3. EU food legislation as perceived by industry

Bernd van der Meulen and Harry Bremmers

3.1 Key findings

The findings of this research are surprisingly positive for the system of EU food legislation in general. It is not considered to be a major factor hampering competitiveness. Nor is the EU system seen as inferior to the US system.

Criticism focuses on details. Quite a few improvements could be made. Improvements would be welcomed in stability, clarity and accessibility of both legislation and authorities. The biggest burdens for SMEs are experienced in food hygiene and labelling legislation.

Pre-market approval procedures are for the happy few. Due to the costs and time involved, it is very hard for a regular food business to bring a new additive, novel food, GMO or health claim to the market. For those who are in a position to follow such a procedure, it is not always clear precisely which procedure applies, what requirements must be met, how long the procedure will take and if a favourable outcome may be expected.

A pro-active role of EU and national authorities in assisting companies to negotiate EU procedures and to comply with legal requirements would be most welcome. On the global market, EU authorities can increase their support for the European industry by engaging in export negotiations and by recognising scientific assessments performed under the jurisdiction of well-equipped foreign authorities.

Very recently the European Commission undertook to reduce administrative costs by 25%. To achieve this ambition, audacious and radical steps are called for. Improvements are possible in the EU system of legislation as such and in EU food legislation in particular.

3.2 Introduction

As the economic parts of this study show, competitiveness of the food industry in the European Union is under pressure compared to other sectors in the EU and the food industry elsewhere in the world, in particular the US. We address the question whether the legal framework (1) provokes additional costs (and benefits) to businesses[6] in the European Union and/or (2) influences the market responsiveness (and especially the innovativeness) of these businesses, and (3) can be improved to enhance competitiveness.

Problem statement
This part of the study focuses on an assessment of the quality, utility and burden of the existing European legislative framework i.e. food legislation in terms of food industry competitiveness. Does the EU regulatory framework on food affect costs and benefits, as well as market responsiveness (innovativeness) of businesses in the EU?

EU Food legislation has developed tremendously over the last 15 years to respond to growing concerns as regard food safety, consumer information and the functioning of the internal market, whereas the effects of the changes are carried by the European businesses (administrative burdens, additional investments etc.). So far there has been little understanding with respect to additional costs and benefits and effects on the market responsiveness of businesses, especially SMEs.

---

6 We refer to the players in the field as 'businesses' or 'companies'. Also the abbreviation FBOs is used referring to 'food business operators', the official term used in EU food legislation (see: Article 3(3) GFL).

Research questions

From the problem statement, the following research questions can be formulated.

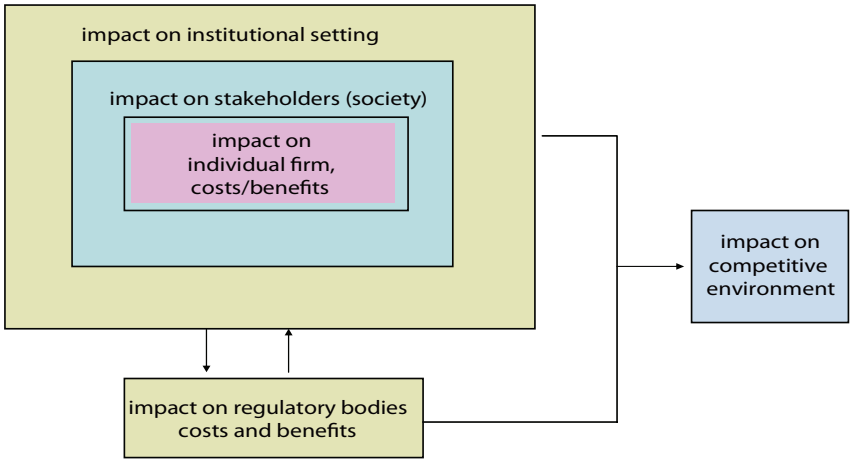
– how is the present legal framework for the food sector in the EU perceived by the food companies, also compared to the US system (section 3.3);
– what costs and benefits are connected to the European legal system and how do these influence the competitiveness? Five topics are addressed in this context:
– what is quality of legislation (section 3.4);
– what is the impact of legislation changes (section 3.5);
– which effects are there on innovation and pre-market approval (section 3.6);
– is there an overdose of control (section 3.7);
– other administrative burdens (section 3.8);
– what recommendations can be made and what discussion points can be discerned to improve and redirect Community legislation dealing with food safety with the aim of achieving a better balance between industrial competitiveness and consumer protection (section 3.9)?

Research framework

The general research framework is given in figure 3.1. It shows that new legislation can influence the internal business processes of a business to which it is addressed. Cost effects can be distinguished in effects on operational costs, costs of investment and additional administrative requirements (such as information collection, auditing, reporting etc.).

Food labelling requirements for example have an impact on the operational costs, while investments in tangible fixed assets would normally be minimal. Also, the extra administrative requirements are relatively low. On the other hand, prohibition of certain food ingredients can change the production process dramatically. It can cause previous investments to become obsolete, necessitate additional investments, ask for audits and for additional information to external stakeholders

Figure 3.1 Research framework



External relations towards stakeholders can change too. They can change towards consumers, if enforced legislation influences consumer's choices and/or alternatives, if distortions on market competition are mended by harmonisation of regulatory requirements, and/or if suppliers are locked out of competition who previously had a 'licence-to-deliver'. Even more broadly, the institutional setting can change if regulations ask for the creation of auditing and controlling governmental bodies, whose costs and infrastructure are borne by the businesses concerned.

It is clear that changes in cost structure and/or turnover for companies obeying new regulatory requirements have an impact on the competitive position of these companies if:

– some companies are following more strictly than others;
– some companies benefit from regulatory requirements more (easily) than other.

There are situations in which this distortion of the present competitive status quo may even be desirable, for example if previous distortions (e.g. because of lack of transparency or discongruent legal obligations in member states) are intended to be repaired.

More specifically, to assess the effect of regulations on business performance, we use the 'costs of quality' model[7] analogously to assess the effects on costs, benefits and market position (in general: business performance). Quality costs are defined as costs of preventing, finding and correcting defective work (Kaner, 1996). The rationale behind the model is that lower failure costs can be compared with increasing appraisal and prevention efforts, if product quality is improved. The scheme can easily be adapted to serve purposes in other fields, like environmental management (see for example: Watson et al., 2004), or the costs of law implementation. We distinguish:

– internal legal effects: adverse effects of non-compliance and (the 'reverse side of the coin') internal benefits of compliance;
– external legal effects: effects on the stakeholder environment of the individual businesses;
– 'appraisal' costs: costs of operating food safety and quality assurance systems;
– prevention effects: effects on the performance of companies of actions undertaken to prevent a-conformity with legal requirements.

Some remarks should be added:

1. by 'internal' we not only mean effects on the operations of businesses, but also effects on the company's strategy, that give ground to the actual functioning of the business;
2. the four distinguished areas partly overlap; for example, appraisal costs are made to prevent a-conformity (prevention effects);
3. the four areas are linked with the general framework proposed; for example, external legal effects will definitively provoke prevention and appraisal efforts at company level.

Research methods

To address the research questions within the given timeframe and limits in resources, we apply:

– desk research, mainly to give a solid foundation to address the research questions.
– survey research. We developed a questionnaire.8 This questionnaire aims at measuring businesses' appreciation of the applicable regulatory framework and identifying aspects of this framework that might influence competitiveness. Some respondents returned a completed questionnaire but in most cases they were completed in an interview either by telephone or in person. As the main representative of the group of neighbouring countries exporting to the EU, Croatia was chosen. As Croatia is a candidate for EU membership, it was considered that businesses in that country are likely to address issues of implementing EU food legislation.

An open invitation to participate was published in the European Food and Feed Law Review.[9] An electronic version of the questionnaire was posted on the websites of IFAL, the European Institute for Food Law and the Law and Governance Group at Wageningen University. Where in this chapter quantitative information is provided on stakeholder opinions, this refers to this part of the project;[10]

– Semi-structured and open interviews with stakeholders in the food industry and experts.

The interviewees and stakeholders were selected to represent a cross section of the relevant stakeholders: SMEs, big companies and multinationals, companies from various product groups, from various areas in the EU and exporting to the EU. A relatively large section of the interview-

---

7 We use the cost of quality classification, given below, to categorise effects of new legal requirements on competitiveness. This cost-of-quality framework distinguishes internal failure costs, external failure costs (costs that are incurred after a product has been sold), appraisal costs and prevention costs (costs made to prevent bad quality to occur).

8 See www.food-law.nl.

9 Volume 1 (2006) issue 4, p. 247-248.

10 See annex E on the distribution of interviewees.

ees is from the Netherlands as this is the researchers' home base. However we ensured that there was a sufficiently diverse group from other countries to filter out the risk of national bias.

On 13 July 2006 an expert meeting was held at the Chamber of Commerce in Münster (Germany) organised in cooperation with this Chamber of Commerce and the IFAL® Institut für angewandtes Lebensmittel- und Futtermittelrecht, Produktentwicklung und Lebensmittelqualität. On 14 September 2006 an expert meeting was held at the office of FNLI in Rijswijk (NL) and on 15 September 2006 at the office of the European Commission in Brussels, in cooperation with CIAA. The expert meeting in Münster focussed on the legal part of the research, while the meetings in Rijswijk and Brussels addressed the entire project. A visit to the US took place between 12 and 22 October 2006. During this visit several experts, an official and food companies were interviewed. We are very grateful to all who have contributed to our research, see Annex H.

3.3 The food business' perception of the food regulatory framework in the EU

3.3.1 Perceptions of the EU food regulatory framework in general

The food regulatory framework in the EU is characterised by a restless nature. Between 1 January 1997 and 10 November 2006, the Official Journal published 1,359 measures addressing the food industry in whole or in part.[11] This amounts to an average of two to three publications each week.[12] These figures may represent the tip of the iceberg only. Eur-Lex, the regulatory database on the EU-website gives in its category 60 'Agri-foodstuffs' 56,811 entries.

On top of this innate restless nature, in response to the BSE crisis, the White Paper on Food Safety (2000) announced a fundamental restructuring of the system of food legislation and enforcement. An Action Plan consisting of 84 points was annexed to the White Paper. This overhaul started in earnest in 2002 with the publication of Regulation 178/2002 the so-called General Food Law.[13] For a general background on the history and system of food legislation in the EU[14] see Van der Meulen (2004) and Van der Meulen and Van der Velde (2006); and in particular on enforcement: Van der Meulen and Freriks (2006).

This section addresses the respondents' impressions of the impact of food legislation on:
– the European competitive field and institutional context;
– the stakeholder ('exchange') environment;
– the company level, in accordance with the costs and benefits approach we presented in the research framework.

Level playing field
Several interviewees pointed out that through harmonisation EU law provided a blessing that can hardly be overestimated. On the internal market of the 25 member states, a level playing

11 See the website of the University of Reading (www.foodlaw.rdg.ac.uk).
12 According to an overview published on the website of DG Sanco until 2006 95 legal texts have been published on BSE alone, excluding market regulations, financing decisions and rules with respect to cosmetic and medicinal products and medical devices. See: http://ec.europa.eu/food/food/biosafety/bse/chronological_list_en.pdf.
13 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ 1.2.2002 L 31/1.
14 Strictly speaking the term 'food law' would be appropriate as it includes case law and soft law like policy documents and administrative practice. The term has been defined in Article 3(1) GFL as follows: "'food law' means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, foodproducing animals." However we have been informed that in circles of the European Commission 'food law' is understood to refer to Regulation 178/2002 only, we opt for 'Food legislation' as second best to describe the subject of this report.

field has been achieved where the same legal conditions apply to all. It is perceived in particular in relation to the ten new member states that joined the EU on 1 May 2004.

In fact this level playing field goes beyond the borders of the EU-25. To a large extent EU food legislation applies in the European Economic Area (EEA) that includes the EFTA countries, Iceland, Liechtenstein, Norway and Switzerland.[15] Further neighbouring agricultural economies that depend on exports to the EU like Croatia and Serbia adapt their national legislation on food as far as possible to EU regulations and directives. A Serbian government official[16] pointed out that it is practically impossible to export to the EU if national legislation in the exporting country is not adapted to EU legislation.

Substandard competition

In its impact assessment of the hygiene package, the FSA touched upon another aspect of the level playing field. It expected an improvement of competition rather than adverse effects. The hygiene package might even drive out substandard competition from the EU market, since the same standards are applied to all or groups of businesses.

Uncertainty

The institutional context can increase agency costs: costs of gathering information by businesses (agents) to be able to comply and project investment decisions. 71.7% of the respondents totally agree with the question 'Your company is aware which European legislation applies to its activities' (table 3.1).

Table 3.1 Awareness of companies on European legislation a)

Valid	All companies		Companies > 250 employees	
	Frequency	Percentage	Frequency	Percentage
1 totally applicable	38	71.7	24	85.7
2	5	9.4	0	0
3	5	9.4	3	10.7
4	3	5.7	1	3.6
5	2	3.8	0	0
6	0	0	0	0
7 not applicable at all.	0	0	0	0
Total	53	100.0	28	100.0

a) Informedness measured on a 7 point scale; 1 (= totally applicable) to 7 (= not applicable at all).

