Regulatory Factors Affecting the Agri-Food Biotechnology Sector in the European Union

by

María del Carmen Fernández Díez
and María de los Reyes Corripio Gil-Delgado

WP 03-13

Department of Agricultural and Resource Economics
The University of Maryland, College Park

Regulatory Factors Affecting the Agri-Food Biotechnology Sector in the European Union

Dr. María del Carmen Fernández Díez[+]

Dr. María de los Reyes Corripio Gil-Delgado[*]

WP 03-13

Abstract

In Europe, in addition to public opposition to genetically modified food, the slow pace of development in agricultural and food biotechnology has been attributed to the lack of basic preconditions for commercial and innovative activities. The role and justification of a significant degree of regulation related to crop biotechnology is discussed. We try to clarify the existing broad structures which regulate these genetic technologies by focusing on several areas: environmental regulation, international trade, labelling and intellectual property rights. We attempt to involve the growing range of actors with different interests in the agri-food chain: biotechnology companies, the seed industry, farmer, and consumers. Finally, we discuss implications and limitation of the interpretation of the current European legislation.

Key Words: agricultural biotechnology, legislation, environmental regulation, labelling, patents, innovation, Europe

Acknowledgments: The authors acknowledge the comments of the participants in the Sociology of Science and Technology Conference (SSTNET) of the European Sociological Association (ESA), Murcia, Spain, 24 September 2003, as well as the suggestions of anonymous reviewer. M.Carmen Fernandez thanks the hospitality and the research environment at the Department of Agricultural and Resource Economics, University of Maryland, during the revision of this paper. The usual disclaimer applies.

December 2003

[+] Facultad de CC.EE. y Empresariales, Universidad Pontificia Comillas de Madrid, c/ Alberto Aguilera, 23 CP: 28015; email: mcarmen@cee.upco.es; tlfno: +34.91.542.28.00 (ext:2453). Visiting Profesor, Department of Agricultural and Resource Economics, University of Maryland, Fall 2003.

[*] Facultad de Derecho, Universidad Pontificia Comillas de Madrid, c/ Alberto Aguilera, 23, CP: 28015; email: rcorripio@infjur.upco.es; tlfno: +34.91.542.28.00 (ext:2199)

Regulatory Factors Affecting The Agri-Food Biotechnology Sector In The European Union

1. Background and Theoretical Framework

The application of biotechnology in agriculture and food sectors has dramatically accelerated crop improvement efforts. As is well known, initial genetic modifications have ranged from protection against pests and tolerance herbicides to the production of enzymes for industrial food processes – so called first generation biotechnology products-. Nowadays, food plants are being genetically modified (GM) in order to enhance levels of essential amino acids, micronutrients or antioxidants and the overall quality of grain- so called second and third generation-. These plant traits can reduce crop losses and production costs, raise crop yields and the returns to growers and the food industry; ultimately expanding choices available to consumers[1].

However, some critics are concerned over the possible consequences for environmental and human health, the concentration and consolidation of the agricultural industry and the intensification of external dependencies in farming[2]. In the EU public opinion towards agri-food biotechnology is decidedly negative, reflecting uncertainty and a host of diffuse negative risk perceptions[3]. In addition, uncertain regulatory environment in relation with agri-food GMOs is argued as a main reason by the biotechnology industry in the EU for investment in non-plant activities and for cancellation of research projects [4]. From the economic theory viewpoint, some of these agri-food biotechnolgy criticisms could be considered as market failures that could justify government intervention as regulation.

This research paper will focus on the existing regulation affecting biotechnology enterprises in the EU. We will set out a theoretical justification for government intervention and clarify legislation from different areas - such as Sanitary and Phytosanitary conditions of trade, environmental norms, traceability and labelling legislation, and Intellectual Property Rights (IPR) related GMOs- that could be conditioning the future evolution of the agro-food biotechnology sector in Europe.

In this introduction we examine briefly market failures theory. Section two refers to environmental regulation affecting EU enterprises and farmers and the regulation of GMO commerce in Europe, including the complex system of monitoring products for human consumption. Section three summarises public concern with GM food and the specific regulation based in the labelling of products. The fourth section sets out the innovation process in European biotechnology industry and the legal controversies under regulation on Intellectual Property Rights (IPR) in Europe, which emerged to stimulate innovation in this field. Finally, we present the conclusions.

Properly functioning markets provide a valuable service to society, but a) the presence of externalities, b) lack of provision of public goods, or c) imperfect information cause markets to fail and not to reach an efficient allocation of goods and services, resulting in the reduction of social welfare. The literature on market failures is voluminous [5], and refers to situations in which some of the assumption of the welfare theorems does not hold and in which, as a result, these failures undermine the Pareto optimality of market equilibrium [6].

We will now describe these market failures.

a) Potential risks to the environment and public health reduce the social benefits of agricultural biotechnology. In both cases, the actions of the agents involved in the agri-food biotechnology sector (industry and farmers) directly affect the utility functions of the consumers in the economy. Due to the presence of these nonmarket externalities, market equilibria cannot be relied on to yield Pareto optimal outcomes. Regulation should try to control externality problems of biotechnology production, by passing the costs back to biotechnology producers ("internalize" the externality). Article 174.2 of the European Union Treaty (1977) states that Community policy on the environment shall be based on the *precautionary principle* and on the principles that preventive action should be taken, that environmental damage should, as a priority, be rectified at source and that the polluter should pay.

b) Much new knowledge produced from agricultural research, as Biotechnology inventions, could be considered basic knowledge, and as such, a public good. The public-good nature of agricultural research output has been analyzed by Pray, C. and Echeverría, Ruben G. [7] and Huffman, W. and Evenson, R.E.[8] among others.

Agrobiotechnology inventions have the characteristics of *nonrivalvess* and *nonexcludability* of a public good. The first one means that the research is available to everybody at zero marginal cost. The second one, *nonexcludability*, implies the infeasibility -or high cost-of denying use to those who do not pay for it so that a "free rider" problem is present. Private sector enterprises are not interested in produce goods that are *nonrival* or *nonexlcludable* because they would unable to capture benefits to cover the costs resulting from their research activities. Prior to the IPR legislation, the discovery, evaluation and storage of germplasm and plant breeding were carried out in the public sector because of market failure attributable to the absence of effective property rights. Private companies have historically found it unprofitable to invest in R&D for open pollinated crops because of farmers' ability to save and replant their own seed. Hence, given the difficulty of capturing benefits from a crop with no plant variety protection, private firms alone produced suboptimal quantities of varieties.

Thus, the characteristic of *nonrivalness* in agricultural research encourages the market mechanism to fail or the attainment of an inefficient outcome in the market and provide a justification for government regulation. Free-rider problems emerge unless there are clearly defined property rights. This provides a theoretical justification for IPR. Patents could be economically justified as an incentive for investment in inventive activities. In that sense, IPR serves as a mechanism to transform non-exclusionary knowledge into private property[9]. Consequently, the expansion of IPR would provide some form of "right to exclude" others from using genetic resources and stimulate more private sector breeding activity.

c) As GM products have been considered a negative attribute for European consumers, that is, a "strictly inferior" product as compare to the traditional counterpart products, and the superior product cannot be distinguished from the inferior one, there will be a problem of asymmetric or missing information. In this situation, producers posses knows of relevant information about the product that consumers do not –asymmetric information- (e.g. contains GMOs) or the market information does not exist or is contradictory – imperfect information- (e.g. health consequences of consumption). In these cases Akerlof [10] demonstrated in 1970 in the "lemons" model, that regulation may be desirable to maintain product diversity. In our case, GMOs products and GMOs free products. Government intervention could also reduce producers´ incentives by offering too high a proportion of low quality products. Mandatory labelling would address this information problem.

