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# **THE IMPACT OF REGULATION ON THE DEVELOPMENT OF NEW PRODUCTS IN THE FOOD INDUSTRY**

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**The impact of regulation on the development of new products in the food industry**

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**Abstract**

The paper gives an overview of the general regulatory framework relevant for the food industry in the EU and USA, as well as some information on the character of innovations in the food chain. In a second step three very innovative fields in the food industry are analysed whether the existing regulatory framework has hindering or facilitating impacts on innovations: the use of genetic engineering, health-oriented Functional Foods and organic food products. Empirical results among a survey of EU food manufacturing firms are presented which assess the current framework in the EU and its impact on innovation activities. The paper concludes with some remarks about the role of regulations for R&D and marketing of new products in the food industry.

**Key words**

Food industry, regulation, innovation, biotechnology, organic food, Functional Food, European Union, United States

## **The impact of regulation on the development of new products in the food industry**

The question of regulation, innovation and their impact on competitiveness in global markets has a high relevance for the food industry. However, little has been done to understand the effect of regulation on the capacity of such a traditional industry like the food industry to innovate and to introduce new products and services in the market. The debate has taken place at a level of anecdotal evidence and poor systematic empirical foundations. In addition, most of the approaches assume a static framework, not recognising the long-term dynamic feedback loops between regulation and technical progress and new markets. Finally, the majority of the expressed statements, especially from industry, come to the conclusion that the negative impacts of regulation outweigh the positive effects. This paper aims to bridge the gap between the challenge to shape a regulatory framework, which allows the emergence of new markets, and even to use regulation as an instrument to foster innovation and the lack of adequate, reliable and systematic knowledge on their interrelationship.

### ***Methodology***

For this purpose a methodological set was used, consisting of reviewing existing literature and reports, marketing statistics, press releases and other documents of companies and trade associations as well as regulatory and legal documents. In addition, a questionnaire-based survey among manufacturing companies and research institutions of the EU was carried out in order to analyse the view of different industries – among others the food processing industry – concerning the regulatory framework in the EU and its interrelationships to innovation activities in different fields. The target group of the survey were besides the food processing industry the environmental sector, pharmaceutical industry, mechanical engineering, electro-technology, and transport and telecommunication services. Finally expert interviews were used to complement the picture and give additional background insight in the analysed processes.

### ***Regulatory regime of the food industry***

Due to the increasing internationalisation of food and commodity markets, political and regulatory influential factors gain increasing relevance for the food industry. By speeding up the integration of international markets and increasing numbers of international joint ventures, the food industry is more and more influenced by international legislation. Against this background single national states are no longer able to perform an independent food legislation for their own country.

A specific relevance for food production and food processing have the standards of the so-called *Codex Alimentarius*. The *Codex Alimentarius* encloses all standards, voluntary agreements and recommendations of the so-called *Codex Alimentarius* Commission. This Codex Commission is the highest international committee for defining worldwide accepted standards for foods. It is a common committee of the Food and Agriculture Organisation of the United Nations (FAO) and the World Health Organisation (WHO). In 2000 the membership of the *Codex Alimentarius Commission* comprised 165 countries representing 98 % of the world's population. In 2003, the *Codex Alimentarius* contained more than 230 standards, more than 3,000 upper levels of pesticide residues and more than 1,000 assessments of food additives (Codex Alimentarius 2003). The Codex develops standards or gives recommendations to labelling issues, food additives, dietary food products, harmful substances in food, analytical methods, aspects of general food hygiene, the control of food imports and exports as well as levels of residues of veterinary pharmaceuticals and pesticides on foods. The increasing relevance of this type of standards is underlined by the fact that an increasing number of countries are transforming the Codex's standards into national law.

The *EU legislation on foodstuffs* (with some exceptions like novel foods and novel food ingredients) leaves food industry companies free to market their products without pre-market approval. Food manufacturers have to assure that their products are safe and do not mislead the consumer. These requirements must be met under the sole responsibility of the company and are subject to post-marketing controls by public authorities. In April 1997 the European Commission published a Green Paper "The general principles of Food Law in the European Union" which defines a regulatory framework which covers the entire food chain. The Green Paper had the objectives to ensure a high level of protection of public health and safety and of consumer protection, to ensure the free movement of goods within the single market, to base legislation on scientific evidence and risk assessment, to ensure the competitiveness of the European industry and enhance export prospects, to place the primary responsibility for safe food with industry, producers and suppliers as well as to ensure that legislation is consistent, rational and clear (European Commission 1997).

Following a series of food scandals in the 1990s the European Commission suggested in a White Paper on Food Safety in January 2000 the establishment of an independent European Food Safety Authority (EFSA) which should be responsible for independent scientific advice on all aspect related to food safety, operation of rapid alert systems and communication of risks (European Commission 2000). In addition, suggestions for a new legal framework concerning food safety, control activities, consumer information and international arrangements related to food safety were given in the White Paper. Furthermore, the European Commission announced its intention to streamline and simplify the EU decision-making process for foodstuffs "in order to ensure efficacy, transparency and rapidity" (European Commission 2000).

In the *United States of America (USA)* foods are regulated under the Federal Food, Drug and Cosmetics Act (FFDCA). This Act was the first and most comprehensive law in the world covering production, distribution and trade of foods, drugs, medical devices and cosmetics. The FFDCA defines foods and standards for food, adulteration of food as well as regulations for misbranding. Under FFDCA the Food and Drug Administration (FDA) oversees safety and labelling of food products with the exception of those containing meat or poultry which are controlled by the United States Department of Agriculture, Food Safety and Inspection Service (FSIS).

In the USA there are no federal requirements that food manufacturing companies have to be registered or get pre-market approval of food as it is the case for manufacturers of pharmaceuticals and medical devices. However, for some categories of food, such as seafood and low-acid canned foods, complex quality control programmes for manufacturing are mandatory (Greenberg 2000). The US food safety system is based on strong but flexible science-based legislation and industry's leader responsibility to produce safe foods. The regulatory approach used in the USA to control food safety refers to a so-called Hazard Analysis and Critical Control Points (HACCP) system. A HACCP system requires manufacturers to identify the likely hazards, like e. g. contamination from outside sources, or deterioration due to failure to maintain refrigeration. These "critical control points" are spots in the process where a failure could lead to a hazard (e. g. unsafe levels of dangerous micro-organisms). Manufacturers establish critical limits, then, if a manufactured product falls outside the limits, the maker knows something needs correction. HACCP systems require extensive record keeping, so the history of manufacturing processes can be easily reviewed and monitored (Greenberg 2000).