Of the 28 respondents with more than 250 employees, 85.7% totally agrees with this statement. It appears that big businesses are well aware of EU legislation that applies to their line of business. SMEs sometimes express the feeling that some dark cloud is hanging over them. Compliance assistance can mitigate the cost businesses have to make and assist them in projecting organisational changes in order to come up to institutional demands. An interviewee related that inspectors often hide behind 'Brussels' blaming the EU legislature for unwelcome requirements instead of explaining the reason for certain legislation.[17]

15 European Free Trade Association; see: www.efta.int.

16 In an informal conversation not counted as interview in this research.

17 The interviews show a striking difference in the way food legislation is perceived as a factor influencing competitiveness. Managers in big companies do not seem to worry very much. Legislation is a requirement to be met. SMEs on the other hand either perceive legislation as an almost insurmountable obstacle, or they ignore it altogether. One of the managers of a big company who does not consider legislation as a major problem, did remark however: 'The most time and energy consuming part is to adapt packaging and labelling to the various international requirements.' Packaging law is outside the scope of this research.

In contrast to the respondents from industry, the experts regard access to EU food legislation as highly problematic. See paragraph 3.4.

Companies were asked: 'Do you think that in your company's activities on the EU market, EU legislation gives your company an advantage or a disadvantage over the following competitors'.

Table 3.2 Advantages of EU legislation over competitors a)

		Mean b)	Standard deviation
A.	Advantage towards big companies within EU	4,06	1,4
B.	Advantage towards small companies within EU	3,59	1,3
C.	Advantage towards new members of EU	3,22	1,4
D.	Advantage towards companies in central/west EU	3,85	1,3
E.	Advantage towards companies south EU	3,69	1,5
F.	Advantage towards northern companies	4,08	1,2
G.	Advantage towards companies from US	3,93	1,3
H.	Advantage towards third world companies	3,29	1,5

a) range of N:30-48; b) Score on a seven point scale: 1 = big advantage, 7 = big disadvantage.

Figure 3.2 Advantage of EU legislation over competitors. See Table 3.2 for the labels A-H of the type of competitors.

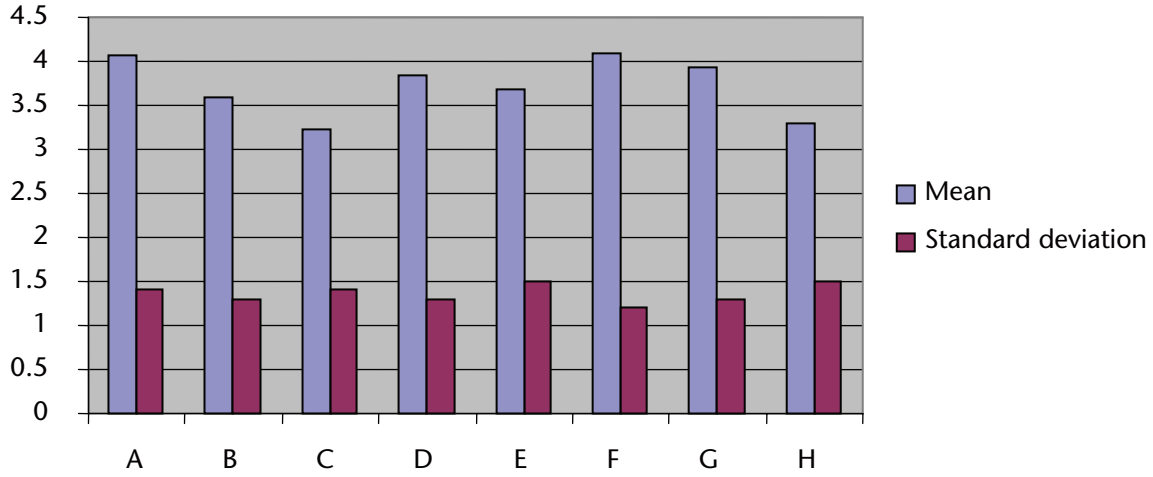


Figure 3.2 shows among others, that the respondents are neutral towards the influence of EU food legislation on the competition with US-based companies.

Relative influence

We now address the stakeholder relations impact of (changing) food legislation:
– a comparison of the impact of food legislation in combination with media attention on effective competition, profitability and quality;
– a comparison of the nuisance caused by food legislation to other branches of legislation.

The results indicate that:
– the respondents tend to the opinion that increased media attention to food topics is an important impulse to food quality;
– the nuisance that is felt from food legislation is comparable to other areas (like spatial, environmental, and fiscal issues).

The effects of extra media attention on quality, effective competition and the pressure on profitability are given below.

Table 3.3 Opinion of companies on the effects of media attention on quality, competition and profitability a)

	Extra quality	Effective competition	Pressure on profitability
1 totally applicable	30.4%	11.1%	7.1%
2	28.3%	35.6%	0%
3	15.2%	28.9%	28.6%
4	19.6%	22.2%	28.6%
5	0%	0%	9.5%
6	2.2%	0%	2.4%
7 not applicable at all	4.3%	2.2%	23.8%
Total	100%	100%	100%

a) Measured on a 7 point scale: 1 = totally applicable; 7 = not applicable at all. N = 42-46.

The impression of the respondents is that media attention enhances quality of food (mean = 2.54, SD = 1.6), leads to effective competition (mean = 2.73, SD = 1.2), and is relatively neutral towards profitability (mean is 4.36, SD = 1.8).

A comparison with other fields of legislation is given in table 3.4. The question was 'EU requirements on food cause more problems than'(legislative domain):

Table 3.4 Comparison of food legislation with other domains

Domain	Mean a)	Standard deviation
Tax	4.20	1.8
Social	4.20	1.7
Employment	4.15	1.7
Environment	4.15	1.7
Waste	3.73	1.5
Spatial	4.50	1.7

a) Score on a seven point scale: 1 = totally agree, 7 = do not agree at all. N = 42-46.

The empirical evidence shows that food legislation is not perceived as better or worse than legislation in other fields.

Stability

We asked to what extent the stability of the institutional context is perceived as preferable to the positive effects of a changing legal environment. The answers indicate that legal certainty is valued over the quality of the regulatory framework, although much weight is attached to this quality as well.

Table 3.5 Opinion of companies on the need to change food legislation

Food law should change the least possible	Frequency	Percentage
1 totally applicable	5	33.3
2	4	26.7
3	1	6.7
4	2	13.3
5	0	0
6	2	13.3
7 not applicable at all	1	6.7
total	15	100.0

The statement 'Food law should change the least possible' received an average score of 2.87 on a 1-7 scale (N=15, SD 2.066), which represents an average tendency towards agreement with the statement, but a big spread round the mean value. On the other hand, the question regarding improvements scored 2.60 (N=15). From these answers to the questionnaire and the interviews, it is clear that the restlessness of the regulatory framework is a burden to industry, although changes in a positive sense are welcome. One interviewee proposed that if the legislature aimed at fixing a specific date every year for the entry into force of new food legislation, the sector could adapt by concentrating their efforts on this date and then enjoy a period of stability and consolidation followed by a new effort at preparing for change.

3.3.2 EU compared to the US

To assess EU food legislation, a comparison was made with the system in the US. It has been suggested to the European Commission that the legal environment in the US might give the American food industry a competitive advantage over the EU food industry. Furthermore, the US is the largest export destination for the EU food industry. For these reasons, this research addresses the American approach as compared to the EU and in particular to the perception of the interviewees and experiences of companies active on both markets.

Legal culture in the US

From the European point of view, the legal situation in the US is characterised by a claim culture, while the regulatory system in the EU is perceived as over-cautious by the Americans.

At the expert meeting in Münster, it was claimed that the US system is more reactive, while the European system regulates in advance 'but by this very nature is innovation-unfriendly.' According to one interviewee insurer, the high rate of claims makes doing business in the US very risky. Only about one in four export insurers is willing to provide coverage for exports to the US or Canada. All else being the same, the premium for exports outside the EU is about double compared to exports within the EU. Coverage for US and Canada costs about six to eight times the premium for exports within the EU. The reason for this price difference is that liability costs are high in the US. Several factors contribute to explaining this situation, such as the system of punitive damages, lay juries, the political character of the juridical system etc. In about one in fifty cases, intentions to export to the world are abandoned due to these costs. In case of exports to the US or Canada, this is in about one in ten cases. It seems fair to conclude that the legal culture in the US forms a de facto barrier for the EU food industry to the American market.

Legal structure in the US

Food legislation in the US is hardly less complex than in the EU. A synopsis of US food legislation is published by the USDA.[18] Further details can be found on the FDA website.[19] Competences are divided between the federal and the state level. At federal level over ten agencies are involved (USDA 2001, Hammonds, 2004).

US food legislation is similar to EU food legislation in its focus on food safety and consumer protection. The regulatory instruments focus on pre-market approval of certain products, the properties of products, their handling and labelling, not unlike EU food legislation.

Some differences between EU and US food legislation

Two of the interviewees preferred the American system to the European system because of its clarity. They consider it to be substantially easier to know one's legal position in the US than in the EU. FBOs in the US are free to market food products that are generally recognised as safe (GRAS). The status of GRAS can be based on a history of safe use or scientific consensus. The FBO may submit its reasons to consider a food GRAS to the US Food and Drug Administration (FDA). For other foods, mainly covered by the concept of food additives, pre-market approval is re-

[18] The Food And Agricultural Import Regulations And Standards Report (FAIRS) United States of America, 2001 (http://www.fas.usda.gov/itp/ofsts/usa2.pdf).

[19] www.fda.gov.

quired. A specific procedure applies to dietary supplements containing new dietary ingredients. A striking feature of this procedure compared to the EU Novel foods regulation is a system of pre-market notification. The company wishing to market the new product must notify the FDA 75 days in advance. At the notification, proof of the safety of the product must be provided. FDA can use these 75 days to decide whether or not the proof provided is sufficient.

Food handling requirements largely rely on good manufacturing practices; however HACCP is being introduced in an ever increasing range of sectors. The US legislature feels less need to create safeguards like traceability. For the EU legislature, science is one factor among others. In its rhetoric the European legislature places emphasis on science partly as a means to compensate for the loss of credibility suffered by business and politics in the BSE crisis. However it never let go of the democratic notion that consumers' wishes are a value in itself.

Labelling requirements are comparable to the EU. The most important difference is that in the US, unlike the EU, nutrition labelling is mandatory.

Interviewees on US food law

Interviewees were asked whether they do business in the US and whether they consider the legal environment in the US preferable to the EU. It turned out that the majority of interviewees who do not do business in the US did not take a position on the comparison between the two systems. Of those respondents that do conduct business with the US (N =19), the vast majority does not prefer the US legal environment. For all respondents, this picture is confirmed (N=42)

Table 3.6 Opinions of companies on the preference of the US legal environment over that of the EU.

Valid	Companies with US experience		All respondents	
	frequency	percentage	frequency	percentage
No	10	52.6	17	40.5
Yes	4	21.1	4	9.5
Do not know	5	26.3	21	50.0
Total	19	100.0	42	100.0

Table 3.7 gives an overview of responses, distinguishing between Croatian companies and EU companies, and companies that do business with the US (yes) and those that do not do business with the US

Table 3.7 Opinions of EU and Croatian companies with or without experience in business with the US on the legal environment in the US compared to EU.

Experience in business US	Legal environment US more preferable				
	Location	no	yes	do not know	Total
no	Croatia	4		6	10
	EU	1		10	11
	total	5		16	21
yes	Croatia	4	3	1	8
	EU	6	1	4	11
	total	10	4	5	19

Croatian companies may not be not well informed about the US juridical climate: they seem unable to make a good comparison. However, for the EU companies the picture is confirmed. For example, looking at only the respondents with head office in Germany, the following data can be obtained.

Table 3.8 Opinion of German companies on the legal environment in the US being preferable to the EU Legal system

	Frequency	Percentage
No	4	44.4
Yes	0	0.0
Do not know	5	55.6
Total	9	100.0

Asked if they consider that EU food legislation gives them an advantage or a disadvantage over competitors from the US, the majority of respondents thought that the effect of EU food legislation in this respect was neutral. We asked 'Do you think that in exporting food products from your country to other countries outside the EU, EU legislation gives your company an advantage or a disadvantage over the following competitors (1 = big advantage; 7 = big disadvantage):

– bigger companies within the EU;

– smaller companies within the EU;

– companies from the US;

– companies from third world countries.

Table 3.9 Opinion of companies on the advantageous effects of EU legislation on the export to non EU countries compared to four types of competitors

	Big companies	Small companies	US companies	Third world companies
Number of respondents	35	36	29	31
Mean a)	3.77	3.61	3.79	3.45
Standard deviation	1.114	1.358	1.048	0.961

a) Score on a 7 point scale: 1 = big advantage, 7 = big disadvantage.

