about the results. During the project a web site will be available with actual activities and results.

Expected results

Discussion and definition of sustainable breeding goals per species and across species.
Discussion on cultural differences influencing acceptability of new (bio)technologies and sustainable breeding and reproduction strategies.
Dialogue between industry, society and science and information material for policy makers and society on sustainable animal breeding and reproduction. In short, the aim of SEFABAR is to find sustainable, economically sound and accepted breeding scenarios for ruminants, pigs, poultry and fish, and a

broad overview of sustainable breeding possibilities for farm animals as a whole. The advantage of the thematic network is that it provides a safe environment in which discussion, opinion forming and dialogue building can take place. The aim of the first year was to establish a network of over 40 industry and research managers ("members") to make well-discussed definitions of sustainable breeding and reproduction for ruminants (milk and meat), pigs, poultry (eggs and meat) and aquaculture, an overview of ongoing research and business efforts with regard to sustainable breeding and reproduction, and to define knowledge gaps. This information will be used in the second year as background information for the socio-economic partners to get their opinion on sustainable farm animal breeding and reproduction, and to work out sustainability across species by the network members. In the third year the results will be integrated, to come with a report and a brochure on sustainable farm animal breeding and reproduction for policy makers and extended audiences.

First year results

The animal breeders and scientists, equally divided between species and between industry and research, cooperated in working parties per group of species: ruminants, pigs, poultry and aquaculture.

They started their discussions in the Start-up meeting of SEFABAR in April 2001, and continued in e-mail communities per species and in group workshops. Based on the discussions, they prepared for each species a report containing an introduction to the history and current state of the art in breeding/reproduction, key traits and trends, an overview of ongoing research and business efforts, knowledge gaps, and options for sustainable breeding and reproduction in the future. Their report will be used for internal reference - a report for publication will come available in March 2002.

The socio-economic partners made their work plans at the end of the first SEFABAR year. Draft breeders' reports and draft work plans were commented and taken into account at e.g. a combined meeting for the MG and the socio-economic partners in November 2001. The limitations of the communication possibilities were solved in the following ways: 1) the coordinator and network manager visited some of the partners; 2) some socio-economic partners visited breeding facilities, 3)
most working parties organised an extra discussion meeting, and 4) a SEFABAR Newsletter. The network manager was the central contact point of the Network. Additionally, two MG members had
monthly progress meetings with the network manager and the coordinator for regular scientific and industry input and advice, fine-tuning and discussing desirable additions and corrections to the original work plan.

SEFABAR developed a web site for public information and internal use: www.sefabar.org.

Partners

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III - RESEARCH UNDER THE 6th FRAMEWORK PROGRAMME (2002-2006)

NEW APPROACH FOR THE INTEGRATION OF THE ETHICAL, SOCIAL, LEGAL AND WIDER CULTURAL ASPECTS INTO RESEARCH PROJECTS

The 6 Framework Programme highlights that consideration of the ethical, social, legal and wider cultural aspects of the research to be undertaken and its potential applications, as well as socio-economic impacts of scientific and technological development and foresight, will where relevant form a part of the activities".

This approach is fully in line with the actions proposed by the Commission in its "Communication on Life Sciences and biotechnology – A strategy for Europe "(Action 14), where it is stated that the Commission will strengthen and focus Community support for research into socio-economic and ethical issues and that the Commission will ensure that the ethical, legal and social implications are taken into account at the earliest possible stages of Community supported research.

The Commission responsibility is to ensure that the ethical debate becomes a natural part of the research and development process in life sciences and that society is involved as much as possible. This approach will be essential for achieving the ambitious goal of translating the progress in life science into real benefits for society.

In order to achieve this goal the ethical, social, legal and wider cultural aspects need to be addressed at several levels, mainly :

A. by promoting the integration of the analyses of the ethical, legal and social aspects into research projects

B. by encouraging public dialogue and participation of stakeholders in research projects

A. INTEGRATION OF THE ANALYSIS OF THE ETHICAL, LEGAL AND SOCIAL ASPECTS INTO RESEARCH PROJECTS

In the context of this publication, the thematic priority 5 "Food quality and safety**"** is especially relevant. Its objective is to help establish the integrated scientific and technological bases needed to develop an environmentally friendly production and distribution chain of safer and healthier and varied food, and also to control food-related risks, relying in particular on biotechnology tools, as well as health risks associated with environmental changes. In addition, under the thematic priority 1 "Life sciences, genomics and biotechnology", fundamental research on genomics in all organisms will be fund[10]ed, including genomics [11]and post-genomics research on crops and animals as

models in the elucidation of the human genome (possible downstream applications in food quality and safety –Priority 5).[12]

In order to ensure that the ethical, social, legal and wider cultural aspects are fully taken into account, these two thematic priorities should not only be directed towards exclusive scientific objectives but should ensure that, when relevant, the identification and analysis of the possible ethical, legal and social implications takes place at the earliest possible stage of the development and before the technology is ready for use by the society

Experts in ethics, law and social sciences should, whenever relevant, be encouraged to participate in the research projects. The integration of these holistic disciplines in the research projects can strongly help to explore scientific uncertainty regarding ethical arguments, legal framework and social research which can help to streamline the development of new technologies in life sciences. This co-operation will undoubtedly help to prepare the ground for the debate with society and to anticipate problems that cannot be properly addressed by concentrating exclusively on scientific objectives. The integration should permit each discipline to use its one approach and allow mutual education and dialogue. Similarly, this collaboration will allow experts in ethics, law and social sciences to check that their assessment and proposed solutions toward these new research and technologies are relevant and appropriate, and ensure that due account is taken of the ethical and social concerns, our obligations towards future generations and the rest of the world. International participation will be an important aspect of this inclusive approach.

The relevance, quality and level of integration of these different aspects will be assessed during the evaluation process.

The Commission hopes that this approach will constitute a step further for building bridges between “the two cultures” of natural sciences and humanities.

Finally, it should be noted that specific support for research projects focusing exclusively on ethical, legal and/or social aspects in a generic way, may be eligible under the section “Science and society” of the programme "Structuring the European Research Area".

B. ENCOURAGING PUBLIC DIALOGUE AND PARTICIPATION OF STAKEHOLDERS

Without broad public acceptance and support, the development and use of life sciences and biotechnologies in Europe will be contentious and their benefits will be delayed. The participants in research projects should be encouraged to engage in an interactive dialogue involving all stakeholders (scientists and physicians, patients, consumers, farmers, animal welfare organisations, ethicists, lawyers and the public at large) as well as to promote science popularisation and public information. These aspects will be considered as important components of the dissemination strategy within the projects.

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[12] For more information on priority areas and FP6 see ftp://ftp.cordis.lu/pub/fp6/eoi-instruments/docs/eoi_annex1.pdf , http://www.cordis.lu/fp6