The US food safety programmes are risk based in order to ensure that consumers are protected from health risks of unsafe food. Decisions within these programmes are mainly science based and involve risk analysis processes. Regulations in the food safety area are often developed and revised in a public process that encourages participation by the regulated industry, consumers' organisations and other stakeholders throughout the development and promogation of a regulation.

Another important aspect of food regulation in the US are labelling requirements of foods. The two most relevant legislations in this area are the Fair Packaging and Labelling Act (FPLA) and the Nutrition Labelling and Education Act of 1990 (NLEA) which is an amendment to FFDCA. Before the enforcement of NLEA FDA run a voluntary nutrition labelling programme which was existing more than 20 years (Storlie et al. 2000). In 1990 the US Congress passed the NLEA which made nutrition labelling mandatory on most packaged food products and mandated that FDA initiate uniformity in the content and format of the nutrition label on the package. In addition, NLEA set up the regulatory framework for the approval of health claims which are of specific relevance for the development and marketing of Functional Food

### *Character of innovations in the food industry*

Traditionally the food industry is regarded as a sector with low R&D intensity (Martinez & Briz 2000, Grunert et al. 1997, Christensen et al. 1996). Due to lack of statistical information concerning the personnel or financial resources devoted to R&D activities of the EU food industry the situation of the food industry in Germany is analysed as an example. In Germany, R&D personnel of the food industry reached around 2,300 in 1999 (BMBF 2002, 2000), representing around 0.4 % of all employees of the German food industry, compared to around 2.4 % in all industries in Germany (BMBF 2002). In 1999 the food industry in Germany spent around 210 million € for R&D activities (BMBF 2000) and was responsible for 0.6 % of all funds devoted to R&D activities of the German industry compared to 9.7 % regarding turnover and 8.6 % regarding employees (BMBF, 2000). Consequently in 1999 the R&D intensity of the food industry reached 0.4 % compared to 3.5 % in all industries in Germany (BMBF 2002). This low R&D intensity is supported by the EU CIS survey of 1996 in which the food and beverages industry had the lowest R&D intensity of all industrial branches of the manufacturing industry (Eurostat & DG Enterprise 2000).

Innovation activities in the food industry can be analysed on different levels and with differing methodological approaches. However, due to the missing bottleneck for food products there are high variations in the published figures concerning the number of new products in the European food industry. According to the CIS survey around 50 % of the EU food manufacturers in 1996 can be regarded as "innovators" (Eurostat & DG Enterprise 2000). The big differences concerning the published numbers of "new" food products can be illustrated for the example of Germany. While investigations which are based on the EAN code of the products<sup>1</sup>, counted almost 21,000 new food products in 2001 (Madakom 2001), other studies which try to consider products with a higher degree of novelty found much lower figures. According to these investigations the number of newly launched food articles decreased from around 1,600 at the beginning of the 1990s to around 1,050 products at the end of the decade (Deutscher Fachverlag 2001, Hermann 1997, Hermann et al. 1996).

The market research institute Datamonitor continuously collects information about product innovations of the food industry in more than 50 countries. An overview about the product innovations in Germany collected by this institute between mid 1999 and mid 2001 is given in table 1. During this period 1,579 new food products were introduced in the German market. The highest number of product innovations was observed in dairy, confectionery and non-alcoholic beverages (table 1), underlining the findings of the other studies. Around 56 % of the product innovations of 1999 to 2001 have been launched by large companies with more than

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<sup>1</sup> In such surveys each product with a new EAN-code are considered as an "innovation", i. e. each modification e. g. in the packaging or other minor changes in the product design leading to a new EAN-code and thus to a new product.

500 employees (table 1). Regarding the different food categories, large companies showed a high relevance in innovations in baby food, sauces, frozen food and dairy products, whereas SMEs had a specific relevance in innovations in all types of beverages (table 1).

Table 1: Product innovations in Germany 1999 to 2001

Food category	New products		Large company		SME	
	Number	in %	Number	Proportion	Number	Proportion
Baby food	44	2.8	44	100.0 %	-	-
Dairy	250	15,8	156	62.4 %	94	37.6 %
Bakery	197	12.5	113	57.4 %	84	42.6 %
Pasta and rice	19	1,2	10	52.6 %	9	47.4 %
Confectionery	250	15,8	135	54.0 %	115	46.0 %
Canned food	50	3,2	27	54.0 %	23	46.0 %
Chilled food	69	4,4	41	59.4 %	28	40.6 %
Frozen food	157	9,9	115	73.3 %	42	26.7 %
Sauces	52	3,3	39	75.0 %	13	25.0 %
Snacks	42	2,7	22	52.4 %	20	47.6 %
Hot beverages	67	4,2	25	37.3 %	42	62.7 %
Non-alcoholic beverages	228	14,4	104	45.6 %	124	54.4 %
Beer	97	6,1	32	33.0 %	65	67.0 %
Alcoholic beverages	57	3,6	23	40.4 %	34	59.6 %
<b>Total</b>	<b>1,579</b>	<b>100.0</b>	<b>886</b>	<b>56.1 %</b>	<b>693</b>	<b>43.9 %</b>

Source: Own investigations based on Datamonitor 2001

The same discrepancy in number of new food products which was illustrated for the German market can be found in the USA as well. The specialised magazine *New product news* (Dornblaser 1998) reported that the number of new food products introduced in 1995 and 1998 in the USA ranged from 13,000 to 16,000 food products. On the other hand, Marketing Intelligence Service Ltd. found that of around 11,000 new food products introduced in the US market in 1996 only 7.2 % featured innovations in formulating, positioning, technology, packaging or creating a new market (Messenger 1997). According to a more stringent classification of new products Ernst & Young found that instead of the more than 15,000 new food products, which are reported annually by *New Product News*, only 1,100 to 1,200 new products are introduced each year in the US food market, of which 22 % are new brands and 78 % are line extensions (Lord 2000).