There is a slight tendency towards perceiving an advantage compared to all categories. Given the standard deviation of around 1 in all categories, the effect seems to be best qualified as neutral in all categories. Similar questions focusing on innovation and imports yield similar results.

3.3.3 Food safety and legislation

This part of the research deals with the external legal effects of EU food regulation. As proposed, external legal effects refer to the relationships with the stakeholder environment. The main stakeholder is the consumer: food safety is the main goal that provokes changes in the legal environment.

External legal effects incurred by the implementation of rules refer to the impact of these changes on the economic relationship with external stakeholders (like consumers: less sales, supplier: increased quality and information requirements). For example, GMO products can negatively influence the country's image on European markets (Knight et al, 2005).

General perception of food safety and its legislation
An overview of the response on question relation to food safety and legislation is given in table 3.10.

Table 3.10 Opinion of companies on the impact of food safety regulation and administrative burden.

		Number of respondents	Mean a)	Standard deviation
A	EU law can achieve a higher level of food safety	46	2.35	1.449
B	The administrative burdens are acceptable in the light of the results	44	3.27	1.531
C	Higher administrative burdens are acceptable if higher food safety is achieved	47	2.77	1.507
D	Lower food safety is acceptable if lower administrative burdens are achieved	47	5.66	1.619
E	The present level of food safety is not the result of EU law	45	3.73	1.959
F	Food safety law in the EU is good	45	2.67	1.279

a) Score on a 7 point scale: 1 = totally agree; 7 = do not agree at all.

Interviewees are quite satisfied with the current level of food safety that is achieved through legislation in the EU. They however tend to express that the safety level can be increased by EU legislation (mean = 2.35 on a 1-7 scale, N = 46, SD = 1.44). Although they express different opinions concerning the question whether EU legislation contributed significantly to this state of affairs, the interviewees tend towards the opinion that the administrative burdens incurred are warranted by the results (mean = 3.27, N=44). They further think that some increase in administrative burdens is acceptable if it leads to higher food safety (mean = 2.77, N = 47) while a decline in food safety is not acceptable to lower administrative burdens (mean = 5.66, N = 45). One interviewee elaborated that food safety is not purely a matter of legislation but of controls. According to this interviewee apart from the BSE crisis, there has not been a single food safety crisis in the EU that was attributable to a lack of legislation. It was mainly lack of compliance that escaped the attention of or was accepted by the authorities.

Safety versus sterility

Several interviewees considered the level of food safety to be too high. Surprisingly they do not defend this position from a compliance costs point of view, but from a public health point of view. They argue that the population in the EU is losing its natural resistance due to lack of exposure to pathogens. They also believe that the increase in allergy cases is attributable to an excessively hygienic lifestyle.

Limits to food safety

One interviewee strongly criticised EU food safety policy, the communication on food safety and the emphasis on the responsibility of business operators. According to this interviewee, the EU creates a false sense of security by overstating the current level of food safety. It is the paradox of the perfect systems that when things go wrong, they go badly wrong. The success of the efforts to regain consumer confidence leads to consumer carelessness.

External legal costs and benefits

The interviewees were asked to what extent the changing safety requirements by consumers influenced quality activities, competition and profitability (see table 3.11).

Table 3.11 Opinions of companies on the effects of safety requirements by consumers

	Number of respondents	Mean a)	Standard deviation
Safety wishes stimulate quality	45	2.53	1.120
Safety wishes are an effective base for competition	44	2.77	1.255
Safety wishes are a threat to profitability	44	4.25	1.767

a) Score on a 7 point scale: 1 = totally applicable; 7 = not applicable at all.

It seems that these wishes influence profitability in a neutral/negative way (mean = 4.25, SD = 1.767, N = 44), while effective competition is stimulated (mean = 2.77, SD = 1.3) as well as food quality (mean = 2.53, SD 1.1). Food legislation will affect the relative competitiveness of European countries in comparison with competitors outside the EU.

3.3.4 Concluding remarks

The analysis of the perception of the legal framework by the food companies shows that companies have a balanced view on EU food legislation. They see a number of benefits. First of all the food safety level is seen as satisfactory. That is also in the interest of business, as products perceived as less safe will be hard to sell. Also positive impacts on the competitive environment are recognised: the legal system creates a level playing field through harmonisation for all players, including those from abroad. It also provides companies with a positive reputation outside the EU. The EU system is also preferred over the US system.

However the interviewees report a number of remaining problems in harmonisation. Harmonisation is not fully achieved (e.g. differences in allowed use of pesticides), there are national derogations and interpretation of European law as well as enforcement differing between member states.

In the next sections we report on five issues that influence costs of the legal system for businesses as well as their innovativeness.

3.4 The quality of legislation

Internal and external legal effects (see the presented framework in figure 3.1) will only occur if the legal system is transparent and of high quality. Only then will negative responses (internal: e.g. penalties, shut-down of production facilities; external: e.g. negative publicity and recalls) be transformed into systems and managerial actions to comply (appraisal and prevention measures). The White Paper on Food Safety set out with clear ambitions with regard to legislation. 'There is a need to create a coherent and transparent set of food safety rules.' 'Individual legislation needs to be clear, simple and understandable for all operators to put into effect.'[20] To what extent does EU legislation meet the standard set down in the White Paper? This paragraph deals with this issue.

Structure

In time the legislative approaches to food have changed dramatically. In the first two decades after the Treaty of Rome, vertical directives were the instrument of choice. After the Cassis de Dijon case law, the emphasis shifted to horizontal directives. One interviewee commented that vertical legislation is often perceived by individual producers and producers' organisations as being more practical and more transparent than horizontal legislation. Vertical legislation is easier to defend for certain interest groups like particular sectors of industry. It has been remarked that vertical legislation favours small companies dealing with few products. They find all the applicable requirements in one text.

The transition to horizontal legislation has not been completed. For example companies will not find all labelling requirements in the horizontal Labelling directive. Besides this general codification of food labelling law, countless other provisions exist.[21] The new legislation on claims for example is laid down in a separate regulation. Many other texts that deal with specific subjects of food law, like legislation on beef, the Novel foods regulation and the GMO regulations, include labelling requirements as well. The burden to collect all relevant requirements is on industry. When the introduction of the General Food Law became a news item, several companies -

[20] White Paper on Food Safety, p. 22-23.

[21] The author of a book on food labelling told us that it concerns several dozens of provisions.

misled by this nickname - believed that the EU legislature had taken it upon itself to provide a systematic codification of food law. This was heralded as a major improvement. Disappointment soon followed.

Box 3.1 DG Sanco on codification of labelling law

18. **What is the most appropriate legislative instrument** to implement these laws more homogenously in the European market (Member States have regularly spoken in favour of a regulation instead of a directive) **and how should the labelling provisions be brought together?** It is absolutely true that labelling or labelling-related provisions are included in many pieces of legislation, but this is the consequence of the widely used rule of Lex generalis and Lex specialis. Common labelling requirements applicable to all foodstuffs are laid down in horizontal legislation (Directive 2000/13/EC and related texts), whilst specific provisions, because of specific needs to informing consumers, are included in vertical legislation, as a result of specific composition or quality standards to which they are closely linked. The same structure is used in Member States national legislation as well as in international standards of Codex Alimentarius (DG Sanco 2006, p. 5).

DG Sanco seems to consider it impossible even to codify all requirements on food labelling in one piece of legislation. DG Sanco's reasoning is misleading. The rule of lex generalis and lex specialis is a rule on conflict, not on legislative technique. At the heart of the matter is the choice that is or is not made. The question is who takes the burden to bring together the legislation: the legislature or the user? If the legislature so wishes, it is perfectly possible to bring together general and specific rules. Customs law provides an excellent example where the EU legislature undertook a major effort at codification.[22]

Impact of regulations on national legislation

After the White Paper on Food Safety, the EU legislature changed its legislative strategy again. Instead of directives, the legislature turned more and more to the use of regulations. In general, the advantage of regulations over directives is that they apply directly and uniformly in all the member states of the EU. However several EU regulations on food - primarily the General Food Law - address the national legislatures. This seems to create confusion. By general theory of European law, national legislatures may not transpose EU regulations into national legislation. How do national legislatures have to deal with explicit and implicit requirements in regulations to transpose?

At the expert meeting in Münster, it was further remarked that directing national legislation through regulations results in the national legislation becoming unreadable. It is thought that national legislatures may not quote from regulations and therefore have to refer their readers to the regulation if they use concepts from the regulation.[23] To understand the national text, the user must always have access to the European text as well.

Complexity of EU food legislation.

The White Paper on Food Safety was very explicit about the ambitions on accessibility of food legislation: 'legislation needs to be clear, simple and understandable for all operators to put into effect.' In contrast, many interviewees perceive food legislation as impenetrable. Indeed the new structure is sometimes rather complex. The hygiene package, the heart of food safety legislation, may serve as an example (box 3.2).

Box 3.2 Example the EU hygiene package

The White Paper on Food Safety envisaged one new comprehensive regulation recasting the existing legal requirements to introduce consistency and clarity throughout the food production chain.

Six years later, the Hygiene package consists of four regulations of the Council and of the Parliament and two directives of the Council and of the Parliament (Regulation 852/2004 on general food hygiene; Regulation 853/2004 on food of animal origin; Regulation 854/2004 on official controls of hygiene requirements; Regulation 183/2005 on feed hygiene; Directive 2002/99 on animal health requirements; Directive 2004/41 on transitory measures). These provisions elaborate on Regulation 178/2002 (the General Food Law), and Regulation 882/2004 on official controls.

---

22 Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code. In pharmaceuticals there exists: Directive 2001/83/EC on the Community code relating to medicinal products for human use.

23 This 'Zitierverbot' is deduced from case law such as ECJ 7.2.1972, case 39/72, Commission vs. Italy, ECR 1973, p. 101.

Implementing measures have been taken by the Commission in four further regulations (Regulation 2073/2005 on microbiological criteria; Regulation 2074/2005 on food chain information, testing methods, etc. Regulation 2075/2005 on Trichinella; Regulation 2076/2005 on transitional arrangements). Five guidance documents on the new hygiene legislation have been published by DG Sanco (Guidance document on the implementation of certain provisions of Regulation (EC) No 852/2004 On the hygiene of foodstuffs; Guidance document on the implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin; Guidance document on the implementation of procedures based on the HACCP principles; Guidance document on certain key questions related to import requirements and the new rules on food hygiene and on official food controls; General guidance on EU import and transit rules for live animals and animal products from third countries). The Standing Committee for the Food Chain and Animal Health issued a guidance document on the General Food Law.

The hygiene package is further supplemented by EU, national or industry hygiene codes.

The old system may have been complex, but is seems somewhat bold to label the new system 'simple' and 'transparent'.

Clarity

A major complaint with regard to the quality of EU food legislation is the ambiguity of texts. This problem is highlighted by the need to publish interpretive texts soon after the entry into force of the regulations. One major cause is haste; another is trying to achieve compromises.

Box 3.3 Example high pressure techniques

At the expert meeting at Münster, a food consultant revealed experiences with high pressure techniques. A technique has been developed to apply a pressure of 6000 atm or more to food products as a means of decontamination. In the US this technique is considered state of the art. In the EU uncertainty prevails on the question whether or not application of this technique falls within the ambit of the Novel foods regulation. If so, would food products treated with this technique be considered as 'substantially equivalent'? How is this to be judged? In relation to which products?

If the scope of the novel foods regulation had been clearer, this technique would probably be common now in the EU, either because FBOs are free to apply it, or because the novel foods procedure would have been undertaken.

In the US microbiologic reduction is the only criterion for approval.

Despite these facts, the respondents seem to be well aware of the present legislation that is applicable to them. The following table makes a distinction between Croatian companies and EU companies and gives the response on awareness of present and of future rules scale: 1 = totally applicable, 7 = not applicable at all).

Table 3.12 Opinion of companies in Croatia and EU on awareness of European legislation versus informedness on future new regulations

Our company is completely informed on future new regulations		Our company is aware which European legislation applies to its activities					
	location	1 totally applicable	2	3	4	5	Total
1. totally applicable	Croatia	5					5
	EU	15					15
	Total	20					20
2.	Croatia	1	3		0		4
	EU	2	0		1		3
	Total	3	3		1		7
3.	Croatia	3		0	0	0	3
	EU	2		2	1	1	6
	Total	5		2	1	1	9
4.	Croatia	0					0
	EU	1					1
	Total	1					1

Our company is completely informed on future new regulations	Our company is aware which European legislation applies to its activities					
	location	1 totally applicable	2	3	4	5	Total
5.	Croatia			1	1		2
	EU			0	0		0
	Total			1	1		2
7. not applicable at all	Croatia					1	1
	EU					0	0
	Total					1	1

In general, the companies seem to feel reasonably well informed. The correlation between informedness about the present and coming legislation is high and significant ($p<0.01$) within the sample (table 3.13), indicating that if informedness is high, predictive power of the companies is perceived as high also (and vice versa).

Table 3.13 Correlation (spearman's rho) between being aware of current and future legislation.