Therefore, public intervention through regulation could be considered justified when these legal instruments contribute to increases in social efficiency, although allocation of benefits will necessarily occur.

Identifying the costs and benefits of regulation is not a simple task, as it involves diverse actors in the agro-biotechnology chain, all invocating their own rights and social interests. At the beginning of the chain, the joint activity of agro-biotechnology enterprises together with public research institutes and universities are responsible for the generation of knowledge (see Figure 1). The diffusion of innovation in the form of a new genetically modified seed variety is conducted by seed companies, usually multinational enterprises. Once farmers adopt the biotechnology input, this is finally processed by manufacturers who are commercialised in the domestic market and the product are either consumed by European citizens, or exported. Each of these market participant decisions affect each other, e.g. negative public attitudes in E.U. towards transgenic foods which imply health and environmental risks, influence not only the rate at which differentiation occurs in the market, but also that at which new technologies are adopted by farmers and to what extend innovations occur in the biotechnology firms. In the same way, government regulatory actions at each stage, -which continue to advance along with advances in biotechnology in

the E.U.-, play an important role in allocating costs and benefits of biotechnology innovations among agents.

The regulatory management structure in the EU is integrated by the roles of three institutions: a) The European Council, which represents each Member State at ministerial level and has competence in ratifying international agreements to be adopted by its own legal order, e.g. the Cartagena Protocol on Biosafety; b) The European Commission, which represents and defends general interests in the EU, (not those at national level) has the role of ensuring that the provisions of the Treaty, and the measures taken by the institutions pursuant thereto, are applied. It can also propose different issues and approve Communications, e.g. Communication setting out a strategic vision for life sciences and biotechnology up to 2010; and c) The European Parliament, -the only international institution whose members are elected directly by the citizens-, which is made up of individual representatives from within the different political groups. Although community legislation does not emanate from the Parliament as such, its participation is important in the two principal procedures of community legislation: cooperation and codecision. Over 60 per cent of the European Parliament's amendments are accepted in the final version.

It is important, therefore, to examine possible instances of legislation enforcement related GMOs in the EU for the agri-food biotechnology sector. By doing so, this study balances the advantages (or benefits) and the risks (or costs) posed by regulating the use and expansion of these new technologies with particular emphasis on the effects on the agri-food biotechnology sector. We will focus on the divergence of regulatory systems and their impact on the European market for GM products.

2. Environmental regulation and International Trade Legislation affecting the EU biotechnology sector

The two principal applications of biotechnology in agriculture -increases in breeding efficiency and in crop/farm productivity- depend on the biotechnology supply of the seed industry and on the accessibility of farmers to those new technologies. Environmental

Regulation and Trade Legislation may affect the rate of diffusion by seed enterprises and the rate of adoption of this innovation by the farmers, and in that sense commerce (see figure 1). Since the adoption of new technologies initially benefits early adopters most, it would be necessary to study potential users of biotechnology and their market and regulation conditions that will shape the future of agri-food biotechnology in Europe.

Although farm-level evidence suggests that intermediate consumption and seeds and plants costs represent just 6.8% of the total input cost in European agricultural enterprises, (in the year 2000, The Farm Accountancy Data Network)[11], the adoption of GM crops by farmers reduces the costs of production by improving agronomic properties, such as herbicide tolerance and resistance to particular insect pests [12].

Genetically modified varieties are planted in 16 countries all around the world by 6 million of farmers. During the period from 1996 to 2002, the global area of transgenic crops increased 35 fold [13]. This high rate of adoption reflects growing acceptance of transgenic crops by farmers using the new technologies. By type of crops, industrial crops are relatively more important, so GM maize, cotton, soya and colza increased the arable area in 2002. In fact, GM soya represents 50% of soya arable land in the world[14]. In the EU, there has been a rise of conventional industrial crops that grew by a factor of nearly five between 1975 and 1997. It has increased by a factor of 12 in the United Kingdom and by 10 in Italy. It has changed the agricultural landscape, and fibre crops like cotton, and also oleaginous crops like soya and colza quite literally gained most ground. However, of the 15 Member States, it is Greece where industrial crops have more importance, they occupied 24% of the countries' arable land in 1997; followed by France (11.1%), Spain (9.5%) and Germany (9.1%)[15]. These four countries' final agricultural production amounted to approximately about 56% of all EU Member State production in final agricultural production in 1999.

On the one hand, it appears that the potential area for these GM crops has increased the possibilities of future adoption of GM technologies by European farmers. On the other hand, the EU is only a net importer of some of these industrial crops, like corn (EU produced 37.3 tons and consumed 38.9 tons per year, during the period from 1997 to

2001)[16]. This corn has been imported from Argentina, and currently represents a small share of the US market (5% of the US corn exports). In addition, US soybeans exports represent a large share; about 10% of the US production has been exported to the EU over the past three years. Although the main exporter to the EU is still the US, import levels have recently decreased and settle at 1994 levels. Nowadays, Brazil and Argentina are the main suppliers of soybeans to the EU, the former of GM-free soybeans[17]. The soybean meal and corn gluten for animal feed are the most important in the international trade between the US and the EU. Thus, the EU is the most important export market of these wet-milling byproducts (85% of the US total export of these byproducts exceeding the value of corn imports of the EU). In this way, strict regulation, especially on processed food labelling, could impact on US producers.

In the EU, there are fourteen GM plants produced by different companies that have been approved for commercialisation so far[18]. Several GMOs were approved for the EU, under Council Directive 90/220/EEC[19], but after 1999 no authorisation has been given, either pursuant to the previous Directive 1990/220/EEC, or to the present Directive 2001/18/EC.

Furthermore, in June 1999, Environment Ministers of the EU Council imposed a moratorium on approval of new transgenic crops. The moratorium was to remain in place until the revised GMO deliberate release Directive entered into force and future Traceability/Labelling regulations were be clarified.

Dialogue is open to all stakeholders (industry, scientists, farmer organisations, trade unions, NGOs and church representatives) and a prolonged round of consultations has taken place during this period in the EU[20]. In contrast, this moratorium essentially closed European markets to new agricultural biotechnology products[21] and the new regulations will force the food industries to duplicate their systems to meet European requirements of keeping identical products separate. This has also provoked anti-protectionism action by GM crops exporters, mainly in the US. In addition, the price-reduction benefits from biotechnology seem minor to consumers in the EU, while the unknown dangers are magnified by lack of information and mistrust in the ability of governments to regulate the safety of the food

supply[22]. There are only a few international legal agreements setting out the World Trade Organization legal framework regarding trade in GM products. But the EU have reinforced the presently applied measures in response to the demand of the European citizens, being willing to pay for a regulatory regime that provides higher standards and minimizes risks.

At the international level, the Sanitary and Phytosanitary Agreement (SPS)[23] allows countries to adopt their own standards with reference to international trade but these restrictions must be based on science[24]. Measures should not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail and shall not be applied in a manner, which would constitute a disguised restriction on international trade. The agreement suggests the use of international standards when possible. In that sense, the EU policy could be maintaining standards of food safety in a way that unfairly discriminates against foreign suppliers.

As there is no international food safety standard that really applies to GM products, some countries, like those in the EU, invoke the "precautionary principle" that allows the setting of standards provisionally, where relevant scientific evidence is lacking. Therefore, it is argued that this principle is being abused in order to protect less efficient domestic producers from foreign competition.

Certainly European decision makers have based their policy (as stated by the Article 174.2 of the Treaty of European Community) on the precautionary principle and preventive action in order to reach a high level of environment protection[25]. Following these principles Member States can take provisional measures for non-economic environmental reasons subject to a Community inspection procedure.

In particular, the precautionary principle is also adopted on international regulations, as Principle 15 of the Rio Declaration on Environment and Development and Article 10.6 of the Cartagena Protocol on Biosafety[26] which states that: "Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the

potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects". Its implementation into EU legislation shall be accomplished with the formal adoption of the Regulation on the transboundary movements of GMOs (actually at the stage of Common Position published in the Official Journal number C 107 E, of 06/05/2003 pp. 0001 – 0016).