Given the high number of product innovations in the food industry it is not surprising that a relatively high percentage of the newly introduced products only “survive” a limited period of time in the market. During 2000 and 2001 around 50 % to 67 % of the new products have been withdrawn within one year from the food retailing shelves in Germany, indicating the high competition in this field. After three years the “survival” rate of the new products tends towards the 25 % level (Mada-kom 2001). This high rate of product failure in food retailing is supported by other authors as well (Mehler 1997, Martinez & Briz 2000, Behr's Verlag 2002) and mainly caused by limited sales and shelf areas in food retailing and in tendency saturated food markets with low total growth rates in the EU.

High failure rates of launched food products can be found on the US market as well. The 1996 IRI Pacesetters report included estimates of the rate of new product success and failure and calculated that approximately 72 % of new products and 55 % of line extension fail. Another study which analysed the introduction of new products of 20 major US food companies in 1995 found that of the 1,935 new products introduced by these companies 174 were “new” and 1,761 were line extensions. These new items experienced a success rate of 52 % while line extensions had a 78 % success rate what equals to an overall success rate of 76 % (Lord 2000).

Given the high numbers of product and process innovations, several studies have shown that radical innovations are very rare in the food industry. Most innovations in the food industry can be characterised as incremental innovations or even imitations (Grunert et al. 1997). According to different studies, only around 3 % of the new products which were introduced in 1996 and 1997 in the German food market were assessed as “innovative”, while 80 % were regarded as me-too products (Behr's Verlag 2002, Mehler 1997), and were also reported for the US and the Spanish food industry (Martinez & Briz 2000). Galizzi & Venturini (1996) attribute the incremental nature of food product innovation to constraints on the demand side. European consumers tend to be conservative in their food choices and may initially reject new products. Therefore, fundamentally radical innovations are a high risk for food manufacturing companies.

### ***Impact of regulation on innovation activities in the food industry***

In following part of the paper three very innovative fields in the food industry are analysed whether the existing regulatory framework has hindering or facilitating impacts on the development and introduction of new products: the use of genetic engineering approaches for food production and food processing, the field of health-oriented Functional Foods and organic food products.

### ***Genetically modified organisms (GMOs) and Novel Foods***

Since the mid 1990s genetically modified (GM) plants are marketed and cultivated which directly or via animal feed can enter the food chain. In addition, genetic engineering approaches are regarded by their protagonists as major tools to increase productivity and efficiency in food processing in future (Garza & Stover 2003). On the other hand, an intensive public debate is carried out globally concerning the safety of these approaches and derived novel foods as well as their socio-economic impacts (Otsuka 2003). Critics of genetic engineering see the potential that this technology may result in harm for the environment and human or animal health. In addition, the wider impacts of the use of genetic engineering in the agro-food sector on society as a whole are often questioned in the public debate (Menrad et al. 2003).

Since GMOs and derived novel food products represent new developments in the area of food production and food processing, there have been relatively restricted experiences with this type of products. Therefore, state authorities took specific activities to deal with potential risks of GMOs. The general targets of the respective legislations are to ensure human health when consuming GMOs or derived novel foods, to prevent or minimise potential harm of GMOs to the environment as well as to provide the necessary information in order to ensure the freedom of choice of consumers or users of such products. In particular, the EU policy related to GMOs was intensively influenced by the emergence of the BSE and other food crises during the 1990s, the public criticism and undermined trust in public authorities to adequately manage such crises in the sensitive area of food production and food processing as well as the low consumer acceptance of agro-food biotechnology (Loureiro 2003, Eurobarometer 2001, Gaskell et al. 2000).

The fundamental question which arises concerning regulation of GMOs is whether GM crops or other GMOs have to be acknowledged like conventional crops or organisms, and therefore it is sufficient to use the general legislation valid for such crops or organisms or whether it is necessary to adopt different and specific regulations for GMOs. In the USA GM crops are considered specific and different in terms of intellectual property rights since a patent can be granted to them but not to conventional crops. On the other hand, the introduction of GM crops in the environment and into the market follows the principle of “substantial equivalence” and therefore the same steps are required like for conventional crops (Esposti & Sorrentino 2002).

The EU takes the opposite approach concerning regulation of GMOs compared to the USA. Even after Directive 98/44/EC patents cannot be granted to GM crops, but they are protected by the same breeders rights acknowledged to conventional crops. In contrast to the US procedure, the EU approach for environmental release and market approval of GMOs follows a rather strict interpretation of the “precautionary principle”. For this purpose specific regulations have been put into force dealing with GMOs which require different and often more complex procedures than for conventional products (Esposti & Sorrentino 2002).

GMOs have been regulated by the EU since the beginning of the 1990s. The EU Directives 90/219/EEC and 90/220/EEC were the first regulations which tried to establish a system for controlling R&D and commercialisation of GMOs in the EU. These regulations were designed to protect citizens' health and the environment, and addressed authorisation, labelling and traceability issues relevant for GMOs. Since its enactment in the year 1990 Directive 90/220/EEC was criticised by different stakeholder groups. In addition, all notifications for market approval of agricultural GMOs raised concerns of one or several EU Member States during the 1990s (Sauter & Meyer 2000). Therefore, in June 1999 a *de facto* moratorium on commercialisation of GMOs was agreed by the Community's Council of Environmental Ministers to suspend all approval applications for GMOs until implementation of the revised Directive 90/220/EEC, in order to provide a more strict legal framework covering not only safety issues but also labelling and traceability of GMOs (Lheureux et al. 2003).

Directive 2001/18/EC on the Deliberate release into the environment of genetically modified organisms was passed in February 2001 which replaced Directive 90/220/EEC. This Directive modified the rules for environmental release and market approval of GMOs significantly by restricting market approval to ten years and the requirement of post-market monitoring of each GMO. In further regulations a tolerance level of 0.9 % is foreseen for adventitious admixture of GM material: food products which exceed this level have to be labelled accordingly. In addition, the European Commission has suggested labelling rules for GM derived novel foods irrespectively whether DNA or protein of GM origin can be found in the final product. Another area of intensive debate is to ensure co-existence between GM crops, conventional and organic farming as well as the question of liability in case economic damage results from admixture of gene flow (European Commission 2003).