Rules known		Our company is aware which European legislation applies	Our company is completely informed on future new regulations
Our company is aware which European legislation applies	Correlation coefficient	1,000	.646 a)
	Sig. (2-tailed)		.00
	Number of respondents	53	48
Our company is completely informed on future new regulations	Correlation coefficient	.646 a)	1,000
	Sig. (2-tailed)	.000	.
	Number of respondents	48	49

a) Correlation is significant at the 0.01 level (2-tailed).

Superfluous legislation

Several interviewees complained about excessive legislation. The EU legislature is thought to overburden industry with unnecessary provisions. The interviewees provided very few examples of legislation they regard as expendable.[24] However, the Dutch enforcement authority responsible for food and product safety, VWA - Voedsel en Waren Autoriteit - issued a report[25] stating that it considers about 20% of the regulations within its competence of such limited value for the protection of consumers or animals that it will no longer enforce them. VWA calls upon the legislatures to reconsider the regulations concerned. See Annex I.

Lack of legislation

Only one interviewee pointed to a lack in legislation. He said that no legislation exists on decontamination. This interviewee suspects that the EU legislature fears that the system of HACCP will be undermined if the legislature acknowledged that contamination in food production is unavoidable and that measures must be taken to solve problems when they present themselves. According to this interviewee, this lack in legislation leads to a lack in legal certainty.

Risk management versus enforcement

One of the principles of EU food legislation is that it is based on risk analysis (art. 6 GFL). Risk analysis comprises risk assessment, risk communication and risk management (Article 3(10) GFL). At the expert meeting in Münster, it was pointed out that in practice risk management is taken

[24] The GMO regulations were explicitly mentioned. Most interviewees just indicated 'too much' legislation.

[25] Voedsel en Waren Autoriteit, Handhaven met verstand en gevoel, The Hague, June 2006, available at www.vwa.nl.

to mean either legislation or enforcement.[26] Specific administrative instruments for risk management are lacking. This emphasis on enforcement fails to appreciate that risk in food cannot always be traced back to unlawful behaviour of FBOs. In situations requiring immediate action like a food safety crisis, but also in situations that call for application of the precautionary principle because scientific doubts have arisen, enforcement instruments may not always be adequate. In the face of enforcement, FBOs enjoy the rights of defence enshrined among others in Article 6 of the European Convention on the Protection of Human Rights and Fundamental Freedoms. Decisive action requires cooperation in targeting the problem, not a struggle targeting people. The legislature should create fine tuned instruments for risk management, taking into account the requirements of dispossession law in so far as the seizure of food products is necessary.

National authorities

According to several interviewees, lack in understanding of EU (food) law by national authorities is a problem. For one of them, problems mainly concern veterinary requirements if (semi-finished) products including raw materials imported from third countries are exported within the EU. Too often national authorities in member states lack knowledge of applicable EU law and make unwarranted demands.

Accessibility of sources

The accessibility of EU food legislation was not a topic in the questionnaire used for this research as such, nevertheless the topic came up in some of the interviews. While in general the efforts made by the EU to make its policy and legislation accessible through its websites were lauded, some critical remarks were made as well. One consultant pointed out that unnecessary hurdles have been put in the way of users. More and more users have to register and acquire a password to get access to documentation and even to illustrations on the EU website. At the same time, urls and the structure of websites change on a regular basis.[27] The EU retains copyrights, in particular with a view to commercial use. This consultant is of the opinion that in a situation, where it has become so difficult for industry to find its own way to EU legislation - at least to those providing the service of making it accessible - all possible entrance should be given.

The biggest problem is that the Institutions have not agreed to a common standard. It is annoying that not all documents are given a date and a reference. Even if there is a reference, it is applied carelessly. Another odd feature is DG Sanco's practice of providing documents to industry associations but withholding them from the general public. Information that is available to some members of the public should be made available to all. This consultant made some specific suggestions for improvements. It would be very useful (as DG Sanco increasingly does) if it was indicated when documents were put on the Internet. FSA is a good example in this respect. It would be great if there was a database of old and new hyperlinks and deleted documents, so that one can retrace documents or at least know that there was no use continuing a search.

US Federal Register System

The problem of accessibility is not unique for the EU. In the US measures to address this problem have been integrated into the legislative process. Back in 1934, Congress recognised the need for a centralised system of communication and introduced the Federal Register Act, which became law on 26 July 1935.[28] The Act established a uniform system for handling agency regulations.

The Administrative Procedure Act, which became law on 11 June 1946,[29] added several important requirements to the Federal Register System. Against the background of the observations that surfaced in this review, two issues stand out: structured publication and continuous codifica-

[26] This opinion can also be found in the White Paper on Food Safety, no. 32.

[27] This very project illustrates the point. It is almost impossible to reach the background information on the EU website. Even landmark documents like the Medina Ortega Report concerning the BSE crisis and the Green Paper on the general principles of food law in the European Union, we could not find at the EU website.

[28] 44 U.S.C. Chapter 15.

[29] 5 U.S.C. 551 et seq.

tion could reduce the costs businesses have to make to come up to new legislation. Likewise, benefits from new legislation could be more easily harvested.[30]

Concluding remarks
European food legislation is complex. On some issues, like hygiene, several regulations, directives and interpretive documents are relevant. Regulations are sometimes used as Directives to address national legislators. Interpretative documents are often required to achieve clarity. Reductions in legislation are possible, as the Dutch food safety authority (VWA) concluded.

The burden of legislation could be reduced for businesses by codification, clarification and simplification. Guidelines for implementation of food regulations by member states could also help. Food safety inspectors should not only check the compliance but also explain legislation to businesses.

3.5 The changes in legislation

EU food legislation has consequences for the financial performance and competitive position of individual companies. In general, positive and negative aspects of food legislation compliance can be discerned. Positive impacts are the mitigation of failure costs (fewer products abandoned, fewer liability claims and the impact on the attractiveness of products for consumers), whereas negative impacts relate to the costs of compliance and extra administrative burdens that are imposed. Economically, improvements in the legislative requirements are only beneficial to businesses (and there will be a positive attitude towards fulfilling new directives and provisions) if benefits exceed costs.

Measuring costs and benefits of changing food legislation
To grasp the complexity of cost and benefit effects of new legislation, costs and benefits should be conceived as multidimensional concepts. There are methodological and practical limitations in assessing the costs and benefits of legislative efforts. This has brought us to measure costs and benefits using perception scales instead of absolute (money measures). Where we used money measures, the data were heavily influenced by the size of companies, while the spread of size appeared to be big (average size in personnel 6566, SD 34403!).

Before proceeding, we will give a general overview of the measurement limitations. Limitations are vested in, among others, the multidimensionality of cost concept(s)

Multidimensionality
The cost concept can be interpreted in different ways. Examples are integral costs, differential costs, opportunity costs, tacit cost effects (like social and environmental costs), variable and fixed, etc. Impact assessments try to categorise these costs in case new EU legislation is to be adopted by national authorities, as in the cases reposted in box 3.4.

Box 3.4 UK impact assessments

The implementation of Commission Directive 2004/14/EEC in England, Scotland, Wales and Northern Ireland, amending rules for regenerated cellulose film (RCF; i.e. food contact materials) provides a 'positive list' of substances that are allowed to use in the production of cellulose film. Negatively formulated, it prohibits the use of certain substances, which can lead to changes in the production process and product design. Whereas the environmental and social costs are expected to be negligible, given the fact that local authorities already have the duty to control for 'Materials and Articles in Contact with Food' (Regulations from 1987), the extra resource implications to the enforcement authorities were unlikely to be significant. However, administrative costs and investments for businesses are unlikely to be nil we guess.

[30] See: www.gpoaccess.gov/fr

The impact assessment of General Food Law Regulation EC/178/2002 mentions for the introduction of enforcement regulations benefits for diverse stakeholder groups, relating to more effective recalls and withdrawals and better traceability systems. Social and environmental costs were not anticipated. For the large food companies and retailers, the additional costs and competitive implications would be limited, since traceability systems have already been widely installed in the UK. A proposed regulatory requirement in accordance with the commitments in the White Paper on Food safety and Directive 2001/18/EC, a safety assessment, authorisation procedure and food labelling requirements were proposed to limit and make transparent the inclusion of GMOs. An impact assessment makes clear that a transparent and coherent regulatory system is created. It was expected that this would have a positive impact on competition, since business with lower standards with respect to food safety, environmental care and human health otherwise have an unfair advantage over those companies that are strict with respect to creating transparency and adjust their business processes.

Further problems in assessing costs and benefits are: setting borders to the cost concept (indicating what cost categories should be measured), (2) homogenising the methodology of measuring costs and benefits is another, (3) a-causality, occurrence of negative costs, opportunity costs and accounting diversity is yet another.

A-causality

As an effect of food legislation often the costs that have to be made are carried by one supply chain member, whereas the benefits are collected by another. For example, in the Finnish Salmonella Control Programme, necessary because of the Zoonoosis Directive 92/117/EEC (1992), the surveillance and control measures focus mainly at the level of primary production, whereas the benefits are harvested at the last stage of the chain, the consumer (Maijala et al., 2005). A Dutch study on campylobacter (Havelaar et al., 2005) showed similar effects. The fact that costs can occur in one stage of the supply chain and benefits can be harvested in another makes it difficult to assess the net effect of new requirements.

Negative costs (benefits)

Some legal requirements not only impose burdens on the companies in a certain country, but also cause benefits, like extra sales due to better labelling and informedness of consumers. Should these extra benefits be treated as a 'negative' cost factor in assigning the impact of implementation of EU directives in national legislation? More and more, consumers are put central in the discussion about the design of food supply chains (see for example: Dagevos, 2005), the costs being borne by the businesses and the benefits being harvested at the end of the supply chain. The companies can only earn back their costs by means of non-market (subsidies) and market (price) incentives. However, according to Gellynck et al. (2006), the effect of information about meat safety on consumer trust through labelling, traceability and QA systems is only limited. The willingness-to-pay should be considered in conjunction with the isolation paradox (Randall, 1999 referred to in: Maijala et al. (2005)). For a single company, taking measures is difficult and expensive if the other companies in the supply chain do not share the goal (Maijala, 2005).

Benefits can be divided into direct effects to sales and lower production costs and indirect effects on the image of companies (and through a better image and effect on the value of businesses and supply chains). The direct effects on sales (turnover) will only occur if the transparency of the system allows consumers to assess the improved quality/hygiene of procurement and if consumers appreciate the improvements by either buying more and/or at higher prices. Labelling can improve the transparency of the system and thus have a positive effect on consumer preferences and demand (see in this respect: Van Rijswijk et al. (2006)).

Benefits can be created by reduced production costs. In general, managerial priorities show that immediate costs and benefits impact managerial behaviour more than long-term effects. Arihara (2006) states that novel functional meat products are not easily marketed, since these products are unconventional and there is a negative image of meat and meat products, which are perceived as bad for health (perceived high fat level and cancer-promoting). The author concludes that there is an urgent need to provide information on the physiological value of meat and functional meat products. With respect to soybean consumption, research by Schyver and Smith (2005) showed that despite the positive health consequences of soybean consumption, many consumers were unaware of them and a negative image was associated with the product (supposed cancer effect).

Opportunity costs
As already stated, some legislation will not only create additional costs, but also cause reduced turnover (for example products that are withdrawn following new legislation). Should reduced benefits be considered as costs? The administrative burden discussion in the Netherlands has excluded these effects from the administrative cost concept. In policy discussion supported by this study, given the fact that this effect can influence the competitive position of individual businesses and sectors on a national and international basis (reduced exports), they should be taken into account.

Accounting diversity
Accounting diversity refers to the fact that accounting principles for the assessment of costs and benefits are different between EU countries. So even if we can categorise costs and benefits of new legislation, the national effects can be measured in different ways, depending on the specific principles used. One example is the measurement of the administrative burden as a consequence of a (change of) legal requirement. Administrative burdens are defined by authors and legal authorities in different ways. Administrative burdens are measured by the Ministry of Financial Affairs of the Netherlands by means of a 'standard cost model' (Meten is Weten, Ministry of Financial Affairs, The Hague). Administrative loads are defined as the costs that are made to comply with the information requirements as a result of rules and laws of government (based on a method developed by the Dutch Institute for SMEs (Instituut Midden- en Kleinbedrijf). A new policy to reduce administrative loads for private enterprise by 25% in 2007 in grants advantages in sectors and in general has been installed in the Netherlands (see in this respect: Suyver and Tom, 2004: 4-5).

The conclusion that can be drawn from this section is that (1) measuring costs in an 'objective' way is not easily performed, and (2) costs are strongly connected with the benefits that are caused at the same time. For example, Bata, et al. (2006) measure the costs of HACCP adoption by distinguishing between costs of development, installation, certification and operational maintenance. Another example is the positive association that was reported between the level of HACCP implementation and exports to US, Japan, Korea etc (43% of sales of companies with a fully implemented system were exports, see Maldonado et al., 2005).