The Commission's position with respect to the precautionary principle is set out in two communications. The first one, referring to consumer health and food safety[27], states that "the Commission will be guided in its risk analysis by the precautionary principle, in cases where the scientific basis is insufficient or some uncertainty exists". The second, Communication on the precautionary principle in the EU[28], extends applications of this principle to other fields and states that its scope covers those specific circumstances where *scientific evidence* is *insufficient, inconclusive or uncertain*, and there are *reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection.*

From a legal point of view, measures based on the precautionary principle should be accepted if they fulfill some requirement, *inter alia*: *proportional* to the chosen level of protection, *non-discriminatory* in their application, *consistent* with similar measures already taken, based on *an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis), *subject to review,* in the light of new scientific data, and *capable of assigning responsibility for producing the scientific evidence.* And these are also requirements of applications of precautionary principle in Europe as stated by the Commission[29].

Applications of those principles can be found in Article 4.1 of the EU Directive 2001/18/EC,[30] which establishes a general obligation for Member States to ensure that all appropriate measures are taken to avoid adverse effects on human health and the

environment which might arise from the deliberate release or the placing on the market of GMOs.

GMOs may only be deliberately released or placed on the market in conformity with Part B or Part C respectively. This rule establishes both Community and national[31] authorisation procedures for the placing on the market of GMOs, as or in products, where the intended use of the product involves the deliberate release of the organism into the environment. The Community authorisation states in article 12 Directive 2001/18/EC referring to those cases for which the Community legislation provides for a specific environmental risk assessment (e.r.a.) carried out in accordance with the principles set out in Annex II (Principles for the environmental risk assessment which describes in general terms the objective to be achieved, the elements to be considered and the general principles and methodology to be followed to perform the environmental risk assessment) and on the basis of information specified in Annex III (information requirement in notification) without causing detriment to additional requirements provided for by the Community legislation. All general principles that should be followed when performing the e.r.a. as Annex II states, are established following the precautionary principle.

The recent Opinion of the EU Economic and Social Committee states that the precautionary principle must prevail and must also be consistently applied in the context of biomonitoring. European regulation also establishes a complex system of monitoring products for human consumption. Monitoring is defined[32] as the systematic measurement of variables and processes over time, and assumes that there are specific reasons for collection of such data, for example, to ensure that certain standards of conditions are being met, or to examine potential changes with respect to certain baselines. Notifiers are required, under Article 13(2)(e) of the Directive, to submit a plan for monitoring, in accordance with Annex VII of the Directive, which describes in general terms the objective to be achieved and the general principles to be followed to design a monitoring plan referred to in Article 13(2), Article 19(3) and Article 20. This should include a proposal for the time-period of the monitoring plan, which may be different from the proposed period

for the consent[33]. All the difficulties must be recognised in the same way by the entire international community and applied uniformly at international level[34].

However, this complex legal procedure in the EU could be impeding the adoption of GM crops in the Member States. In contrast, since the mid-1990 there has been a rapid adoption of GMO crops in agricultural exporting countries like USA, Argentina and Canada (98% was planted in these three countries). There is a clear potential conflict between two basic approaches being adopted to regulate GMOs. On the one hand, there is the US approach to evaluating GMOs, which is based on a scientific, risk-based assessment that also appeals to the concept of substantial equivalence, and the notion that zero risk in foods safety regulation is not practical, given that conventional foods are already presumed to be safe. On the other hand, there is the approach adopted by the EU, and the Biosafety Protocol, based on a precautionary approach to risk assessment and management of GMOs. The World Trade Organization (WTO) is unlikely to become involved in evaluating the institutional structure through which individual countries develop their regulatory processes.

Nevertheless, the WTO would be concerned with the fact that specific aspects of GMO regulation are trade distorting. Sheldon, I. M.[35] argues that it is unlikely that the EU would either explicitly discriminate against US exports of GM products, or allow domestic production of GM product without regulation, but impose regulation on the imported product. In spite of this, were the EU to ban imports of a GM product and allow imports of the conventional product, there might well be a claim of discrimination against the EU, as a deliberate act of the trade policy. The USA would probably argue that if GM and conventional food are essentially equivalent, then the process-based regulations are in violation of GATT Article III[36], and they would receiving "less favourable" treatment. In particular, if GM products are considered safe, and have no effects on imports inside the EU, then basing GM regulation on the process of genetic modification would constitute a trade barrier. Exporting countries argue that importing countries' regulations are too restrictive, given the existing scientific knowledge of the safety of current GM crops, and

that labelling of GM foods is unnecessary because they are typically similar to their conventional counterparts.

On the other hand, importing countries remain unconvinced about the safety of such crops and wonder about the ethics of the technology. Nevertheless, GMO regulation will be very difficult to handle within either current or any future WTO-GATT rules where consumers in different countries have different perceptions of the risks associated with GM foods.

Government positions of all the biotechnological countries in Europe are clearly in favour of the moratorium and the restricted rules governing GMOs crops. Most of the Members States have not yet implement the Directive 2001/18/EU and in 15 July 2003 Commission has taken Court action against France, Luxembourg, Belgium, Netherlands, Germany, Italy, Ireland, Greece, Spain, Austria and Finland) for failing to adopt and notify national legislation implementing the Directive on the deliberate release of GMOs into the environment (the agreed deadline of this Directive was 17 October 2002). Spain, which is one of the most pro-GMO Member States and is the only country in the EU where any significant amounts of GM crops are grown (about 25.000 hectares of Bt maize), has recently implemented the EU Directive in the Regulation 9/2003 of 23 April 2003.

Furthermore, France, Italy, Germany, Austria, Luxembourg, Denmark, Belgium, Greece and Portugal asked the European Commission to propose strict and precise rules to ensure the co-existence of GMOs and non GM agriculture; in other words, to ensure European farmers the right to grow conventional and organic crops without incurring any additional costs due to the cultivation of GMOs. This further action at Community level has been avoided by the Commission's Agriculture services, which consider the approach based on subsidiarity to be "more suitable"[37]. An informal agreement between Council and Parliament, accepts this approach, and Commission has approved the Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming[38].

Although these barriers are limiting GM crop expansion in the EU, consumer concerns about GM food have been identified as the main restriction in the future of the agri-food biotechnology market. In the following section a very brief review of the consumer attitudes are presented, explaining mandatory labelling and traceability regulation in the EU.

3. Public concern about GM food and Mandatory Labelling

Consumer concern about GM products may be expected to affect consumption decisions and to influence the public policy response demanded by consumers. In Europe, Eurobarometer surveys reveal that public expectations of non-medical biotechnology are moderate[39]. GM crops are supported in some European countries like Spain, Portugal, Ireland, Belgium, the UK, Finland, Germany and the Netherlands, and with the exception of Belgium, all the countries that called for the extension of the de facto moratorium on the commercial exploitation of GM crops (France, Italy, Greece, Denmark, Austria and Luxembourg) have publics that are, on average, opposed to GM crops[40]. In order to change these negative attitudes, the present European strategies are based on the labelling and traceability of the products.

This relatively high aversion to GM technology, in addition to a lack of price reductions for GM products, is an opportunity for EU countries to rationalise mandatory labelling. In that sense, Giannakas and Fulton[41] show analytically that when the existence of market imperfections in one or more stages of the supply chain prevents the transmission of cost savings associated with the new technology to consumers, GM results in welfare losses for consumers, and the desirability of mandatory labelling by consumers grows.