In contrast to the EU, in 1992 the US Food and Drug Administration (FDA) outlined a policy that did not require the market approval for GM crops and placed the responsibility for investigating and reporting potential problems associated with GM foods to the companies. During this phase FDA recommended voluntary labelling of specific GM foods but opposed mandatory labelling of GM foods (FDA 1992). The practise of FDA was modified in 2001 when the Authority announced a mandatory notification by manufacturers for plant-derived bioengineered foods (FDA 2001). In 2003 the USA with Canada and Argentina decided to instigate an action at the World Trade Organisation (WTO) against the EU, due to the inability to sell GM crops and derived products in the EU and because of concerns about the impact of the EU *de facto* moratorium on GMOs on imports of such products by developing countries (Kinderlerer 2003).

In the EU there is still a broad pipeline of R&D activities related to agricultural and food GMOs which is fuelled by differing organisations like large multinational companies, SMEs, universities and non-university research institutions (Lheureux et al. 2003). However, EU publication intensity in plant biotechnology grew signifi-

cantly below average compared to other field of biotechnology (Reiss & Dominguez Lacasa 2003). In addition, field trials with GMOs have dropped by 76 % since the introduction of the de facto moratorium (Lheureux et al. 2003) and a significant number of companies mentioned in a survey carried out in 2002 that they have cancelled R&D projects related to GMOs in the last four years (table 2). Companies highlighted the unclear legal situation in the EU, high costs and time requirements for safety testing, low consumer and user acceptance of GM products as well as uncertain future market perspectives as main obstacles for GMO-related innovation activities in the EU (Lheureux et al. 2003). Although 14 GM plants have got market approval for the EU before 1998 (and 20 are awaiting market approval), only 20,000 to 25,000 hectares of Bt maize are commercially planted in Spain (Brookes 2003). Altogether, the impression arises that the de facto moratorium has had a negative impact on pre-market innovation activities related to GMOs in the EU (Menrad 2003b). This relates in particular to SMEs which often have given up such projects due to their limited financial and personnel resources.

Table 2: Cancelling of R&D projects related to GMOs in the last four years

Institution	Number of respondents	GMO projects cancelled	
		Yes	No
SME	33	54.5 %	45.5 %
Large company	28	67.5 %	32.5 %
University institutes	44	25.0 %	75.0 %
Public research institutes	37 <sup>1)</sup>	21.6 %	75.1 %
Total	165 <sup>2)</sup>	38.8 %	60.6 %

<sup>1)</sup> One respondent answered "Don't know"

<sup>2)</sup> Other institutions are included, 3 questionnaires without an answer to this question.

Source: Lheureux et al. 2003

In contrast to the situation in the EU, field trials with GMOs did not fall significantly in the USA in the last six years. In addition, a high number of mainly herbicide and/or insect resistant GM plants have been approved for commercial use in USA and Canada (AGBIOS 2004). With almost 43 million hectares in 2003 USA also has the world-wide leadership concerning commercial cultivation of GM plants (mainly soybeans, maize and cotton) (James 2003), while in Canada particularly GM rapeseed is grown for commercial use.

The EU regulatory framework adopted during the 1990s has played an important, largely negative role for the development of GMOs in the EU in the last decade. During this time period increased regulatory oversight in agro-food biotechnology coincided with growing negative public opinion and diminished trust in public authorities and regulatory agencies. In this context companies regarded the "constantly changing regulatory environment" as one major constraint for R&D and commercialisation of GMOs in the EU. In particular the practical handling of the existing regulations was strongly criticised as being too slow, bureaucratic and caus-

ing extraordinary costs. Politics was criticised for not taking any clear decision regards GMOs (which will form a reliable planning basis for the companies) and periodically intervening in the regulatory processes.

Combining the findings of Lheureux et al. (2003) with the analysis of the performance of scientific publications in different subfields of biotechnology (Reiss & Dominguez Lacasa 2003) provides evidence, that the unclear legal situation with respect to the commercialisation of GMOs which emerged in the second half of the 1990s led to the cutting down of research activities in plant biotechnology which can be measured as decreasing scientific output. In more general terms, the unclear legal situation related to GMO on the commercial side seems to have a negative feedback on the science base. This could give reason for concern that once the legal environment would become more stable and/or more favourable for commercialisation of GMOs, the EU knowledge base would be less prepared to provide the required know-how.

The “proof of principle” of the differing GMO-related regulatory approaches of USA and EU cannot be provided so far since no consumer or user reactions which are based on purchasing behaviour can be measured in the EU. In this sense the case study on GMOs represents a field in which political decisions impede the functioning of the market mechanism, i. e. other areas of political intervention are regarded as being more relevant than innovation aspects. In addition, the GMO case represents a good example of the differing acceptance levels of risk and the handling of uncertainty which a society is willing to accept – what results in differing regulatory regimes and differing priorities of political actors.

### ***Functional Food***

In addition to satisfy hunger and provide humans with the necessary nutrients, Functional Food is intended to provide additional benefits to consumers by preventing nutrition-related diseases and increasing physical and mental well-being of humans. For this purpose Functional Food contains specific “functional” ingredients to which particular effects on human health or well-being are attributed. These substances aim at reducing the risk of e. g. coronary heart disease, specific types of cancer, diabetes or osteoporosis which are amongst the most important causes for death in many industrialised countries (Menrad et al. 2000).

From a legal point of view, Functional Food is positioned in a transitional zone between food and pharmaceuticals. In the EU, its Member States and USA food and pharmaceutical products are subject to different regulation regimes and are – at least in the EU – regulated by differing relevant authorities. Another fundamental difference between these two product fields is the aspect that pharmaceuticals and other medicinal products require pre-market approval by state authorities, while EU and US legislation on foodstuffs (with a few exceptions like e. g. novel foods or food additives) leaves companies free to market their products, if they are safe and do not

mislead consumer and afterwards they are subject to post-marketing control by public authorities. Since Functional Food is positioned in a “grey zone” between these two areas, high uncertainty emerges both for commercial activities of companies as well as for consumers. Due to the novelty character of Functional Food, additional questions arise concerning the safety and efficacy of such products, the required testing and monitoring methods, their impact on consumers’ nutritional behaviour as well as the institutional procedures and responsible authorities.