Internal legal costs
Internal legal costs are the internal negative (company level) effects of non-compliance to food safety requirements. Non-compliance can mean that, for example, foodstuffs are not marketed, personnel suffer health problems or that lack of food safety causes social and environmental problems which intrude on the 'licence to produce'. There is a complementary 'other side of the coin': compliance can positively influence company level gains. Drivers for internal costs and benefits mentioned here, are:
– the organisation's innovation capabilities;
– the capability to export;
– the capability to specialise.

Cost estimates
As explained above, it is hard to measure the different type of costs (monitoring costs, information costs opportunity costs) of food legislation for businesses. It is therefore not surprising that not many research studies are available. In this study we focussed on perceptions, but we were unable to identify (net) costs either.

In the Netherlands, the Ministry of Public Health (Bex and Duits, 2006) published a study on the costs of food legislation. This was estimated at € 939 million per year, of which €404 million was the result of the national implementation of European laws. Important cost drivers were Hygiene and Labelling. A study by the UK FSA (see box 3.4) on the impact of the General Food Law concluded that 'relevant control systems are in place' in British companies. Costs for Hygiene and HACCP were estimated at £96.1 million per year. A study on HACCP compliance costs in dairy and meat businesses in Italy, the UK and the Netherlands (Romano, 2005), estimated them at 0.7 to 3% of turnover. The study concluded that 'costs are justified, there are benefits'.

A study in Danish food businesses (Baker, 2006) looked at differences between businesses. This study concluded that winners and losers depend on the quality of the management of businesses, not so much on the type of legislation. This is in line with many studies in primary agriculture that conclude that management levels differ, especially in SMEs, and are important for the long term viability of the company (Poppe and van Meijl, 2006). Companies with a high level of management have lower compliance costs and focus on opportunities and growth. Others have more problems and are more often dependent on government support.

Concluding remarks

Legislation changes from time to time. EU Food legislation is characterised by a continuous flow of updates and new regulations. As disclosure of legislation is not structured, this creates additional problems. The Official Journal is chronological, consolidation and codification are an exception and the EU website is not official. The connection between Regulations and national legislation is problematic.

Interviews suggest that the bigger food companies outsource the burden of staying informed or incorporate the activity of keeping informed fairly easily in normal management practices of specialised staff. This makes it difficult to measure costs. Small and medium-sized enterprises (SMEs) are not able to solve the problem that easily. They have a less formalised management style. The size-effect is however not confirmed by Baker (2006) nor by our own questionnaire.

To cope with the changes in legislation a number of solutions are possible. One solution is the introduction of a regulatory rhythm. The US system of continuous codification and structured disclosure could be copied as a best practice. Compliance assistance (see also previous section) and more self-regulation (see section 3.7) also contribute to alleviating the problems of changing legislation.

3.6 Innovation and pre-market approval

The ability to innovate is an important aspect of the competitiveness of the EU food industry. In innovation studies, a distinction is made between different forms of innovation (Jongen and Meulenberg, 2005; see also CIAA 2005). In the case of the application of known technologies, we talk about product improvement or range extension. The general requirements on safety and the use of ingredients apply. Labelling requirements may present a bottleneck. The second is bringing known products to new markets. In our research this would mean exporting from the EU or importing into the EU. If new technologies are applied, we talk about product development.

It can be seen as an unwritten principle of EU legislation that FBOs are free to bring food products to the market unless specific provisions decree otherwise. FBOs may apply new recipes, new ways of combining, new ways of preparing and new ways of presenting their products. Exceptions to this principle are addressed below.

As far as legislation is concerned, the general requirements apply to safety, including traceability and consumer information in particular through labelling.

The question is, whether EU legislation hampers innovation activities and what special legislative activities/factors have such an influence (see table 3.14). We asked respondents to reply on a 7 point scale (1=totally applicable, 7 = not applicable at all) to the question: 'Our company feels restricted in innovation by (obstruction)'. (N=36-43). The table and annexing figure shows that for the sample, 'Novel Food requirements' are most restrictive for innovation, although the score (4.19) is almost in the middle of the scale from 1-7. The relatively high SD indicates that there are strong differences between the respondents.

Box 3.5 Fraunhofer study

A groundbreaking project on the impact of the regulatory framework on innovation was carried out on behalf of the European Commission (DG Enterprise) by the Fraunhofer Institute for Systems and Innovation Research. The final report was issued in 2004 (Fraunhofer 2004). It was based on several case studies one of which focused on the EU food industry (Menrad 2003). The current study focuses on EU food legislation which by the token of its aim to assure a high level of human life and health and protection of consumers' interest (Art. 5(1) GFL) is mainly - in the wording of Fraunhofer - 'social regulation' with a touch of 'administrative regulation' in particular as far as it is concerned with the free movement of goods within the EU (Art. 5(2) GFL). Fraunhofer is very critical in its assessment of EU food legislation: 'Unclear competences and regulations or very restrictive market approval procedures impede new products or even the establishment of new markets' (Fraunhofer 2004). This conclusion is based on three case studies: Functional Food, GMOs and organic food products. In the interim report on the EU food sector it is concluded among other things that: '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'.

Table 3.14 Restriction for innovation according to companies

	Mean a)	Standard deviation
General food safety requirements	4.88	2.1
HACCP	5.07	2.1
Traceability	4.72	2.1
System (ISO etc.)	5.19	2.0
Administrative requirements	5.22	1.8
Allergy	4.62	2.3
GMO	4.19	2.3
Hygiene codes	5.02	2.1
Novel Foods requirements	4.19	2.1

a) Score on a 7 point scale (1= totally applicable; 7= not applicable at all).

Food product development

Over the last ten years the number of exceptions to the freedom to market food products has rapidly increased. Products that are not normally consumed as a food or that do not have a history of safe use in the EU are subject to pre-market approval requirements.[31] On top of this, pre-market approval requirements are currently being introduced for claims made on functional foods.

Additives

The use of additives[32] (like anti-oxidants, preservatives, colours etc.) is forbidden unless explicitly authorised. Authorisation takes place in so-called positive lists. These lists are annexes to the applicable directives, stating which additives may be used in which foods. One interviewee pointed out that additives relate to the concept of innovation in different ways. On the one hand they provide opportunities for innovation. The more additives there are available, the more new compositions and recipes are possible. According to this interviewee, additives often contribute to food safety. This is particularly the case with preservatives. On the other hand additives receive a reluctant reception from many consumers who perceive them as artificial. In this context another interviewee described a trend of 'clean labelling'. This is a policy followed by an increasing number of producers to use as little food components as possible to avoid mentioning ingredients on the label that might deter certain consumers. In particular 'unnatural' ingredients and ingredients with chemically sounding names are avoided.

31 And also to novel food contact materials, see Regulation 1935/2004.

32 Framework Directive 89/107 defines the concept of additive in Article 2 as: any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods.

Pre-market approval of new additives is altogether a different matter. Only the biggest companies stand a chance of successfully concluding a procedure. Very recently the Commission introduced a proposal for a new regulation on additives. The interviewee who addressed this proposal welcomed the attempt to reform the procedure to become less political and more objective.[33] One interviewee drew attention to the system of E-numbers. This interviewee considered this system to be a total failure. Consumers do not understand the information contained in these numbers. They perceive them as something to avoid. For this particular interviewee, this provided an advantage in competition because he produces alternatives (with enzymes) to which no E-numbers apply.

Interviewees pointed out that in practice it is very difficult to convince the European Commission to rely on existing safety assessment or similar evaluation or even to take it into account. They are said not to be interested in judgments by the FDA or JECFA. JECFA is the joint FAO/WHO committee on food additives. It is not just an outside player. The EU is represented in it. This approach of the Commission is not very helpful on a global market. Countries in Asia and South America are far ahead of the EU as far as recognition of evaluations is concerned. An interviewee strongly recommended that in future the Commission should take external evaluation into account when deciding on market approval for the EU (see also CIAA, 2005, p. 11). At the Rijswijk expert meeting and to some extent also at the Brussels expert meeting, this suggestion was endorsed.

Novel foods

Most interviewees avoided initiatives that might bring them within the ambit of the Novel foods regulation (Regulation 258/97). They agree that this road is closed but for the biggest players (because of the costs of scientific substantiation, time involved (three years on average)[34] in the procedure and the unpredictability of its outcome).

As discussed in the section on the clarity of legislation, the ambit of the novel foods regulation is unclear for interviewees and experts. They have difficulty distinguishing cases to which the procedure applies from those to which it does not apply.

One interviewee advised to take a history of safe use of a food outside the EU into consideration in approving novel foods.

Genetically modified foods

Several interviewees were careful to avoid GMOs because of consumer preferences. It is business policy and in particular its understanding of consumer preferences that impedes innovations through genetic engineering of food products in the EU, rather than the complex nature of the regulatory system. However one interviewee took a radically different stance. This interviewee from retail indicated that they had 72 GM products on their shelves. Sales matched conventional products. However, suppliers feared that their names would be associated with genetic modification and insisted on supplying from alternative sources. For this reason, only three of the original 72 products remain today.

---

[33] On 28 July 2006 the Commission introduced four proposals: Proposal for a Regulation of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings, COM(2006) 423 final, 2006/0143 (COD); Proposal for a Regulation of the European Parliament and of the Council on food additives, COM(2006) 428 final, 2006/0145 (COD); Proposal for a Regulation of the European Parliament and of the Council on food enzymes COM(2006) 425 final, 2006/0144 (COD); Proposal for a Regulation of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods, COM(2006) 427 final, 2006/0147 (COD). In conformity with the new policy on legislation, impact assessments of these proposals have been made. See: http://ec.europa.eu/food/food/chemicalsafety/additives/prop_leg_en.htm.

[34] DG Sanco published a list on its website of applications that have been received under the novel foods regulation. Four applications have been refused. The decision was reached between six months and 3 years after the application. Twenty-two authorisations were granted. The time involved varied between nine months and eight years. The average was a little under three years. Nine applications were withdrawn after three years in average. Twenty-six applications were pending, the longest for six and a half years.

Functional foods and claims
Foods - as opposed to pharmaceuticals - that are brought to the market under the claim that their consumption has a specific beneficial effect on certain health factors or bodily functions are also known as functional foods. There is no specific regulatory framework for functional foods. They have to comply with general food safety requirements. If they are new, they have to go through the pre-market approval procedure. Otherwise the general rule of free marketability applies. With regard to the claim however, coming legislation requires prior approval. Most interviewees that addressed the issue of claims shared the view that the requirements that have to be met under the proposed Health claims regulation are too high.

Pre-market approval
Most interviewees agreed that the pre-market approval procedures for additives, novel foods, GMOs and (health) claims are beyond reach for the vast majority of food businesses in the EU. Legislation reserves this type of innovation to the happy few. But even for them, life is not easy. Each pre-market approval requirement has its own procedure. Harmonisation is limited. If you choose the wrong procedure, you cannot simply switch, but have to start all over again.

No help from the authorities can be expected in finding the right procedure or negotiating it successfully. Interviewees worry whether the authorities will meet their deadlines. One of them provided an example of a procedure that took fourteen years to complete. One of the problems perceived by interviewees is uncertainty on the range of pre-market approval schemes. Does the application of a certain preparation technique bring the food within the ambit of the Novel foods regulation? Does this application of a genetically modified organism in processing bring the food within the ambit of GM legislation? Is this information concerning the product a claim under the Claims regulation? Etc.

Interviewees advise devising a simple procedure to answer preliminary questions. In particular the decision that a certain procedure does not apply (negative clearance) can be most helpful to open up to innovation. DG competition has developed an informal form, the so-called comfort letter, in which the Commission gives its interpretation on the legal situation. Similar practices would be most welcome in food legislation.

Statistics
Since innovation is a driving force behind competition, the respondents were asked about the extent to which European food legislation favours or hampers innovation in comparison with major competitors. Excluding Croatia (that serves as a mirror/benchmark for the other organisations included in the questionnaire) and excluding those companies for which the questions are not relevant, the results are given in table 3.15 (1 = big advantage; 7 = big disadvantage; range of N = 31-42).

Table 3.15 Opinions of companies on the effects of EU legislation on innovation compared to four types of competitors

	Big companies EU	Small companies EU	US companies	Third world companies
Number of respondents	41	42	33	31
Mean a)	4.20	3.71	4.30	3.52
Standard deviation	1.327	1.019	1.287	1.180

a) Score on a 7 point scale: 1 = big advantage; 7 = big disadvantage.

In general, only the position towards third world companies seems to deviate from the neutral (4) position; no special advantages and disadvantages can be discerned for the other categories. This picture is confirmed if we include Croatian companies (N=7); also in that case the response tends to neutral, with a slight advantage towards third world companies.

Capability to export and import

One of the interviewees, a FBO active in flavourings, pointed out that it is very difficult to import from the US. Imports from the US are severely hampered by EU requirements. In particular products of animal origin remain in the customs warehouses for a long time. EU authorities are suspicious of American products among other things because American legislation is more open to gene technology and less strict in traceability. Everything is checked before a consignment is cleared.