In addition, some food retailers and food manufacturers have moved quickly to establish voluntary standards and labels relevant to their market situation. Voluntary standards have been set to zero or near zero tolerance for biotechnology products leading to “non-GMO” or “GMO-free” claims. Voluntary GM-free or non GMO labels have become the standard, in this way, mandatory labels and thresholds could become practically irrelevant[42]. As a

result, mandatory biotechnology labelling has been questioned and qualified as an unwise policy[43]. Why would EU governments also decide that information about GM products should be labeled?. Economic theory justifies the "consumers' right to know" when the market does not supply enough information to allow consumers to make consumption choices reflecting their individual preferences (asymmetric or missing information). In this sense, the market does not work efficiently and social costs and benefits may suggest a different labelling outcome than the one resulting from a private firms' labelling decision. GM products could be identified as an asymmetric information case, as GM foods contain negative credence attributes[44]. Labelling (or certification) becomes a way to transform a credence attribute into a search one. But also as an imperfect information problem, there is missing information about potential health and environmental risks for consumers. These long term effects are unknown and scientific opinions differ about their probabilities.

In such a case, the government would require full disclosure of even preliminary or contradictory information, and consumers' greater access to information will result in an increase in the efficiency of the market[45] .

European regulations establishing product labelling have been adopted in recent years[46]. These regulations will be repealed or amended by Regulation 2003 on genetically modified food and feed, when approved [47]. This Regulation aims to guarantee a "high level of protection for human life and health, animal health, the environment and consumers' interests, as regards genetically modified food and feed, while ensuring that the internal market functions properly". If this objective is sought, the rule establishes clear and transparent Community procedures to assess, authorise and monitor genetically modified food and feed. This rule also shall amend the Directive 2001/18/EC in order to establish transitional measures for adventitious or technically unavoidable presence of genetically modified organisms having benefited from a favourable risk evaluation.

The traceability of genetically modified organisms, was introduced specifically for GMO into the Directive 2001/18/EC (article 4.6), which requires that Member States shall take measures to ensure traceability, in line with the requirements laid down in Annex IV, at all

stages of the placing on the market of GMOs under Part C. But this regulation is on the way to being made adequate and improved.

The future Regulation concerning traceability and labelling of GMOs and traceability of food and feed products produced from genetically modified organisms amending the Directive 2001/18/EC[48] defined traceability as the ability to trace GMO and products produced from GMOs, at all stages of the placing on the market throughout the production and distribution chains, facilitating quality control and also the possibility to withdraw products. In order to facilitate traceability for GMOs, this requires that operators transmit to the operator receiving products the following specified information: a) that the product contains or consists of GMOs; b) the unique code(s) relating to the GMO(s) contained in the product.

However, the principal issue continues to be market uncertainty about how consumers in the EU will react to GM foods. In this respect, Bredahl[49], shows that consumer attitudes and purchase decisions are generally negative towards both the technology and its derived GM products[50]. If European consumers continue deciding that they do not want to consume GM foods, markets will adjust to satisfy their demands, including market segmentation and product differentiation. It is an open issue the United Kingdom as to whether it will be possible to keep all GM food completely separate, because of consumer demand, since the food industry depends on suppliers from all over the world.

If the EU refuses to adopt new technologies and market segmentation occurs, results would be analogous to those expected from increased consumer preferences for organic foods. That is, non GM food will be more expensive to produce and command higher prices in the market; this gap between prices of GM and non GM food reflects cost differences in their production and distribution. Thus, European consumers will not benefit from a price reduction in a good equivalent to GM good, and European producers will not benefit from the higher productivity of GM crops. Nowadays, it seems that European consumers are willing to pay for quality and for specific attributes of goods.

4. Intellectual property rights concerns of biotechnology innovations

Biotechnology innovations are very costly to develop, although comparatively inexpensive to reproduce, especially self pollinated crops like soybeans. In addition, genetically modified plant material can be resold or regrown from seed. Intellectual Property Rights (IPR) systems are intended to solve the problem of appropriation of the returns from the research by the biotechnology research centres. Enforcement of IPR legislation has been associated with privatisation of research in most developed countries.

Besides this process of basic knowledge privatisation in biotechnology, universities and public research centres continue to play an important role in the generation of new products (curtivars) and processes (methods) in European agri-food biotechnology (about 72% of the biotechnologies laboratories are public in Europe[51]). Integration of teaching, research and collaboration with industry appear to be critical in order to transfer research to industry. As a result, IPR should play a key role in favouring the rapid translation of scientific research into industrial R&D and the second aim of IPR, which is to enhance technology transfer[52]. In that sense, the agri-food industry performs a crucial function of transforming fundamental scientific knowledge into technological and commercially valuable knowledge. Through the possible appropriation and transfer of knowledge, specific genes become a product market, and this market cannot exist without IPR. Consequently, the "synergy" between IPR and agri-food biotechnology sector is strong[53] (see Figure 1).

French, German and British biotechnology companies represent a higher fraction of the agri-food biotechnology industry in Europe, as summarised in Figure 2. By country, while France, Italy and Switzerland have a higher proportion of companies active in agri-food, Germany and the UK are more active in other fields (See Figure 3.). Those enterprises are likely candidates for furthering the generation of knowledge though reinforcement of IPR legislation.

Patent data provide relevant information about the geographical distribution of biotechnology research across regions, and so, the location of the innovative activities. The available empirical evidence shows that the US is the most important innovator in biotechnology and that they continue to increase their relevant importance (from 1990 to 2000 the US shared in all biotechnology patents granted by USPTO increased by 9 percent points). Considering patent citations, as a measure of economic value of the innovative activities, eleven of the twenty top institutions in terms of patent citations are American, in the period 1978-1995. The rest of the institutions are German, British, Japanese, Swiss, French and Danish[54]. But if we consider the presence of centres in Europe of absolute excellence, scientific quantity and quality research seems to lag behind the US. It has been considered as the European paradox and could be related to some institutional factors that constrain the innovative activities, e.g. financial constrains, the structure of the research system and the relationship between universities and industry, and finally the regulation of IPR in biotechnology.

The IPR legislation has been reinforced in Europe with the approval of Directive 98/44/EC[55] on the legal protection of biotechnological inventions, which provides in its article 3.2. that "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature". Thus, inventions based on or comprising of, gene sequences or partial gene sequences, can be patented, provided if that they satisfy the normal criteria for any invention, novelty, inventive step or industrial application (Recital 22). Nevertheless, this rule has not until now transposed to national frameworks at all the Member States. In 12 December 2002 Commission has taken Court action against France, Luxembourg, Belgium, Netherlands, Germany, Italy, Portugal and Sweden for failing to adopt this Directive (the agreed deadline of this Directive was 20 July 2000). Spain has yet implemented EU Directive in Regulation 10/2002 of 29 April 2002.

This regulation solves certain legal concerns relating to the patentability of discoveries in the European Patent Convention[56] and the internal patent regulations. However,

exceptions to patentability based on the *ordre public*[57] and morality have been maintained in Article 6 of EU Directive 98/44 and could influence the scope of protection.

Moral considerations could, certainly, limit the number of patents to be granted also in the agrifood sector. The non-exhaustive list of these concerns, which could be relevant for determining whether or not an invention is regarded as immoral, or contrary to *ordre public* established by Article 6.2 of EU Directive[58] does not include references to plants. Even so, environmental protection could be included in *ordre public* concerns. The issue of *ordre public* in reference to plants came up in Plant cells/Plant Genetic Systems[59]. In such cases it is argued that the exploitation of inventions which are likely to seriously harm the environment are to be excluded from patentability as being contrary to *ordre public*. It was held that: "Inventions, the exploitation of which is not in conformity with the conventionally accepted standards of conduct pertaining to the culture inherent in European society and civilization are to be excluded from patentability as being contrary to morality".