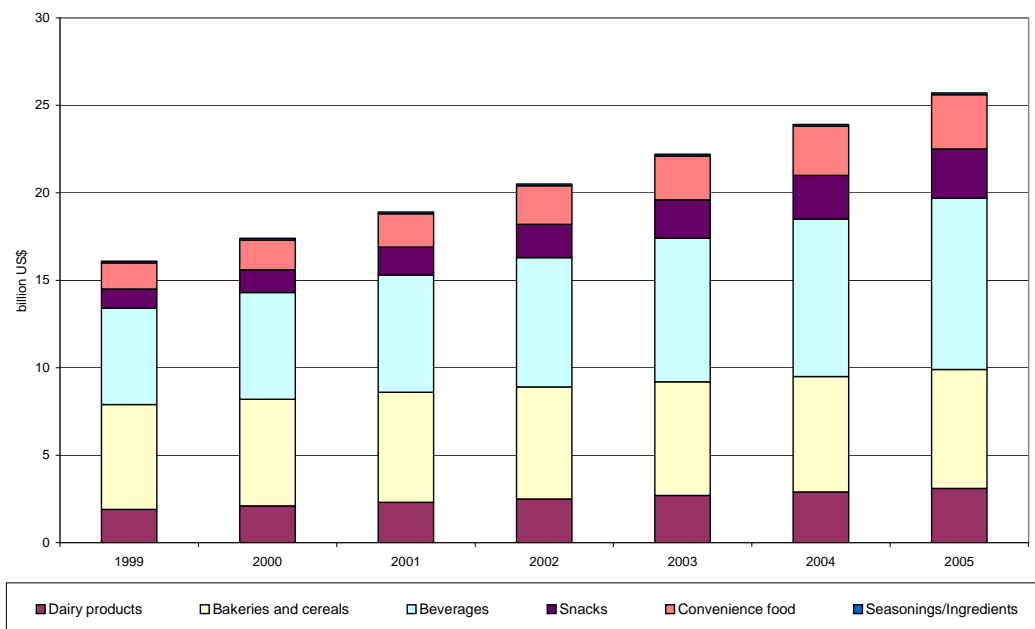
In the EU there exists no harmonised or specific regulatory framework nor a precise legal definition of Functional Food, i. e. the general regulations valid for food are relevant for Functional Food as well. However, there are differences in the practical handling of these general regulations with regard to Functional Food between the EU Member States (Groeneveld 2000) – what hinders the development of a common market for such products. Due to the absence of specific regulations, the so-called Novel Food Regulation (Regulation 258/97/EC) was used for single Functional Food products for applying for market approval in the EU in recent years. Another important bottleneck for Functional Food represents the fact, that there exists no harmonised legislation on health claims on Community level so far, what results in differences in the practical handling of such claims between the Member States (Menrad 2003a). Under the existing regulatory framework in the EU it is prohibited to attribute to any foodstuff the property for preventing, treating or curing a human disease or referring to such properties. The regulation on Nutrition and health claims proposed by the European Commission in July 2003 includes far-reaching suggestions concerning the use and registration requirements of generic claims as well as for the requirements to approve specific health-related claims. In addition, it is foreseen to prohibit certain claims related to e. g. general well-being or slimming (European Commission 2003b).

In contrast to the EU situation, food manufacturers in USA can use about 13 generic claims to inform consumers about the health benefits of Functional Food products which have been approved by the Food and Drug Administration (FDA) since 1990 (Ringel Heller & Silverglade 2001). The regulatory framework for these activities was provided with the passing of the Nutritional Labeling and Education Act (NLEA) in 1990, which established mandatory nutritional labelling for food products in the USA but also set up the regulatory framework for the approval of health claims. In order to protect consumers from unproven health claims, the respective claims have to be supported by the totality of publically available scientific evidence and there must be “significant scientific agreement” among qualified experts. In addition to labelled food products, Functional Food is often marketed as a food supplement in the USA (Heasmen & Mellentin 2001).

Despite definition problems and highly varying market figures for Functional Food it can be concluded that the market of Functional Food (and interrelated food supplements) has developed faster and to larger market values in the USA compared to the EU. While the total US market of Functional Food is estimated to 15 to 20 billion US\$ (figure 1), what equals to around 2 % of the US food market (Marra

2003, CMA 2002). The corresponding EU sales figures amount to around 4 to 8 billion €, what equals to a Functional Food market share of below 1 % of the total EU food and drinks market. Within the EU, Germany, France, the United Kingdom and the Netherlands represent the most important markets for Functional Food, while Mediterranean consumers showed limited interest in this type of food in recent years. Important product categories of Functional Food in the EU are functional dairy products, ACE drinks and non-alcoholic beverages fortified with other functional ingredients, cholesterol-lowering margarine and a multiplicity of niche products mainly in confectioneries, bakery products, breakfast cereals or babyfood (Menrad 2003a, Hilliam 2000).

Figure 1: Market development of different groups of Functional Food in the USA



Source: Nutrition Business Journal 2001 cited in CMA 2002

According to the available future market estimations, it can be assumed that Functional Food will increase its market volume in the coming years considerably. Most market estimations assume that 3 % to 5 % of the food market represent the growth limit for Functional Food in Europe in the coming ten years (Menrad 2003a, Dustmann & Weindlmaier 2002). In this sense, Functional Food has a significant growth potential but will not develop to a mass market in future, i. e. it represents a multi-niche market with a high number of limited product segments and very few high-value product categories. The most important drivers of innovations in the field of Functional Food are scientific and technical developments in nutrition-related research, the interest of food companies to participate in growing segments of an almost stagnant food market as well as consumers' interest in innovative products supporting their health and well-being. So far, multinational food companies as well

as internationally acting food ingredient suppliers are best positioned to overcome specific challenges during the R&D and marketing process of Functional Food, while small and medium-sized food industry companies do only have limited opportunities in this field (Menrad 2003a)

A major bottleneck for the future development of Functional Food in the EU represents the unclear legal situation concerning procedure and factual requirements for market approval of such products as well as the use of health claims. This lack of a clear regulation and definition of Functional Food and non-harmonised procedures between the EU Member States impedes the potential growth of this market. Thus, the EU food industry cannot take full advantage of a potential growth segment in the mature and stagnating food market in the EU. In this sense, an important basic activity with a mid-term perspective is the clarification and standardisation of the regulatory status of Functional Food in the EU both for consumers and industrial companies as legal basis for economic activities (Menrad 2001).