Box 3.6: Respondents on imports

Answers to the question whether interviewees feel advantaged or disadvantaged by EU legislation in importing to the EU are mainly neutral. They indicate slight but not significant advantages for small companies in the EU and companies in developing countries and disadvantages for big companies in the EU and companies from the US.

According to another interviewee, hygiene requirements in the US are similar to the EU, but if a specific factory has not been approved for export to the EU, it is impossible to obtain products from the factory concerned. 'We have to find alternatives or give up a certain line of production'. This remark shows that approval from exporters is not only in the interest of the exporter concerned, but also in the interest of the customer in the EU. Some importers would welcome a structure in which they could acquire clearance for the products they import without depending on the exporter.

The hypothesis is that high standards on the home market give the exporting company an advantage as 'made in EU' becomes a hallmark of safety and quality. One of the interviewees explicitly subscribed to this hypothesis, adding that being used to high standards helps to adapt to foreign standards.

As we have seen above, the high liability risks on the US market prevent some exporters from the EU doing business in the US. This also illustrates that companies which are established on markets with high standards may experience a competitive advantage over companies established on a market with lower standards, at least as far as competition on the same market is concerned.

Competing with third countries on EU market

Interestingly, a large exporter from Croatia considers the overhaul of EU food legislation an advantage in competing on the EU market. Normally, this FBO said, when you enter a new market you have a disadvantage compared to companies that are already on the market because you have to adapt to a new environment, while your competitors are accustomed to the situation. Currently it is easier to penetrate the EU market because established competitors also have to adapt to a new situation and feel too uncertain to respond quickly to the new competitor. This company feels slightly advantaged by EU food legislation compared to companies from the EU. Most important however, is not the legal system but the termination of financial barriers to trade.

At the expert meeting in Münster, it was pointed out that EU companies are disadvantaged if laxer standards are applied to exporting FBOs in third countries than to companies on the home market. An example was given from beef and cattle imports. One of the experts was in contact with integrated animal production businesses in a third country producing for export to EU. In situ they prepare animal material for feed. It is fed to animals that are exported to EU. Thus meat comes to the EU market from animals that are fed in a way that is not acceptable in the EU. By EU standards that should be considered as a BSE hazard and furthermore it distorts competition. According to this expert, the producers say it would be easy not to use this feed for animals exported to the EU, but so far EU inspectors have not required them to do so.

At the expert meetings in Rijswijk and Brussels it was pointed out that third countries discuss with the European Commission the conditions for their industry to export to the EU. Negotiations regarding export from the EU on the other hand are undertaken by individual member states. Consequently the Commission's bargaining power helps competition from third countries enter

the EU market but does not help businesses in the EU access third country markets. As the Commission's bargaining power is greater than that of the member states, this situation disadvantages EU companies compared to competing companies from the US or Japan.

Furthermore, for companies operating in more than one member state, the impractical situation occurs that it can export products from some member states but not from others.

The advice to the European Commission is to take the interests of the European food sector more into account when negotiating import and export conditions.

There appears to be a wide variation in the perception of the impact of food legislation on activities, so no definite conclusions can be drawn on the basis of the data we collected. Data on the relative effects of food legislation on activities of companies in comparison with American companies show a stronger bias towards 'relative advantage'. This can be explained by the fact that strict European Food Legislation negatively influences the relative competitive position of US companies. This interpretation would be in line with the perception of exporters in the US. They feel very much restricted by EU food legislation, to the point where they wonder if the EU is deliberately erecting barriers to trade. Requirements for beef and cattle change so often that exporters wonder if this is done to keep them off the market: first hormones, then traceability and the latest is animal welfare. Soy producers consider it almost impossible to export to the EU due to GMO legislation. For some relatively small producers, however, a niche market is emerging for non GM soy. Demand from the EU and Japan may yield prices that make up for additional costs and loss in quality.[35]

Specialisation: the space for traditional production

99% of the food businesses in the EU are small and medium-sized enterprises. Many of these produce traditional products, applying traditional production methods. Diversity in ways of producing is important for the vitality and versatility of the economy.[36] It provides the backbone for decisive reaction in the face of unexpected developments. Not unlike evolution in nature, (bio)diversity is also a source for innovation. A similar opinion has been voiced by CIAA (2005). One interviewee indicated that small enterprises can respond faster than bigger companies. They can respond spontaneously and have a product the next day. According to this interviewee the biggest hurdle is the labelling requirements.

Small-scale producers of traditional regional products perceive hygiene legislation as by far the biggest threat to their way of doing business. Traditional production sometimes depends on national derogations from hygiene requirements. For example, Italian legislation[37] states that the ban on selling food products which do not comply with EU hygiene legislation does not apply to direct sales by producers or producers' organisations of typical regional products to consumers within the region concerned. It is questionable if at the time of issuing, a sufficient basis in EU law was available for this approach. The new Hygiene regulation 852/2004 remedies this but only with regard to primary products.[38] Some national derogations from the hygiene requirements are possible with the aim of enabling the continued use of traditional methods, at any of the stages of production, processing or distribution of food.[39]

The implied notion that the safety of traditional production methods, like the safety of food products, cannot only be based on science but also on a history of safe use was also expressed by one of the interviewees who stated that the know how of producers should not be underes-

35 Soy is very sensitive to moisture. The right moisture level is usually achieved by blending. This technique cannot be applied in case segregation (identity preservation) is required to comply with EU non-GM standards.

36 In the opinion of the EESC, small and artisanal FBOs are of strategic importance in connection with quality policy as they are the very businesses which can help to promote diversity. Opinion of the European Economic and Social Committee on 'Hygiene rules and artisanal food processors' (2006/C 65/25), OJ 17.3.2006, C 65/141, nr. 3.8.

37 Legge 21 dicembre 1999, n. 526, pubblicata nella Gazetta Ufficiale n. 13 del 18 gennaio 2000 Supplemento Ordinario n. 15 (Art. 10(8)).

38 Article 1(2)(c) Regulation 852/2004.

39 Article 13 (4)(a)(i) Regulation 852/2004.

timated. Often they have a professional sense based on experience even if they cannot scientifically explain why a certain approach is safe. Science should not approach this kind of know how scornfully, but should take inspiration from it for further investigation. As an example, this interviewee indicated that from an HACCP point of view, the use of wood as food contact material is often shunned. Recent research however indicates that it has hitherto unknown pathogen reducing properties.

Protected indications
Companies that lack the financial resources to distinguish themselves through investing in trademarks or patents can profit collectively from the possibility to use protected designations of origin and protected geographical indications that exist for agro-food products that comply with certain requirements (Regulation 510/2006). A new regulation adds to this range a protected designation for traditional products (Regulation 509/2006). Member states can support their home businesses to take advantage of these possibilities.

Concluding remarks
The majority of the respondents and interviewees refrained from innovation that requires premarket approval (new additives, novel food, GM foods, health claims). Four reasons are cited: uncertainty in applicability of the approval process, uncertainty in outcome of the approval process, costs and time (for novel foods almost 3 years in average). These are therefore processes for the happy few.

Innovation could be supported by further harmonisation. This includes parallel procedures for different types of pre-market approval, and recognition of judgements of FDA and JECFA. Preliminary procedures, negative clearance and compliance assistance could also help. Fatal deadlines for authorities (surpassing a deadline means automatic permission) could speed up the approval process.[40]

3.7 Overdose of control

Appraisal: 'operating' the food safety assurance systems
Implementing food safety requirements creates operational costs. The administrative expenses are the most prominent. A question was asked whether the administrative loads are justified by the results of food legislation renewal. The respondents (including Croatia, N=47) scored 2.77 on a 1-7 point scale (SD 1.507, 1 meaning full acceptance, 7 not accepted at all). The perception depends on the administrative burden that is already experienced. Excluding Croatia, the score shows a lower level of acceptance of the increase of administrative burdens. Table 3.17 shows, that if we exclude companies with a domicile in Croatia, the answers are less promising with respect to the administrative burden.

Table 3.16 Opinions of companies on the acceptability of administrative burden

	Number of respondents	Mean a)	Standard deviation
The administrative loads are acceptable in the light of the results	44	3.27	1.531
Higher administrative loads are acceptable if higher food safety is achieved	47	2.77	1.507
Lower food safety is acceptable if lower administrative loads are achieved	47	5.66	1.619

Score on a 7 point scale: 1 = totally agree; 7 = do not agree at al. N=47.

[40] For examples see the last paragraph of this chapter.

Table 3.17 Opinions of European companies on the acceptability of administrative burden

	Number of respondents	Mean a)	Standard deviation
The administrative loads are acceptable in the light of the results	17	3.41	1.326
Higher administrative loads are acceptable if higher food safety is achieved	19	3.37	1.383
Lower food safety is acceptable if lower administrative loads are achieved	19	4.74	1.910

Score on a 7 point scale: 1 = totally agree; 7 = do not agree at al. N=47.

One interviewee indicated that the burden of implementing new legislation would be alleviated if a fixed date could be chosen each year (or better still every second year) as the end date of transitional periods of new legislation. In this way companies could concentrate their efforts to adapt to new legislation and then have the opportunity to consolidate and fine tune before a new round started. The Italian system for traditional products mentioned above provides an example of such a regulatory rhythm in practice.

3.7.2 The role of self-regulation

Prevention costs are costs which are made to prevent a-conformity with legal requirements. During 1999-2003, the US Food and Drug Administration reported a total of 1307 processed food product recalls (Kumar and Budin, 2006). The authors conclude that preventive measures (like HACCP and RFID) can reduce product recalls.

In this context self-regulation comes to bear. The most important legal instruments available for self-regulation are contract law and association law. On the basis of agreements based on the former and membership obligations in articles of association based on the latter, elaborate constructions can be erected. They are made visible through certification. The certificate is the proof to customers and consumers but also to public authorities that the agreed standard has been met. Loss of certification is the ultimate sanction on underperformance.

Food chain integration

Hypothesis has it that the increase in food safety requirements leads to an increase in food chain integration, i.e. vertical cooperation within the food chain. The underlying thought is that where retailers and brand holders are held responsible for the safety they provide consumers, they will want to control their inputs through contractual arrangements structured in quality assurance systems and enforced through third party audits (see for example Loader and Hobbs, 1999). Food chain integration often leads to a concentration of power at the end of the chain. This in turn may call for the creation of countervailing powers earlier in the chain through horizontal cooperation between small-scale producers. Most interviews confirmed this image both with regard to increased cooperation and with regard to power accumulation at the end of the chain.

Motives for self regulation

Motives for self-regulation are manifold. It may be used as a tool to comply with public law requirements or to deal with shortcomings in the regulatory system. In this context it may be used as a way to demonstrate that requirements have been met and that inspections need not have high priority.

Where a public law system is absent, self-regulation may be used to avoid situations that might necessitate the legislature taking action in a direction less favourable to industry. It may also serve as an instrument to deal with differences in legal requirements from various countries that apply to links in international chains. Importers may for example use private law arrangements to ensure that products comply with EU requirements although they are produced under a different public law regime. Companies may even apply it to uphold requirements that in public

law would be considered barriers to trade that have to be removed as a consequence of WTO agreements. In this context one can think of non-trade concerns in the context of sustainability and animal welfare (Freriks forthcoming).

An expert at the expert meeting in Münster was of the opinion that the legislature was outsourcing its work; not by strait forward deregulation or privatisation, but by default. This expert considers the quality of EU legislation to be so poor that industry has no alternative but to re-regulate.

Last but not least, public law requirements set the minimum standard that applies to all on the market. Private law standards may aim at higher levels to distinguish products in the eyes of consumers.

Quality assurance systems

Elaborate self-regulatory schemes have been laid down in quality assurance systems developed by retail chains in the UK (BRC) and continental Europe (EurepGAP). As a result, the data show that investments in BRC, ISO and HACCP are quite common among the respondents (table 3.18). Of the 48 respondents who answered the question whether investments are made in HACCP systems, 40 totally agreed (score 1); 3 scored 2; and 3 scored 3 (mean score 1.44).

Table 3.18 Extent to which companies have invested in HACCP

Valid	Frequency	Percentage
1 totally applicable	40	83.3
2	3	6.3
3	3	6.3
4	0	0
5	0	0
6	0	0
7 not applicable at all	2	4.2
Total	48	100.0

Table 3.19 Opinion of companies on the restrictive effects of HACCP on innovation

Valid	Frequency	Percentage
1 totally applicable	5	11.9
2	1	2.4
3	4	9.5
4	7	16.7
5	2	4.8
6	5	11.9
7 not applicable at all	18	42.9
Total	42	100.0

HACCP requirements do not seem to restrict innovation on average (table 3.19), but there is a wide spread in opinions (mean score 5.07, SD = 2.146, N = 42).

As private law quality assurance systems usually go beyond public law requirements, it was presumed that FBOs applying such systems would experience fewer problems in complying with public law requirements. In general respondents confirmed this presumption stating that the systems they apply are helpful in living up to public law standards.