The social concern related to patentability of inventions has conditioned the effectiveness of Europe's' patent system. For example, the EU Directive has been challenged at the Court of Justice of the European Communities by the governments of the Netherlands and Italy[60], (and Norway is considering not implementing it). Applicants ask for the annulment of Directive 98/44/EC based on human dignity protection. In particular, the Netherlands and Italy refer to recital 36, which notes that the WTO-TRIPs (World Trade Organization trade-related aspects of international property rights) agreement recognises in the context of *ordre public* and morality the grounds of protection of human, animal or plant life or health and the avoidance of serious damage to the environment. That raises the question of whether, for the purpose of Article 6(1), serious harm to the environment, or the risk thereof, may fall within the concept of *ordre public*[61]. At the present time, only five EU countries have implemented the EU Directive: Finland, Denmark, Ireland, United Kingdom and Spain.

In summary, the ability of companies and organizations to acquire patent protection in the agri-food biotechnology sector has increased over time in the European Union according to

the evolution of the legal framework. The patentability of genetic material, although it continues to be more restrictive in its scope of protection than in other countries, permits the establishment of institutional preconditions for a future open gene market, allowing a flow of technological transmission between research centres and the industrial sector in the EU.

Nevertheless, the impact of biotechnology on economic growth does not only depend on the innovation and competitiveness within the industrial sector, it also depends on the transmission process, which includes the adoption of those GM products (cultivars) by farmers. The farmers' decision as to whether to adopt GM crops, in the EU, depends on the costs and benefits. European farmers will be induced to use GMOs if there is a change in the marginal cost of producing the crop between using GMOs and using existing technology. Possibly, in other countries, the lack of strong intellectual property protection, results in considerable benefits for farmers through adopting GMOs, by a reduction in price for seed and then a profit advantage. However, in the EU, with effective property rights, the owner of the GMO is a monopolist, and the gross margin using existing technology would be higher than the farmers' gross margin using GMO technology. Thus, the farmers would rationally remain with the old technology[62].

5. Conclusions

Biotechnology is a new sector in expansion. It was recognized as such by the European Union (EU) at the Stockholm European Council when it identified Biotechnology as an area with possibilities for creating employment in Europe[63]. Supranational public European strategies on innovation, which were implemented to increase levels of private and public R&D in order to reduce the technical gap and competitiveness with the US, also include biotechnology[64].

However, in Europe, applications of agri-food biotechnology have advanced at slow pace in comparison to other areas. The chief reasons for this sluggish are, negative consumer attitudes and purchase decisions towards both the technology and its derived GM products,

together with, the lack of basic preconditions for commercial and innovative activities. This study underlines the importance of regulation as an institutional factor to play in the development of the European agri-food biotechnology market.

Legal regulation as a government intervention could be justified in order to correct market inefficiencies although various interest groups, -agri-food biotechnology industry, farmers and consumers- are affected differently by EU regulation. The purpose of regulators to reduce market failures influences agri-food biotechnology industry in three different areas: 1) at the beginning of the innovation chain, the stimulation of private breeding activities, the generation of knowledge in public research institutes and universities, and the transference to biotechnology industries in Europe is referred to IPR legislation enforcement; 2) at a second stage, the diffusion of new technologies by adopter farmers is constrained by regulation of the GMOs trading in Europe, including the complex system of monitoring products for human consumption and environmental regulation; and 3) European public concern about GM food consumption has led to the labelling and traceability regulation of GM products.

1) The ability of companies and organizations to acquire patent protection in the agri-food biotechnology sector has increased over time in the European Union in accordance with the evolution of the legal framework. Nevertheless, some controversies have emerged concerning exceptions to patentability, which reduce the scope of protection according to the distinction between discovery and invention, and the uncertain legal concepts of *ordre public* and morality. In that sense, social concerns relating the patentability of inventions have conditioned the effectiveness of patent system. As it stands, the patentability of genetic material, despite being more restrictive in its scope of protection in the EU, permits the establishment of institutional preconditions for a future open gene market. Table 1 summarises those effects and controversies.

2) Legal Sanitary and Phytosanitary restrictions on commerce are based on the "Precautionary principle" which allows setting provisional standards where relevant scientific evidence is lacking. This principle could be abused in the EU in order to

protect less efficient domestic producers from foreign competition and to avoid technological dependence on exporters countries, like the U.S.

Political and legal measures based on the precautionary principle should be accepted if they fulfil some requirement, inter alia: *proportional, non-discriminatory, consistent*, *based on an examination of the potential benefits and costs* of action or lack of action, *subject to review,* and *capable of assigning responsibility for producing the scientific evidence.* In those conditions, the precautionary principle must prevail and all the difficulties must be recognised in the same way by the entire international community and be uniformly applied at international level.

As a result of the existing regulations, EU farmers could maintain dependence on old technologies and incur additional costs from the cultivation of GM crops. However, the principle that farmers should be able to cultivate freely the agricultural crops they choose, be they GM, conventional or organic, and that no form of agriculture should be excluded in EU, prevail under the Commission addressing GM crop co-existence.

3) Labelling and traceability regulations could represent the adoption of the "precautionary principle" that facilitates quality controls and reduces uncertain perceptions. Furthermore, if the public negative attitude continues to prevail, there are strong possibilities of continuing market segmentation. In that case, under the mandatory labelling regime in the EU, segregation costs will be higher for producers of the traditional product, due to the effort required to preserve the identity of their production and to keep it separate from the GM product that consumers regard as inferior. As non GM food will be more expensive to produce, consumers in the EU may have to be willing to bear the financial consequences of paying higher prices in the market.

The EU public policy and current regulation are being influenced by consumers' concerns about GM products, but we should also remember that, as a result of a distrust in food safety brought about by the European Public Administration, one of the main aims of this regulation is to generate public trust in this kind of new technology and in

the European institutions. In the long term, European citizens not only will benefit from the application of the precautionary principle as a driving principle, but, in the future, biotechnology firms will also be less vulnerable to the legal and political context, by increasing quality and security controls necessary to reduce over risk perception.

Table 1. Biotechnology Regulation Effects on Agri-food sector in the EU

		POSITIVE EFFECTS	CONTROVERSIES
INDUSTRY'S PERSPECTIVE	IPR Legislation: Harmonisation of European patent systems	1. Stimulation of private breeding activities 2. Enhancement Technology transfer	1. Stimulation of monopolies granted by patents. 2. Existence of undetermined notions*: ordre public* and morality
FARMERS' PERSPECTIVE	Legal Sanitary and Phytosanitary restrictions to free trade	1. Protectionism avoids technological dependence 2. "Precautionary principle" protects less efficient domestic producers	1. EU farmers remain with old technologies or incur in additional costs from the cultivation of GM crops 2. Complex system of monitoring products for human consumption 3. Slow adoption of GM crops
CONSUMERS' PERSPECTIVE	Labelling and traceability regulation	1. Facilitation of quality controls 2. Reduction in uncertain perception	1. Public negative attitudes maintained 2. High probabilities of market segmentation 3. Increases in costs of production and in prices to consumers

Figure 1.