### ***Organic agriculture and food production***

At the end of the 1980s both the EU and USA took initiatives to develop a specific regulatory framework for production, processing and trade of organic products. Major targets of the related policies were reducing costs of market stabilisation measures for conventionally produced agricultural commodities, supporting environmentally friendly ways of agricultural production and protecting consumers from being misled in the area of organic foods (Lampkin et al. 1999). While the US policy focussed almost solely on defining standards for producing, processing, marketing and importing organic products (Greene & Kremen 2003), the European Commission followed a dual strategy which firstly supported conversion of conventional farms to organic agriculture by direct payment schemes and advisory assistance, and secondly improved market transparency by defining, implementing and controlling clear standards for production, processing and marketing of organic products (Lampkin et al. 1999).

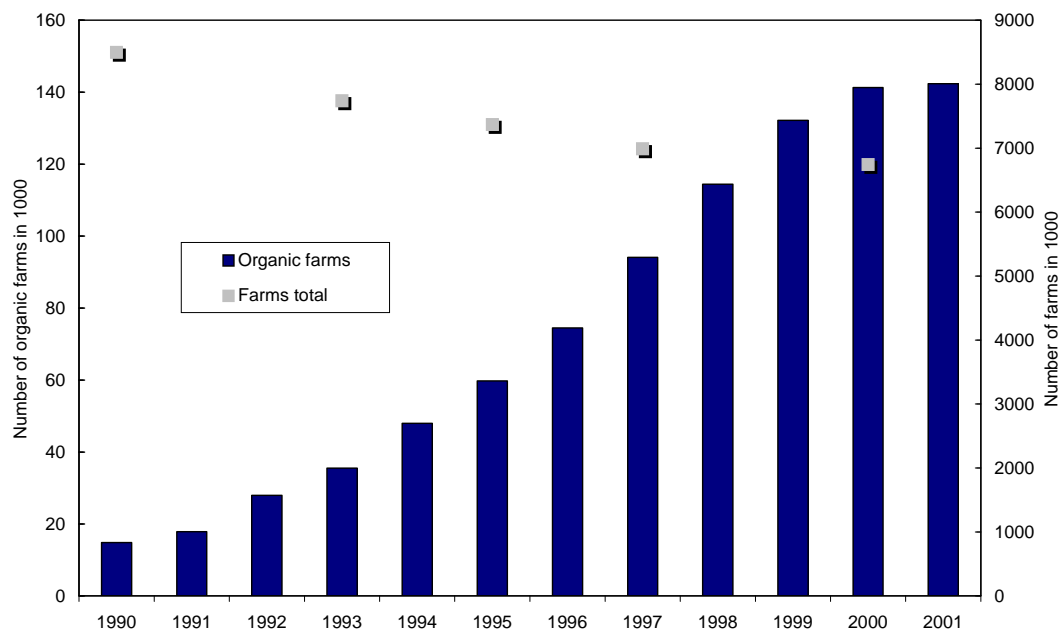
Regarding timing of the respective legislation the USA took the leadership when passing the Organic Food Production Act (OFPA) in 1990 by the US Congress. However, it took more than ten years until with the National Organic Programme, which was published in December 2000, OFPA was fully implemented and nationwide standards for organic products were put into force in the USA (Greene & Kremen 2003). With Regulation 2078/92/EC a common regulatory framework was established for EU Member States to implement policies to support organic farming which was introduced in most countries in 1994 and 1995. An important part of this Regulation are direct payments for conversion to organic farming for which maximum rates eligible for co-financing by the EU are defined in the Regulation. Another important key element of EU legislation in the field of organic food products represents Regulation 2092/91/EEC which created a common legal definition for organic farming and the respective products, covering all EU Member States and trade with third countries. This Regulation required that all fresh and processed



products of plant origin must meet the organic standards defined in the Regulation and that producers and operators must submit their business activities to a publicly-controlled inspection system. In 1999 analogous requirements were put into force for production and marketing of organic livestock products (Lampkin et al. 1999).

Both in the USA and in the EU the introduction of the organic food regulation has had a strong impetus for supply and demand of such products. However, EU farmers and food processors reacted faster and in much higher numbers in order to benefit from the market opportunities provided by organic foods. This can be illustrated by the fact that until 2000 around 2.1 % of all farms (figure 2) which operated 3.1 % of the total Utilised Agricultural Area of the EU (Organic Centre Wales 2003b) have converted to organic agriculture in comparison to 0.32 % of all US farms being organic in 2001 with 0.25 % of the operated farm area (USDA 2003, Yussefi & Willer 2003). In particular producers of plant products like fruits and vegetables, potatoes or cereals have increased organic production significantly during the 1990s, but at least in the EU production of organic livestock products like milk or eggs seems to grow at high rates in recent years (Hamm et al. 2002).

Figure 2: Number of organic and conventional farms in the EU 1990 to 2001



Sources: Organic Centre Wales 2003a, Yussefi & Willer 2003

Besides higher price premia for organic products, this much stronger increase of domestic organic production in the EU can be linked to the direct payments provided by the European Commission and national governments in order to support

conversion to organic agriculture. Since conversion of conventional farms to organic agriculture reduces natural yields significantly and often induces increasing production costs (at least in the first years after conversion), this step includes high technical, market-related and financial risks for farmers. In order to reduce uncertainty and risks associated with such a conversion process, it does not seem to be sufficient to solely reduce transaction costs on the market by introducing standards for organic products and inspection systems for controlling these standards (like it was the case in the USA), but additional financial incentives seem to be necessary to foster such a development – as it was implemented in the EU. It can be questioned how long such direct payments should be given to farmers willing to convert to organic agriculture.