Global Food Safety Initiative

One interviewee elaborated on the Global Food Safety Initiative. A Group of international retailers, the top 20 in the world, developed a benchmark model to harmonise private food safety

standards. Currently only those that have been recognised remain relevant: SQF, BRC, EFSIS, ISO 22.000, IFS, EurepGAP, and the national HACCPs. This led to the guidance Document Global Food Safety Initiative. All major retailers in Europe apply it; similar schemes are being introduced in China and Japan. US depends on the decision that Wall-mart will take.

So far, the big manufacturers are unwilling to go along with GFSI. They have their own Quality Assurance systems that they impose upon their suppliers. A change is in the air. Cargill was the first; Danone is next choosing ISO 22.000.

Costs of self regulation

The costs of quality assurance systems were perceived very differently by SMEs and big companies. SMEs considered private law systems as expensive. Unlike legislation, the standards are not in the public domain but have to be bought as a commercial commodity. Moreover, the audits are a commercial service that have to be paid for. Indications on prices differed. Some auditing organisations charge a fee of €1,500 per inspection. In other cases tariffs per minute apply.

Bigger companies achieve substantial costs reductions through audits. The old situation was that private label companies all did their own inspections. This has now been replaced by third party audits. One interviewee told that a large producer of vegetable oils 'up until 5 years ago was visited by 100 inspectors from customers per year. Today a BRC audit is performed twice a year and that's it. They are happy, we are happy.' At the expert meeting in Rijswijk, it was pointed out that this experience does not apply to all sectors. Where more sensitive sectors are concerned, such as the meat sector, private label companies do not rely on third party audits but continue their inspection practices.

Controls

The controls system that is connected to many private law systems of food quality assurance is third party audit. In this area, self-regulation meets with privatisation. Particularly in meat production, safety and quality inspection that used to be performed by official veterinarians is now being privatised. Interviewees feel that this is to the advantage of big companies and to the disadvantage of SMEs. SMEs are faced with higher costs while big companies can achieve important savings due to economies of scale.

Several interviewees indicated that through privatisation, the legislature is losing its 'eyes and ears'. There is less feed back on the effect of legislation in practice. Furthermore there is less compliance assistance. Private companies are only interested in production, not in the functioning of the law. Where inspectors' time has to be paid by the minute, FBOs also feel little inclined to exchange views with the inspector. The Dutch Ministry of Agriculture is developing a scheme aimed at reducing burdens. The idea is to focus controls on the applied self-control and third party audit systems. If the results are satisfactory, this will be awarded by a reduction of the number of official controls.[41]

Limits to self regulation

In the Netherlands, the competition authority set a limit to the use of quality assurance systems. The big dairy producers representing over 98% of the procurement market for milk, imposed a standard of quality on their suppliers that went beyond public law requirements. The system is called KKM (Keten Kwaliteit Melk - chain quality milk). An agreement between these companies not to accept milk without the agreed KKM quality standard was considered to be in breach of competition law as it virtually excluded milk that complied with public law standards (but no more) from the market. The companies dropped this particular requirement. However the competition authority announced that it would treat any refusal to buy non-KKM milk as a concerted practice infringing on competition law.[42]

---

41 Beleidskader Toezicht op controle (toezicht op toezicht) 22.03.2005: http://www9.minlnv.nl/servlet/page?_pageid=100and_dad=portal30and_schema=PORTAL30andp_item_id=102296

42 NMa 14 maart 2000, zaak 1237, Stichting Keten Kwaliteit Melk (see: www.nmanet.nl).

Statistics

We asked to what extent food quality systems are helpful in meeting food safety requirements. For (non-Croatian) organisations using BRC (8), 62% totally agreed on its usefulness, for ISO (9) (33.3%) and for IFS (7), 56%. For EFSIS, 50% of companies using this system totally agreed with respect to the usefulness of the system in coming up to European requirements.

With respect to investments made to fulfil food regulations and requirements, to this question (N=10) the respondents stated that they strongly invested in requirements like traceability systems and HACCP to comply with GMO regulations or administrative requirements. The score on 'Investments in HACCP' was 86.4% (N=22), and in food allergy labelling 66.7%.

Table 3.20 Extent to which EU companies invest in HACCP or allergy labelling

	HACCP		Allergy labelling	
Valid	**Frequency**	**Percentage**	**Frequency**	**Percentage**
1 totally applicable	19	86.4	12	66.7
2	1	4.5	4	22.2
3	1	4.5	0	0
4	0	0	1	5.6
5	0	0	0	0
6	0	0	0	0
7 not applicable at all	1	4.5	1	5.6
Total	22	100.0	18	100.0

3.7.3 Concluding remarks

Food businesses are confronted with an overdose of controls: self controls under HACCP, audits under private standards, official controls by member states and audits of controls by FVO. In addition businesses miss compliance assistance.

Private standards (like BRC, EuroGap etc.) help to comply with legal requirements. They lower administrative burdens, as they are better integrated in business processes. Therefore the recognition of civil audits in official controls could reduce costs. The public system could develop to a system control of private audits.

3.8 Other administrative burdens

We have already looked at external legal effects in section 3.4. Here we focus on labelling requirements, which are of special interest in the relation to the consumer. Food labels inform and improve the possibilities for consumers to choose. Food labels therefore play a vital role in enhancing fair competition.

We asked to what extent companies invest in allergy labelling and in other labelling requirements. The results show that investments for allergy labelling scores high (1.92 on a 1-7 scale, N = 36) and investments in other labelling requirements even more (1.65, on a 1-7 scale, N = 46).

Table 3.21 Investments in different categories according to companies

	Mean a)	Standard deviation
General foord safety	1.69	1.5
Traceability	1.81	1.4
Recalls	2.21	2.4

	Mean a)	Standard deviation
HACCP	1.44	1.3
Hygiene codes	1.79	1.6
Novel food requirements	3.29	2.1
GGO	2.21	1.6
Allergy labeling	1.92	1.6
Administrative requirements	2.30	1.9
Private systems (ISO etc.)	1.74	1.5

a) Score on a 7 point scale: 1 = important investment; 7 = no important investment. N=46.

According to the Dutch food safety authority VWA the labelling of small quantities of product is a disproportionate burden for artisanal producers. VWA advises exempting small quantities from labelling.

3.9 Discussion, conclusions and recommendations

Although respondents expressed quite a few concerns about the EU system of food legislation, they were nevertheless fairly mild when asked for an overall assessment in terms of 'good' or 'not so good'. These mild judgements are in striking contrast to the opinions voiced by the experts at the meeting in Münster. This indicates that as far as FBOs are concerned, fine-tuning is called for rather than large-scale restructuring. Nevertheless, on the basis of the insights gathered in this research, some suggestions for improvements can be made.

Table 3.22 Opinion of companies on the quality of EU food legislation in general

Valid	Frequency	Percentage
1 very good	7	15.6
2	18	40.0
3	7	15.6
4	11	24.4
5	1	2.2
6	0	0
7 not good at all.	1	2.2
Total	45	100.0

Score on a 7 point scale: 1 = totally applicable; 7 = not applicable at al.

Industry subscribes to the importance of food safety and is willing to take its responsibility. As far as the general principals and structure are concerned, EU food safety legislation is on the right track. Consumer responsibility however is perceived by some as slightly underexposed. This is seen as a matter of communication rather than legislation. EU authorities should consider communicating more openly on accepted levels of remaining risk in order to provide consumers with the opportunity to make their own choices.

Conclusions

The competitive position of companies as a response to changes in food legislation is determined by a multitude of factors. The evidence as represented in tables and figures cannot be interpreted well without the text that guides the reader to conclusions. Based on the hard-fact data, it can be concluded that:

- in general, the companies included in the survey have a positive view on the effects of food legislation;
- the standard (quality)/and effects of food legislation is addressed mildly; in general the level of food law is assessed to be fairly good.

Detailed conclusions:
1. the effect of the legal system on the competitive position against the US is not perceived as being a specific burden. In general, the effect is neutral, meaning that the legal system does not place a special burden on the respondents with respect to competitiveness;
2. positive aspects of EU legislation are the promotion of quality and effective competition, whereas the pressure on profitability is not seen as a special burden by a majority;
3. the food requirements also are not distinct in causing problems compared to other sectors (like taxation, social, spatial and waste);
4. Novel foods requirements restrict innovation on average more than HACCP, traceability and other requirements;
5. food legislation should change as little as possible, but without discarding the advantages of improvements;
6. the companies generally do not prefer the US legal environment;
7. increased consumer awareness of food issues stimulates quality and is an effective basis for competition while the thread to profitability is neutral;
8. surprisingly, the informedness of the rules that have to be applied, and even of the expected rules, is high. Nevertheless, change of the legal system must be confronted with the negative effects of increased uncertainty and adaptation;
9. EU legislation leads to sincere investments in food safety, prevention and administrative devices;
10. lower administrative loads are not acceptable if this leads to lower food safety.

Warnings:
– the representativeness of the sample to the total population has not been checked;
– differences between companies are quite high (standard deviations are relatively high);
– more detailed analysis is necessary, but so far not enough detailed data are available; the total sample is 64 valid observations (questionnaires; excluding open interviews), the results of which are included in the report.

Taking on administrative burdens

The Vice President of the European Commission responsible for Enterprise and Industry all but committed himself to a reduction of administrative burdens by 25% over the next five years.[43] Unlike the economic parts of this research, the legal part does not do very much to enhance the sense of urgency of such measures; it does however provide a basis for some measure that may be taken. It may not be as impossible to achieve such high ambition as it might seem at first sight. Nevertheless, fulfilment requires full commitment from the EU to mustering the audacity to take drastic measures, shouldering the burdens lifted away from industry and investing in the necessary infrastructure.

Drastic measures are measures that go beyond the subtleties of the food regulatory system but that address the long established traditions of legislation in the EC too. To some extent the burdens on industry and the burdens on institutions are communicating vessels. The commitment to reduce burdens on industry is therefore intertwined with the commitment to take on costs and workload.

Currently no measure for the existing level of administrative burden exists; it is therefore impossible to express the achievable reduction in a percentage in this report, but the research does provide some clues for measures that can be taken.

Sales and after sales

The perceived burden of legislation is largely influenced by the extent to which the meaning and necessity of the legislation is understood and does justice to the needs and possibilities of businesses. It is therefore adamant that new legislation is well explained to its addressees and that

[43] Kick-starting the EU economy. Speech/06/577, delivered in Brussels at a business round table on 10.10.2006. See: http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/06/577andformat=HTMLandaged=0andlanguage=ENandguiLanguage=en

the legislature - e.g. the European Commission - receives feedback from the addressees on the practical implications of the legislation.

DG Sanco has organised courses to introduce inspectors to EU food (hygiene) legislation. It is very important that inspectors understand the legislation because they visit the FBOs and are thus best placed to explain the reasons and functioning of the legislation. A similar effort in training should be focussed on FBOs and their consultants.

The inspectors are the first officials to be confronted with the practical consequences of legislation. The Commission would be well advised to invest in communication channels to receive the information collected by the inspectors in order to reduce the problems perceived and improve the legislation.

Deregulation

The most straightforward strategy to reduce administrative burdens is, without doubt, reduction of the quantity of applicable legislation through deregulation. Different strategies present themselves. The first is to delete existing provisions. The Dutch food and product safety authority for example, published a policy document in which it announced that it would no longer enforce 20% of the legislation for which it was responsible because it felt that the legislation concerned could not contribute to food or product safety or to animal health and welfare.[44] Other national and European authorities should be invited to draw up similar lists of legislation which they feel is expendable. The second strategy is codification. Codification not only significantly reduces the number of laws; it also eliminates needless repetitions and improves the accessibility of the system.

Improving EU legislation

Long term

Some of the problems that surfaced during this research can only be remedied by improving the structure of EU legislation. For long-term measures, inspiration can be derived from US legislation, in particular its continuous codification and systematic publication.

EU legislation is published in chronological order in the Official Journal. The final result of an amendment to existing legislation is a text stating what has to be changed. Consolidated texts are published commercially by publishers or as a service with no legal status on the EU website. The burden to have the whole picture of legislation in force is on its users. Experience of commercial publishers shows that creating consolidated texts involves solving countless riddles posed by ambiguities in the legislation. Why should not the legislature take responsibility to decide on the final text of legislation in force? This would require a change in legislative procedure as it is currently applied to the effect that the final result would always be a publication of an official consolidated text. Further the legislature could designate each new piece of legislation a place in a well-structured register. In this way the user can find all legislation in force relating to a certain subject at one official place.

Due to the lack of coherent administrative law in the EU many directives and regulations make specific and often differing provisions on procedures. It would enhance accessibility of EU legislation if a codification would be undertaken of general provisions of administrative law as exists in most member states.

Short term

The use in food legislation of regulations addressing national legislatures, leads to confusion. It would be helpful if such hybrid legislation would be explicit on what the national legislatures are required and entitled to do. Probably if regulations state that certain provisions, in particular those holding definitions, may be copied into national legislation, for the specific case the case law decreeing otherwise can be overruled.