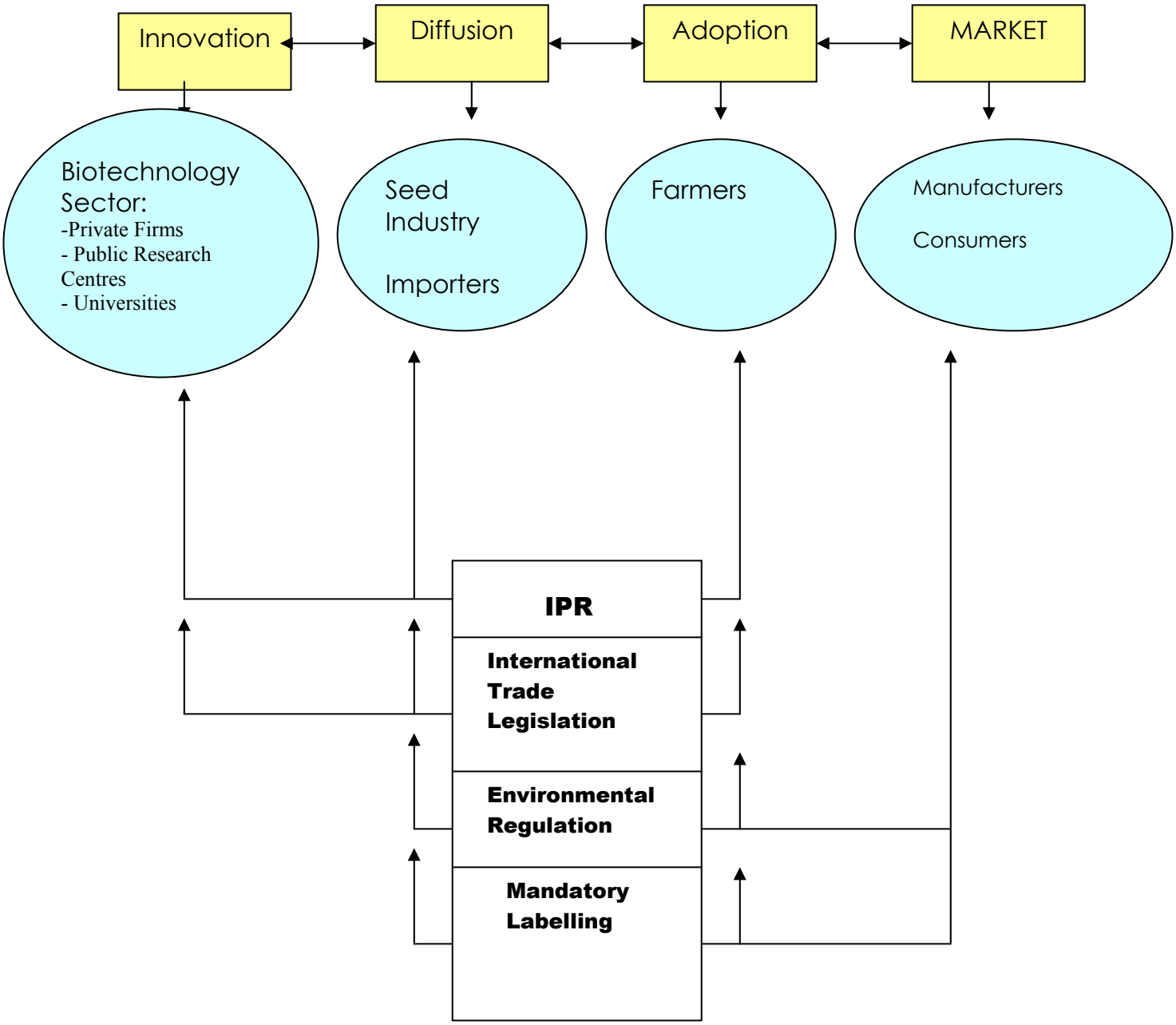
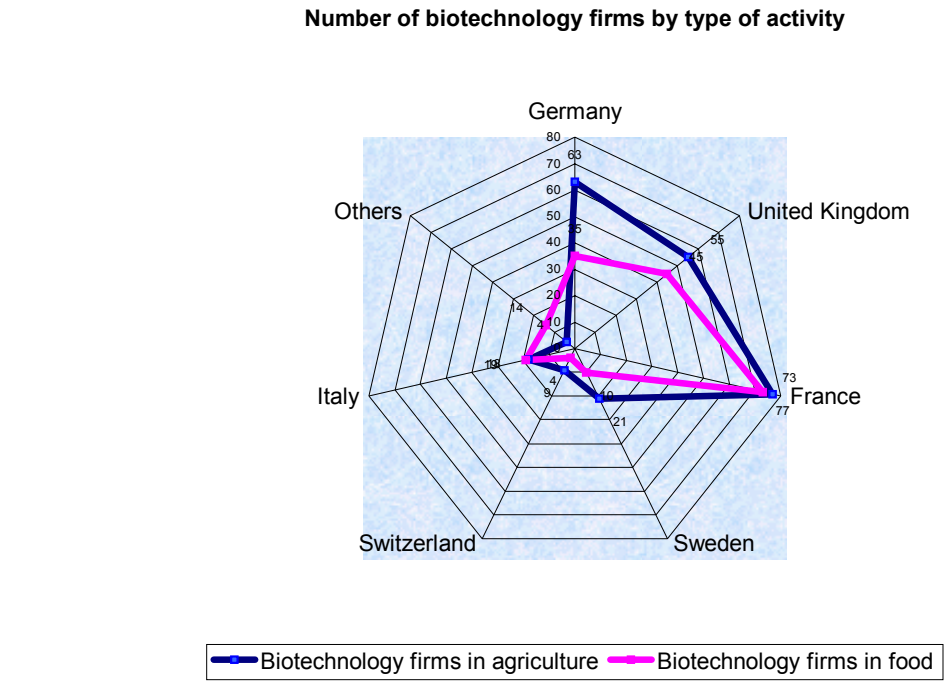
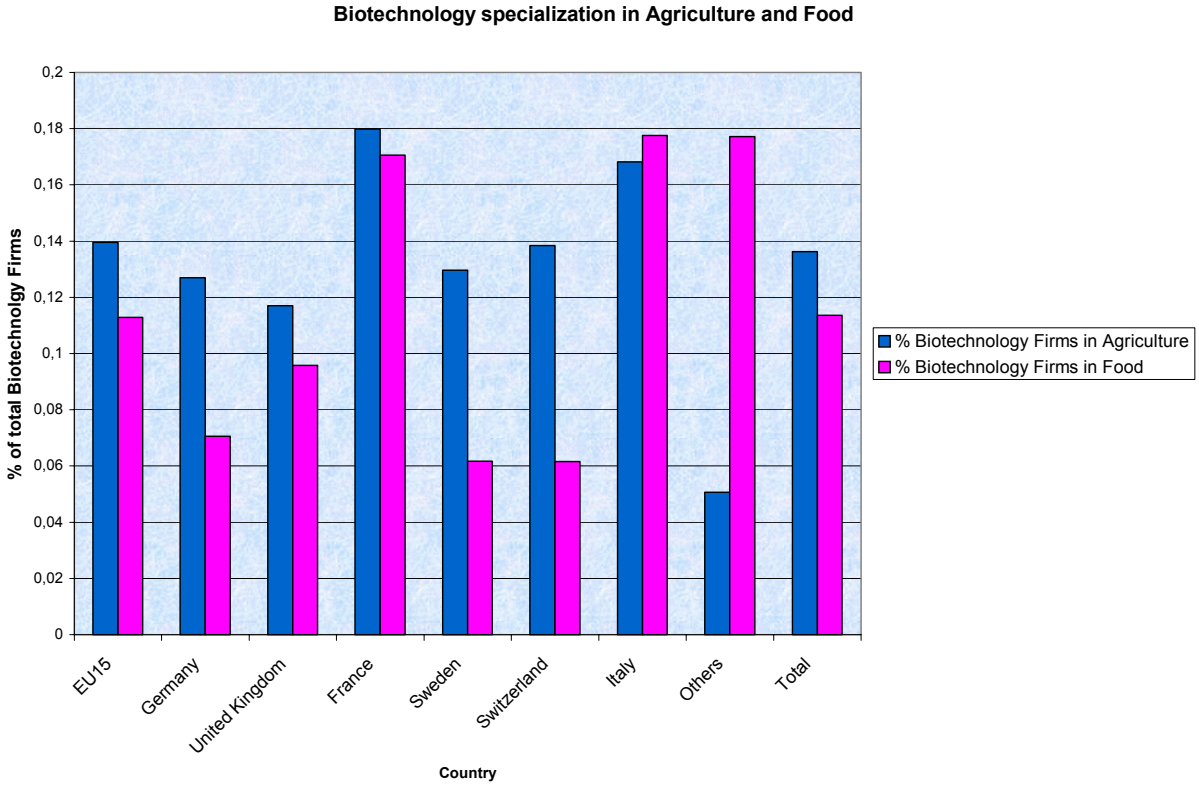

Innovation
Diffusion
Adoption
MARKET
Biotechnology Sector:
-Private Firms
- Public Research Centres
- Universities
Seed Industry
Importers
Farmers
Manufacturers
Consumers
IPR
International Trade Legislation
Environmental Regulation
Mandatory Labelling

Figure 2.