Table 3: Organic products in % of the total sales value of selected products in EU Member States in 2000

	Cereals	Potatoes	Vegetables	Fruits	Milk	Beef	Eggs
Austria	10.2	4.8	6.1	3.8	7.7	3.5	2.7
Belgium	1.5	2.7	1.1	0.8	1.6	0.8	0.6
Denmark	14.5	8.3	12.8	3.2	13.1	3.0	11.9
Finland	5.5	2.3	7.1	1.6	0.6	1.0	2.3
France	1.7	1.9	-	-	0.9	0.4	2.2
Germany	4.7	3.5	3.6	1.8	1.3	3.1	1.9
Greece	0.2	0.0	0.3	-	-	-	0.0
Ireland	-	-	-	-	-	-	-
Italy	5.3	-	0.3	2.0	0.5	0.1	0.6
Luxembourg	3.0	1.3	0.4	0.3	-	0.6	-
Portugal	-	-	0.9	1.2	-	-	-
Spain	-	-	-	-	-	-	-
Sweden	9.7	4.8	4.3	0.9	1.8	1.0	2.1
The Netherlands	1.2	6.0	3.4	0.5	1.6	0.8	2.5
United Kingdom	1.6	0.7	4.4	1.9	1.1	0.4	2.5

Source: Hamm et al. 2002

On the consumer markets, there is a fastly growing demand for organic products in the USA and EU. Although there are some difficulties concerning data availability, both markets are estimated to around 10 to 13 billion € with significant regional differences (Marra 2003, Yussefi & Willer 2003). In the EU “mature” organic markets in countries like Austria, Denmark, Sweden, Finland (with high per capita sales of organic products) can be observed parallel to “emerging” organic markets (e. g. in Greece, Portugal) (table 3). In most EU countries organic plant products achieve higher market shares compared to organic livestock products. For future growth of the organic market which is expected both in the USA and EU clear and reliable

standards for organic products and corresponding consumer information, increasing interest and activities of the processing industry as well as increasing sales in conventional supermarkets are regarded as key success factors. In this sense, the US and EU regulation provided the starting point for innovation activities in the organic food area which was rewarded by consumers in recent years.

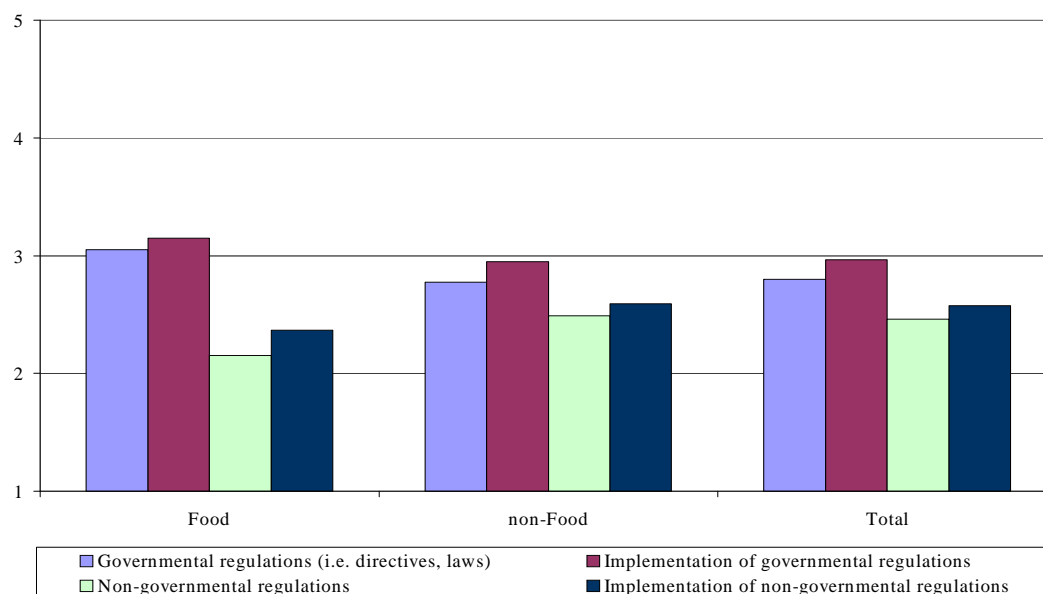
### ***Empirical results of a survey of EU food processing companies***

In the following part of the paper empirical results among a survey of EU food manufacturing firms are presented which assess the current framework in the EU and its impact on innovation activities. In this context we differentiate only between the food and the other sectors, in order to characterise the specifics of the food sector. In total, we received completed questionnaires from more than 260 companies, thereof 20 food companies. The companies were randomly selected by using the commercial database of Dun & Bradstreet. At first, the companies were approached via fax or via mail and asked to fill out the questionnaire either online or to download a pdf-file and return the questionnaire via mail or fax. Secondly, two thousand companies active in the six sector above in further Member States and one thousand companies in the USA and Canada were sent a paper version of the questionnaire.

The response rate was rather low compared to other non-mandatory business surveys in Europe, because the complex issue of regulation and innovation within companies is not yet broadly acknowledged and taken into account, consequently there is very often no one explicitly responsible for this issue. In more than one third of the answers, the chief executive officer answered the questionnaire. The other answers stem from members of the R&D or from the members of the marketing department. Members of the legal department are almost not included in answering the questionnaire.