---

[44] Voedsel en Waren Autoriteit, Handhaven met verstand en gevoel, The Hague, June 2006, available at www.vwa.nl.

Also in the short term, access to documents using ICT can be improved. Anticipating a formal structure of continuous codification and publication through a register, a rigorous policy of continuous consolidation and disclosure through a register can be applied. Password requirements can be minimised and hyperlinks and in particular hyperlink changes can be better managed. Information that is available to some should be made available to all and no copyrights should be retained on regulatory documents.

Improving EU food legislation

The ambition in the White Paper on Food Safety to create clear, simple and understandable legislation on food safety deserves to be revamped.

According to interviewees DG Sanco already does a great job in making official documents including legislation accessible through the Internet. However the legislation itself can also be made more user-friendly.

Long term

Codification of food law could be taken as the final aim of such an operation. Codification has several advantages. It brings the applicable provisions together; the user no longer has to search for them in separate texts. The burden to apply a coherent system, to answer the question how different elements relate to each other is on the legislature and not on the user. It is advisable to take time for this process. First drafts can be seen as authoritative commentary to current legislation. They can be discussed with stakeholders, etc.

Sub codifications can be attempted in clearly defined areas of food legislation. It should be fairly easy to bring all labelling provisions together in one text, probably a regulation. The same is true for the hygiene package. A general code on pre-market approvals might be a third step.

Short term

In the short term, the suggestion made by an interviewee to introduce a 'regulatory rhythm' in food legislation seems very fruitful. The advantages are self-evident. Discussions and actions in the whole sector run parallel and mutually reinforce each other.

A specific issue to be solved is the improvement of risk management separate from enforcement.

Improvement of the most critical parts of EU food legislation

Pre-market approval schemes

The current system of pre-market approvals is probably the greatest barrier to innovation in EU food legislation. At least six measures can be taken: harmonisation, depolitisation, introduction of fatal deadlines, clear responsibilities, fast track procedures and compliance assistance.

Harmonisation: currently each scheme has its own procedure. Novel foods are dealt with at national level, additives, GMOs and claims at EU level each with a different procedure. These procedures should be simplified and unified.

Depolitisation: a major cause of uncertainty in the outcome of pre-market approval procedures is the political character of decision-making. The decision on additives is taken in a legislative procedure including the European Parliament. Other procedures involve the member states through commitology. Politics should focus on the formulation of the applicable criteria. Applying these criteria should be an administrative measure altogether.

Fatal deadlines: Interviewees are very concerned about the length of pre-market approval procedures. They implore the European Commission and the EFSA to rigorously keep their deadlines. They do not however suggest specific actions within the regulatory framework that may guarantee that deadlines are being met. Experience elsewhere, particularly in the notification proce-

dures that apply in competition law to mergers and acquisitions,[45] shows that fatal deadlines for public authorities all but ensure that they do indeed meet their deadlines. Fatal deadlines are deadlines that have the same consequence as a positive decision when they are not met. In other words, legally missing the deadline has the same effect as the decision to grant pre-market approval. The notification procedures in the US seem to work a little in this direction. Food legislation is specific in that it mostly deals with safety. It may therefore require too much courage to equate the passing of time with a decision that a novel food or a GMO is proven safe. In claims however the situation is different. The procedure is not about the safety but about the functionality of the product. Consequences of wrong decisions are therefore less severe. This makes the pre-market approval procedure for health claims an area where an experiment could be undertaken to see whether or not fatal deadlines have the same beneficial effect in food legislation as in other areas of law.

Clear responsibilities: the current situation with regard to GMOs where responsibility to decide shifts between the Commission and the Council depending on the content of the decision to be taken, the advice of EFSA and the meeting of deadlines is unacceptably unclear.

Fast track procedures: a fast procedure should be introduced to answer preliminary questions on the applicability of pre-market approval requirements. This procedure should result in a negative clearance for products that need no approval and an unambiguous decision on which procedure to follow for products that do. For products with a history of safe use outside the EU or that have been approved by an authority outside the EU (like FDA or JECFA), simplified procedures should also apply.

Compliance assistance: much of the burdens of the procedures may be reduced if the authorities actively help the businesses in taking the necessary steps.

Labelling

Labelling requirements are a burden to all FBOs, but in particular to SMEs. As far as possible, they should be simplified. Other information channels than the label should be explored. Information that does not address the consumer has no place on the label. One simple code should direct inspectors and chain partners to the relevant information on the Internet. DG Sanco should create practical instruments (like an exhaustive checklist) to guide FBOs in designing their labels.

Self-regulation

Self-regulation should be supported and encouraged. Businesses are being confronted with a stacking of layers of controls. Food authorities are invited to pursue a policy of decreasing control intensity in situations where private law audits apply that conform to quality standards acceptable for these authorities.

Improving administrative practices

Three types of action seem to be called for: communication, performance and support. If the necessity of legislation is little understood, it seems worthwhile investing in getting the message across. Some interviewees pointed out that inspectors could be the eyes and ears of the legislature. Currently, in the interviewees' perception, inspectors seem to distance themselves from EU legislation. Much would be gained if they could be convinced to act as ambassadors instead.

---

[45] See Article 10 (6) of Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (the EC Merger Regulation), *OJ L 24, 29.1.2004.* See also Commission Regulation (EC) No 802/2004 of 7 April 2004 implementing Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (OJ L 133, 30.4.2004). Other examples of fatal deadlines can be found in: Article 95 (6) of the EC Treaty and Article 16 (3) of Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products, *OJ L 204, 11.8.2000, p. 1–10* and Commission Regulation (EC) No 1825/2000 of 25 August 2000 laying down detailed rules for the application of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the labelling of beef and beef products, *OJ L 216, 26.8.2000, p. 8–12.*

Interviewees are very worried that EU officials will not meet deadlines in pre-market approval procedures. Serious efforts in this regard will be much appreciated.

According to interviewees it is very difficult to acquire assistance in attempting to comply with EU legislation. An active policy of compliance assistance is called for.

References

Arihara, K., 2006. Strategies for designing novel functional meat products. In: Meat Science 74 (2006): 219-229.

Baker, D., 2006. Winners and Losers from food industry policy - an application to Danish food industry firms. In: Food Economics, vol. 3.1.

Bata, D., E.H. Drosinos, P. Athanasopoulos and P. Spath, 2006. Cost of GHP improvement and HACCP adoption of an airline catering company. In: Food Control, Vol. 17, Issue 5, May 2006, pp. 414-419.

Bex, P.H.H.M. and B.H. Duits, 2006. (Administratieve) Lasten in de VWS voedselketen; Onderzoek naar de Administratieve Lasten en beleefde lasten voor bedrijven als gevolg van regelgeving van het Ministerie van VWS die van toepassing is op de voedselketen. Nieuwegein.

Caswell J.A. and D.I. Padberg, 1992. Toward a more comprehensive theory of food labels. In: American Journal of Agricultural Economics, vol. 74, no 2: 460-468.

CIAA, 2005. Reflection Paper on Food and Drink Industry Competitiveness. Brussels.

Cuijpers C., 2006. Verschillen tussen de WBP en Richtlijn 95/46/EG en de invloed op de administratieve lasten- en regeldruk. TILT - Centrum voor Recht, Technologie en Samenleving. Universiteit van Tilburg.

Dagevos H., 2005. Consumers as four-faced creatures. Looking at food consumption from the perspective of contemporary consumers. In: Appetite 45 (2005): 32-39.

DG Sanco, 2006. Labelling: Competitiveness, Consumer Information and Better Regulation for the EU. A DG SANCO Consultative Document.

Food And Agricultural Import Regulations And Standards Report (FAIRS) (http://www.fas.usda.gov/itp/ofsts/usa2.pdf).

Fraunhofer Institute Systems and Innovation Research New Products and Services, 2004. Analysis of Regulations Shaping New Markets. Final Report, http://www.isi.fraunhofer.de/p/Projektbeschreibungen/kb-regulations.htm.

Freriks, A.A., 2006. The impact of WTO-law on animal welfare (inaugural address Utrecht 2006), forthcoming.

Gaag, M.A. van der, H.W. Saatkamp, G.B.C. Backus, P. van Beek and R.B.M. Huirne, 2004. Cost-effectiveness of controlling Salmonella in the pork chain. In: Food Control, Vol. 15, Issue 3, pp. 173-180.

Gellynck X, W. Verbeke and B. Vermeire, 2006. Pathways to increase consumer trust in meat as a safe and wholesome food. In: Meat Science, Vol. 74, Issue 1, pp. 161-171

Green Paper on the general principles of food law in the European Union, Not found on the EU website. For the text see: http://www.foodlaw.rdg.ac.uk/eu/green-97.doc.

Hammonds, T.M., 2004. It Is Time to Designate a Single Food Safety Agency. In: Food and Drug Law Journal 59, pp. 427-432.

Havelaar, A.H. et al., 2005. Kosten en baten van compylobacter-bestrijding. RIVM, Bilthoven.

Jongen, W.M.F. and M.T.G. Meulenberg (eds.), 2005. Innovation in Agri-Food systems. Product quality and consumer acceptance. Wageningen Academic Publishers, The Netherlands.

Kaner C., 1996. Quality Cost Analysis: Benefits and Risks (www.kaner.com/qualcost.htm; 31st August 2006).

Knight J.G., D.W. Mather and D.K. Holdsworth, 2005. Impact of genetic modification on country image of imported food products in European markets: Perceptions of channel members. In: Food Policy, Vol. 30, Issue 4, pp. 385-398.

Kumar S. and E.M. Budin, 2006. Prevention and management of product recalls in the processed food industry: a case study on an exporter's perspective. Technovation 26: 739-750.

Loader, R. and J.E. Hobbs, 1999. Strategic responses to food safety legislation, Food Policy pp. 685-706.

Lugt, M., 1999. Enforcing European and National FOOD LAW in the Netherlands and England. Koninklijke Vermande, Lelystad, The Netherlands.

Maldonado, E.S., S.J. Henson, J.A. Caswell, L.A. Leos, P.A. Martinez, G. Aranda and J.A. Cadena, 2005. Cost-benefit analysis of HACCP implementation in the Mexican meat industry. In: Food Control, Vol. 16, Issue 4, pp. 375-381.

Maijala, R., J. Ranta, E. Seuna and J. Peltola, 2005. The efficiency of the Finnish Salmonella Control Programme. In: Food Control, Vol. 16, Issue 8, pp.669-675.

Menrad, K. (for Fraunhofer), 2003. New Products and Services: Analysis of Regulations Shaping New Markets, Part C: the impact of Regulation on the development of New Products in the Food Industry, 2003,

http://www.isi.fraunhofer.de/p/Downloads/KB_Case_Study_Food.pdf.

Meulen, B.M.J. van der, 2004. The Right to Adequate Food. Food Law between the Market and Human Rights. Elsevier The Hague, The Netherlands.

Meulen, B.M.J. van der and M. van der Velde, 2006. Food Safety Law in the European Union. 2nd reprint, Wageningen Academic Publishers, The Netherlands.

Meulen, B.M.J. van der and A.A. Freriks, 2006. Millefeuille: The emergence of a multi-layered controls system in the European food sector. Utrecht Law Review, Vol. 2, issue 1, pp. 156-176;

http://www.utrechtlawreview.org/publish/articles/000022/english.html

Ministry of Financial Affairs, 2006. Meten is Weten. Ministry of financial affairs, The Hague.

Poppe, K.J. and H. van Meijl, 2006. Differences in farm performance and adjustment to change: a perspective from the Netherlands. In: D. Blandford and B. Hill: Policy Reforms and Adjustment in the Agricultural Sectors of Developed Countries, CABI, 2006.

Rijswijk W. van, J. Cornelisse-Vermaat and L. Frewer, 2006. Can traceability improve consumers' confidence in food quality and safety? - the importance of matching information with con-

sumer needs. Paper presented at the 7th International Conference on Management in Agri-Food Chains and Networks, Ede, The Netherlands, 31 May - 2 June 2006.

Romano, D., A. Cavicchi, B. Rocchi and G. Stefani, 2005. Exploring costs and benefits of compliance with HACCP regulation in the European meat and dairy sectors. In: K.J. Poppe and A. Velthuis: Special issue on Food Safety in a Dynamic World, Food Economics (Acta Agriculturae Scandinavica Section C) volume 2(1).

Schyver T. and C. Smith, 2005. Reported Attitudes and Beliefs toward Soy Food Consumption of Soy Consumers versus Nonconsumers in Natural Foods or Mainstream Grocery Stores. In: Journal of Nutrition Education and Behavior, Vol. 37, Issue 6, November-December 2005, pp. 292-299.

Suyver J.F. and M.J.F. Tom, 2004. Verlichting administratieve lasten 2003-2007 - invloed op sector en bedrijfsgrootte. EIM, Zoetermeer.

Watson K., B. Klingenberg, T. Polito and T.G. Geurts, 2004. Impact of environmental management system implementation on financial performance. Management of Environmental Quality: An International Journal, Vol. 15 (6): 622-628.

White Paper on Food Safety COM(1999) 719 def.