Source: European Commission, 2001

Figure 3.



Source: European Commission, 2001

ENDNOTES

[1] Pardey, Phillip (2001): *The future of food. Biotechnology Markets and Policies in an International Setting.* Pardey, Phillip Editor. Johns Hopkins University Press.

[2] Kydd, Jonathan, Janet Haddock, John Mansfield, Charles Ainsworth y Allan Buckwell (2000): "Genetically Modified Organisms: Major Issues and Policy Responses for Developing Countries", *Journal of International Development, 12: 1133-1145.*

[3] Brendahl, L. (2001), "Determinants of consumer attitudes and purchase intentions with regards to genetically modified foods: results of a cross –national survey". *Journal of Consumer Policy*, 24, pp: 26-61.

[4] Relative importance of agri-food activity compared to that of pharmaceutical areas of application has changed. Thus, the proportion of new firms that entered agri-food industries declined in Europe from 1995, from about 15% to less than 5% in the year 2000. The number of biopharmaceutical companies, on the other hand, rose from 35% to over 50% of the total number of new firms. In total, agriculture and food areas of activity in European Biotechnology comprise less than 14 and 12 %, respectively, of the number of total European Biotechnology Firms. European Commission (2001): *European Competitiveness Report 2001*, Chapter 5: *The competitiveness of European Biotechnology: a case study of innovation*. Available in http://europa.eu.int/comm/enterprise/

enterprise_policy/competitiveness/doc/competitiveness_report_2001/chapter_5.pdf

[5] Further references to externalities and public goods may be found in Baumol, W. J. and W. E. Oates (1988) *The Theory of Environmental Policy* , 2nd ed. , New York: Cambridge University Press, and Laffont, J.-J. (1988) *Fundamentals of Public Economics*, Cambridge, Mass: MIT Press.

[6] In a general sense, an outcome is said to be Pareto optimal if it is possible to make some individuals better off without making some others worse off. Therefore, the concept of Pareto optimality offers an minimal test to be passed.

[7] Pray, Carl E. and Ruben G. Echevería. 1991. "Private Sector Agricultural Research in Less-Developed Countries". In: Pardey, Phillip G., Johannes Roseboom and Jack R. Anderson, eds. *"Agricultural Research Policy: International Quantitative Perspectives"*. Cambridge: Cambridge University Press.

[8] Huffman, W. E. and Evenson, R. E., 1993. *Science for Agriculture: a Long Term Perspective*. Iowa State University Press, Ames.

[9] Maclup, F. (1958): *An Economic Review of the patent system*. Study of the Subcommittee on Patents, Trademarks and Copyrights, Committee on the Judiciary, US Senate, Study No. 15.

[10] Akerlof, George A. (1970): "The Market for "Lemons": Quality Uncertainty and the Market Mechanism". *The Quarterly Journal of Economics* Vol.84, Issue 3, pp: 488-500.

[11] Eurostat, (2003): European Price Trend in the European Union in 2001. Statistics in Focus Agriculture and Fisheries. European Communities 2002.

[12] Marra, Michele M., Philip G. Pardey and Julian M. Alston (2003): "The Payoffs to Transgenic Field Crops: An Assessment of the Evidence". *AgBioForum* Vol.5 (2) pp. 43-50, compile and characterize the farm level evidence of the impacts of transgenic field crops in the US and conclude that transgenic crops have consistently higher average profit and lower pesticide use than the conventional counterpart.

[13] Area increased from 1.7 million hectares in 1996 to 58.7 million hectares in 2002. International Service for the Acquisition of Agri-Biotech Applications (ISAAA) (2003): Summary Report on the Global Status of GM Crops. Available in http://www.isaaa.org/kc/Bin/gstats/index.htm

[14] International Service for the Acquisition of Agri-Biotech Applications (ISAAA) (2003): Summary Report on the Global Status of GM Crops. Available in http://www.isaaa.org/kc/Bin/gstats/index.htm

[15] Eurostat, (2003): European Price Trend in the European Union in 2001. Statistics in Focus Agriculture and Fisheries. European Communities 2002. Ministry of Agriculture, Fisheries and Food (2002): The Spanish Agrofood Sector and Rural Environment: Facts and Figures. VIII. Agricultural Areas and Production. Technical Secretariat General Madrid, 2002.

[16] Source: USDA ERS

[17] Source: Lheureux, K., M. Libeau-Dulos, H, Nislagard, E.Rodriguez Cerezo, K. Menrad, M. Menrad, And D. Vorgrimler, "Review of GMOs under Research and Development and in the Pipeline in Europe", March 2003, European Commission, Joint Research Center, European Science and Technology Observatory.

[18] Recently, important changes have been taken place among agrobiotechnology companies, such as company merges. The most important merges include the forming Syngenta (by Novartis and Zeneca Agrochemicals) in 2000, the Merger by Pioneer Hi-Bred International with Dupont in 2002, as well as the acquisition of Aventis Crop Science by Bayer in 2002. Lheureux, K., M. Libeau-Dulos, H, Nislagard, E.Rodriguez Cerezo, K. Menrad, M. Menrad, And D. Vorgrimler, "Review of GMOs under Research and Development and in the Pipeline in Europe", March 2003, European Commission, Joint Research Center, European Science and Technology Observatory.

[19] Council Directive 90/220/EEC establishes also a community procedure enabling the competent national authority to give consent to the placing on the market of genetically modified organisms

[20] See Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions: Live sciences and biotechnology – A strategy for Europe. Brussels, 23 January 2002, COM (2002) 27 final.

[21] There are 18 biotech food products approved in the EU, with 13 more applications favourably informed by the Scientific Committee and pending under the old Directive 90/220/EEC. Following the entry into force of the New Directive 2001/18/EC, a total of 19 applications have been submitting according the provision of the new Directive.

[22] Recent incidents in European Union as the Bovine spongiform encephalopathy crisis, with dramatic consequences, have eroded trust of consumers in governments capabilities to minimize risks.

[23] The Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement") entered into force with the establishment of the World Trade Organization on 1 January 1995 and concerns the application of food safety and animal and plant health regulations.

See text of the Agreement on http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm

[24] EC-supported research into the safety of GMOs includes 81 programs form 1985 (Biotechnology Action Programme) to 2000 (Fifth Framework Programme). The objective is to resolve uncertainties and provide a sound basis for risk management and science-based regulation.

[25] Also Article 95.3 of the Treaty of European Community establish that the Commission on its proposals concerning health, safety, environmental protection and consumer protection will take as a base a high level of protection, taking account in particular of any new development based on

scientific facts. In addition, the European Parliament and the Council will also seek to achieve this objective.

[26] The Cartagena Protocol was adopted on 29 January 2000. and came into force on 11 September 2003.

[27] Communication of the Commission on consumer health and food safety of 30 April 1997 COM(97)183 final

[28] Communication of the Commission on the precautionary principle. Brussels, 2.2.2000 COM(2000) 1 final.

[29] See section 6 of Communication of the Commission on the precautionary principle.