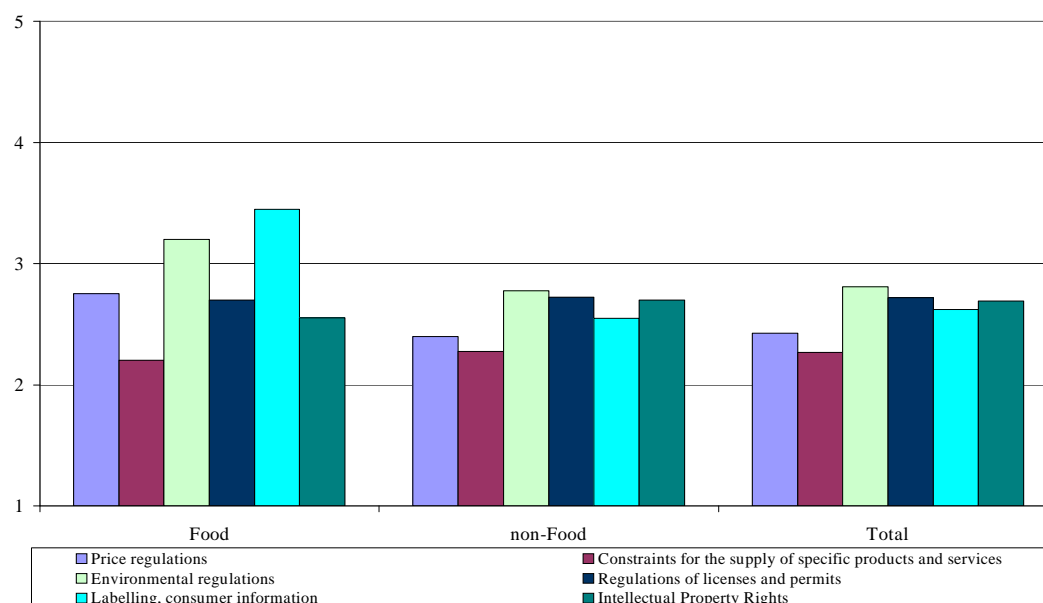
In Figure 3, we present a differentiation of the importance of regulations as hampering factors for innovation. Although governmental regulations are more severe obstacles for innovation than non-governmental regulations, we find in the food sector the highest values and the largest discrepancies to non-governmental regulations. Furthermore, in general the implementation of governmental regulations is a slightly more severe problem than the regulations themselves. Since there are rather different types of regulations, we have to differentiate more precisely between different types of regulations relevant for the development and introduction of new products and services. Figure 4 confirms that especially labelling and environmental regulations have a higher relevance for the food companies compared to the rest of the sample.

Figure 3: Barriers to innovation (1 = very low importance to 5 = very high importance)



Source: Company survey of Fraunhofer ISI 2003

Figure 4: Importance of selected regulations relevant for new products and services differentiated by sector (1 = very low importance to 5 = very high importance)



Source: Company survey of Fraunhofer ISI 2003

Regulation may be a hampering factor for the development and market introduction of new products and services. However, regulation may also have a positive influence on these activities, by forcing firms to search for new products and services. Furthermore, regulation may create new opportunities for new products and services by providing an adequate framework. Based on this background, we asked the companies to assess whether those regulations in the direct context of introducing new products and services into the market, which have been assessed as important are more likely to have positive or negative impacts on these aspects.

In general, figure 5 confirms that the regulations relevant for the introduction of new products in the food sector have more negative and less positive impacts than for the rest of the sample. They have both not the positive impacts on legal security including liability claims, and they have more detrimental impacts on domestic and foreign market shares and on the costs and risks to introduce new products into the market. These results raise serious concerns regarding the regulatory framework for the food sector in the EU relevant for the introduction of new products.

Figure 5: Impacts of the regulatory framework relevant for the introduction of new products and services (-1 = negative impact to +1 = positive impact)



Source: Company survey of Fraunhofer ISI 2003

### ***Role of regulations for R&D and marketing of new products in the food industry***

The focus of innovation activities in the food industry has shifted in recent years. While in the past innovation activities of the food industry strongly depended on

technical developments in their supplying industries, currently innovation activities of the food industry are mainly demand-oriented what results in a high number of new or modified products which are often combined with process innovations. This shifting orientation of innovation activities can be observed in all three case studies in which demand-relating factors are important drivers for the R&D, market introduction and penetration of new products.

In the coming years the agro-food sector is confronted with multiple new scientific approaches and technical opportunities which often have an interdisciplinary character. However, in particular SMEs of the food industry are not well prepared to profit from these developments. Therefore, the creation and building-up of interfacing competencies as well as the establishment of new external knowledge and competence networks seems to be of strategic relevance for many companies of the EU food industry. In this context it is advisable to widen the knowledge base of external co-operations and include clients, retail companies, research institutes, specialised service companies as well as other companies of the food and supplying industries in such networks.

As illustrated in the Functional Food case, in many innovative fields with relevance for the food industry the political and regulatory framework conditions in the EU often do not keep pace with scientific and technical discoveries or developments on the demand side. This relates in particular to regulatory aspects in which intensive discussions and co-ordination activities are required between the different Member States. Such a situation of legal uncertainty or non-harmonised regulatory conditions between the different Member States often impedes innovation activities and may result in loss of market opportunities. In this sense, a clear and harmonised regulatory framework in innovative fields seems to be a necessary but not sufficient prerequisite for the development of new products or services. Such a situation of legal and regulatory certainty is in the interest of both industrial companies (as basis for commercial activities) and consumers (in particular for “credence goods”). In this sense there is need for clarification, harmonisation and implementation of regulations in the EU in particular for those innovative fields with relevance for the food industry in which consumers are interested in the respective products.

In particular in highly interdisciplinary-oriented innovation fields of the food industry (like Functional Food) the institutional organisation and administrative responsibilities impede innovation activities, since differing competent authorities with varying decision-making processes and procedures are responsible for the implementation, administration and control of existing regulations. In this sense, scientific and technical innovations require organisational changes which often take place with significant time delays. This is valid both for the EU as well as for the Member States. Therefore, a more flexible framework for regulations should be created for newly emerging innovation fields which can be jointly formed by public authorities and early innovators.

As shown in the case study on organic food products, the definition of standards and the creation of labelling and control procedures does not seem to be sufficient for an early and fast take-off on the supply side. Although with these activities transaction costs are reduced on the market side, the high technical and market-related risks impede farmers to convert conventional farms to organic agriculture. In such a case time-restricted and adopted final incentives seem to be an adequate instrument to speed up the adoption of an innovation. Such financial payments can be justified because positive environmental effects and reduced costs for financing conventional agricultural production are expected by increasing the rate of organic farming.

The analyses in the case studies have identified the creation of interfacing competencies as one of the most relevant tasks for SMEs of the EU food industry in order to successfully carry out innovation activities in future. Therefore, national and international policies should not solely concentrate on stimulating knowledge generation with relevance for the food industry, but should have the additional target to support advances of the knowledge base of the food industry companies themselves. In this sense, political activities should be stronger targeted to the diffusion of new scientific approaches and technologies in the food industry than exclusively on the support of knowledge generation.

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