[30] Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC Official Journal of the European Communities - 17.4.2001 - Page No L 106/1

[31] Articles 13 to 24 state the national procedure for undertaking a deliberate release into the environment of a GMO, or the placing on the market of GMO.

[32] Decision 2002/811/EC of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC

[33] In addition, when products are destined to human consume it is necessary accomplish with some additional rules states by Regulation (EC) Nº. 258/97 of the Novel Foods and Novel Food Ingredients Regulation.

[34] Opinion of the Economic and Social Committee on the Communication from the Commission to the Council, the European Parliament, The Economic and Social Committee and the Committee of the Regions: Life sciences and biotechnology- a strategy for Europe". JO, C 61, 14 March 2003.

[35] Sheldon, Ian M. (2002): "Regulation of biotechnology: will we ever "freely" trade GMOs?*"* in: *European Review of Agricultural Economics* Vol. 29 (1), pp. 155-176.

[36] GATT Article III is concern national treatment and states "The products of the territory on any contracting party imported into the territory of any other contracting party shall not be accorded treatment no less favourable than that accorded to like products of national origin".

[37] http://www.foeeurope.org/press/2003/GR_03_March_co-existence.htm

[38] (JO, nº L 189, 29.7.2003) (vid www.europabio.org).

[39] EC Communication COM (2002) 27 http://europa.eu.int/comm/biotechnology/pdf/com2002-27_en.pdf

[40] Eurobarometer 58.0 "Europeans and Biotechnology in 2002" (2nd Edition: March 21st 2003) George Gaskell*, Nick Allum and Sally Stares http://europa.eu.int/comm/public_opinion/archives/eb/ebs_177_en.pdf

[41] Giannakas, Konstantinos and Murray Fulton (2002): "Consumption effects of genetic modification what if consumers are right?". *Agricultural Economics*, Vol. 27, pp: 97-109.

[42] Kalaitzandonakes, Nicholas G. (2000): "Agrobiotechnology and Competitiveness" in *American Journal of Agricultural Economics,* Vol. 82 (5), pp. 1224-1233.

[43] Conko, Gregory (2002): Eat, Drink and Be Marry: Why Mandatory Biotech Food Labelling is Unnecessary. Cascade Policy Institute, Oregon. This study presents some drawbacks of mandatory labels: could be misunderstood by consumers as a warning about some important difference (when

they do not), problems of information overload and costs expected fro producers of non-biotech foods, as segregation will occur and every ingredient will need to be tested for "purity" at each step of the production process.

[44] Nelson, P. (1970): "Information and Consumer Behaviour", *Journal of Political Economy*, 81: 729-754, considered a typology of goods based on the consumers' capability of attributes detection: before consumption (search goods); after consumption (experience goods) and those whose attributes cannot be detected after consumption (credence goods).

First generation applications in agro biotechnology (e.g. crop resistance to plagues) are considered credence goods, as consumers cannot obviously perceive those gains. Nevertheless, third generation of agrobiotechnology applications (as fat reduction in oil) could be considered as an experience good. In that situation, government intervention through mandatory labelling should not be economically justified.

[45] Golan, Elise, Fred Kuchler and Lorrain Mitchell (2000): Economics of Food Labeling, Economic Research Service, U.S. Department of Agriculture, Agricultural Economic Report No. 793.

[46] EU consumer regulation on GMO also include: Regulation EC Nº 49/2000 GMO amending Council Regulation EC Nº 1139/98 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC (Official Journal L 006 , 11/01/2000 P. 0013 – 0014) and Regulation EC Nº 50/2000 of 10 January 2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms. (Official Journal L 006 , 11/01/2000 P. 0015 – 0017). See also Regulation (EC) 258/97 on novel foods and novel food ingredients OJ L 43 of 14.2.1997, p. 1.

[47] Common Position (EC) Nº 22/2003, adopted by the Council on 17 March 2003 with a view to adopting Regulation (EC) Nº .../2003 of the European Parliament and of the Council of ... on genetically modified food and feed. OJ C, Nº 113 E, of 13.5.2003 pp. 31 and ff.

[48] Common Position (EC) No 21/2003 of 17 March 2003 adopted by the Council, acting in accordance with the procedure referred to in Article 251 of the Treaty establishing the European Community, with a view to adopting a regulation of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC *Official Journal C 113 E* of 13.5.2003 pp. *0021 – 0030*

[49] Brendahl, L. (2001), "Determinants of consumer attitudes and purchase intentions with regards to genetically modified foods: results of a cross –national survey". *Journal of Consumer Policy*, 24, pp: 26-61.

[50] Differences were found between countries in the degree of negativity. While Danish and German consumers were generally found to be more averse towards GM food, British and Italian are more positive. Negative attitudes were linked to uncertainty and a host of diffuse negative risk perceptions. Brendahl, L. (2001).

[51] European Commission (2001): *European Competitiveness Report 2001*, Chpt. 5: *The competitiveness of European Biotechnology: a case study of innovation*. Available in http://europa.eu.int/comm/enterprise/enterprise_policy/competitiveness/doc/competitiveness_report_2001/chapter_5.pdf

[52] Lesser, W. (2000): "Intellectual Property Rights under the Convention on Biological Diversity" in: Santaniello, R. E. Evenson, D. Zilberman and G. A. Carlson (2000): *Agriculture and Intellectual*

Property Rights. Economic, Institutional and Implementation Issues in Biotechnology. CABI Publising, New York.

[53] Santaniello, R. E. Evenson, D. Zilberman and G. A. Carlson (2000): Agriculture and Intellectual Property Rights. Economic, Institutional and Implementation Issues in Biotechnology. CABI Publising, New York.

[54] European Commission (2001): *European Competitiveness Report 2001*, Chpt. 5: *The competitiveness of European Biotechnology: a case study of innovation*. Available in http://europa.eu.int/comm/enterprise/enterprise_policy/competitiveness/doc/competitiveness_report_2001/chapter_5.pdf

[55] EU Directive 98/44/EC of July 1998, on the legal protection of biotechnological inventions. Official Journal L 213 , 30/07/1998 p. 0013 - 0021

[56] European Patent Convention, Munich, 1973.

[57] In some legal contexts "order public".

[58] Article 6. 2 EU Directive 98/44/EC states that, the following, in particular, shall be considered unpatentable:(a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

[59] Case T 356/93 [1995] OJ EPO 545 http://legal.european-patent-office.org/dg3/pdf/t930356ex1.pdf

[60] STJCE, 9 October 2001 Case C-377/98

[61] Opinion of The Advocate General, Jacobs, Case 377/98 delivered, on 14 June 2001 http://europa.eu.int/servlet/portail/CuriaServlet?curiaLink=%26lang%3DEN%26ident%3D3907%26model%3Ddoc

[62] Previous studies reveal significant differences in magnitude and distribution of the benefits of GMOs between enterprises suppliers of technology and farmers depending on effectiveness of the property rights over GMOs Godden, David. (2000): "GMOs and IP: Embodied Technological Change". *Journal of International Development* Vol. 12, pp. 1179-1182.

[63] Stockholm European Council; March, 23 and 24th, 2001; available in http://ue.eu.int/es/Info/eurocouncil/index.htm

[64] During the Lisbon European Council in 2000, the European Council expressed the will to make Europe "the most competitive and dynamic knowledge –based economy in the world…". The crucial role of R&D for European competitiveness has been underlined repeatedly at successive Council meetings, a high point being the Barcelona Council in 2002, where Heads of State and Government committed themselves to investing 3% of GDP in R&D by 2010. The EU's R&D intensity in 2000 was 1.93%. The EU average was 0.8 percentage points below the figure for the US and over 1 percentage point behind Japan. European Commission (2002): *Towards a European Research Area- Science, Technology and Innovation- key Figures, 2002*. Luxemburg: Office for Publications of the European Communities, 2002, 84 pp.